idorsia

Idorsia – Reaching out for more

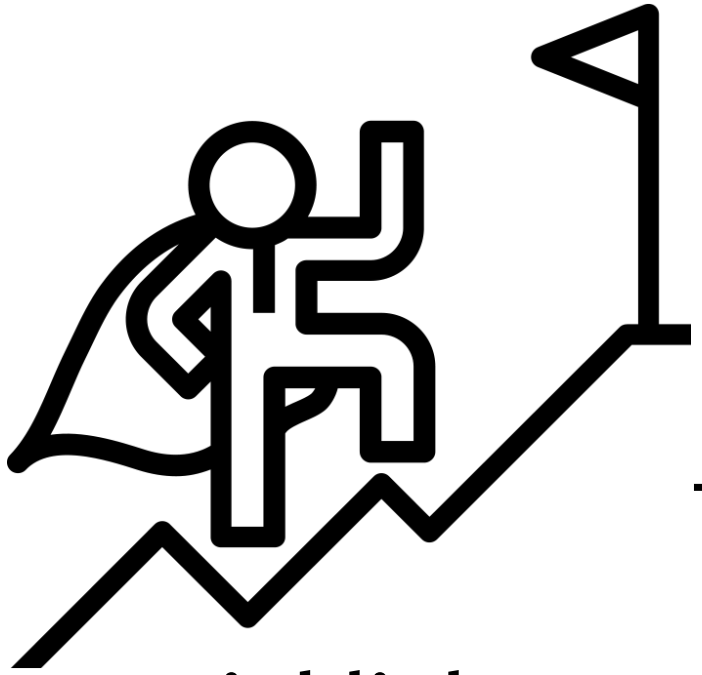
We have more passion for science, we see more opportunities, and we want to help more patients.

The following information contains certain “forward-looking statements”, relating to the company’s business, which can be identified by the use of forward-looking terminology such as “estimates”, “believes”, “expects”, “may”, “are expected to”, “will”, “will continue”, “should”, “would be”, “seeks”, “pending” or “anticipates” or similar expressions, or by discussions of strategy, plans or intentions. Such statements include descriptions of the company’s investment and research and development programs and anticipated expenditures in connection therewith, descriptions of new products expected to be introduced by the company and anticipated customer demand for such products and products in the company’s existing portfolio. Such statements reflect the current views of the company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results, performance or achievements of the company to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

The purpose of Idorsia is to challenge accepted medical paradigms, answering the questions that matter most.

To achieve this, we will discover, develop, and commercialize innovative medicines – either through in-house capabilities or together with partners – and evolve Idorsia into a leading biopharmaceutical company, with a strong scientific core.

Highlights in 2024 and Q1 2025



Viatris collaboration for selatogrel and cenerimod

Restructured convertible bond debt

CHF 150 million new funding

QUVIVIQ unique product with rapidly growing sales

Approval of aprocitentan TRYVIO available in the US JERAYGO in the EU & UK

Advancing early-stage innovative assets

Securing future operations

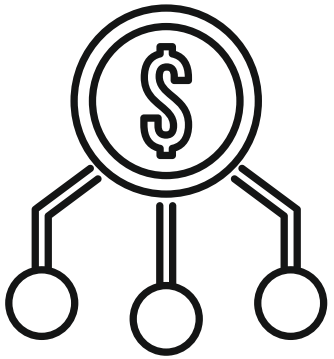
Viatris deal restructuring

Remove significant cash requirements in 2025

Funding

Backstopped CHF 150 million New Money Facility

Balance sheet restructuring



Remove large debt overhang

Future operations secured

Adapt operations across different divisions to optimize the use of the new money facility

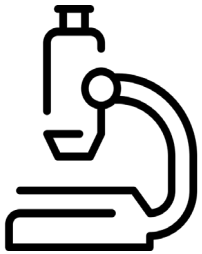
JERAYGO™ aprocitentan

TRYVIO™ (aprocitentan) 12.5mg tablets

Partner aprocitentan
Priority remains to find a partner for aprocitentan, preserve and increase the value of aprocitentan with limited launch in the US

Accelerate QUVIVIQ in EUCAN
Commercial efforts are translating into success – continue to drive sales – expand from specialist prescribers to GP through commercial partnerships

QUVIVIQ in the US
Maintaining the sales while reducing costs, until descheduling can be achieved and real value in the US market can be unlocked



Leverage our innovation
Optimize out portfolio within our budget constraint through targeted development and potential partnering

Idorsia active ingredients

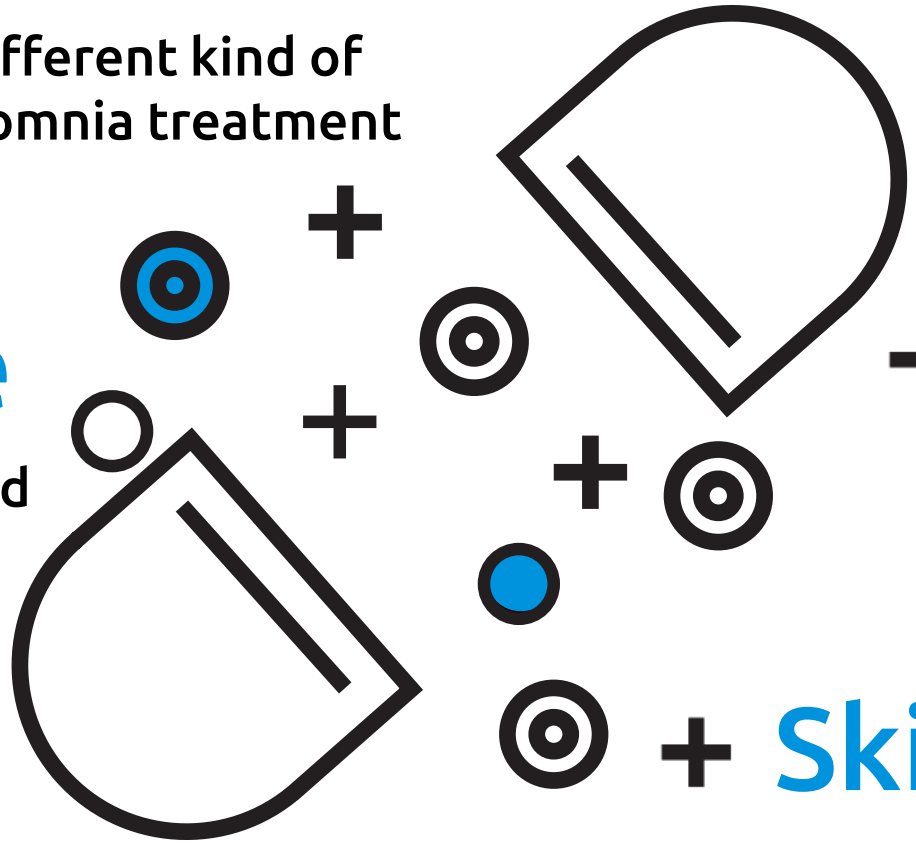
The company is distinguished by our key strengths:

+ QUVIVIQ

a different kind of insomnia treatment

+ Partners

maximize the value of our portfolio



+ People

Highly qualified professionals

+ Pipeline

Promising in-house assets

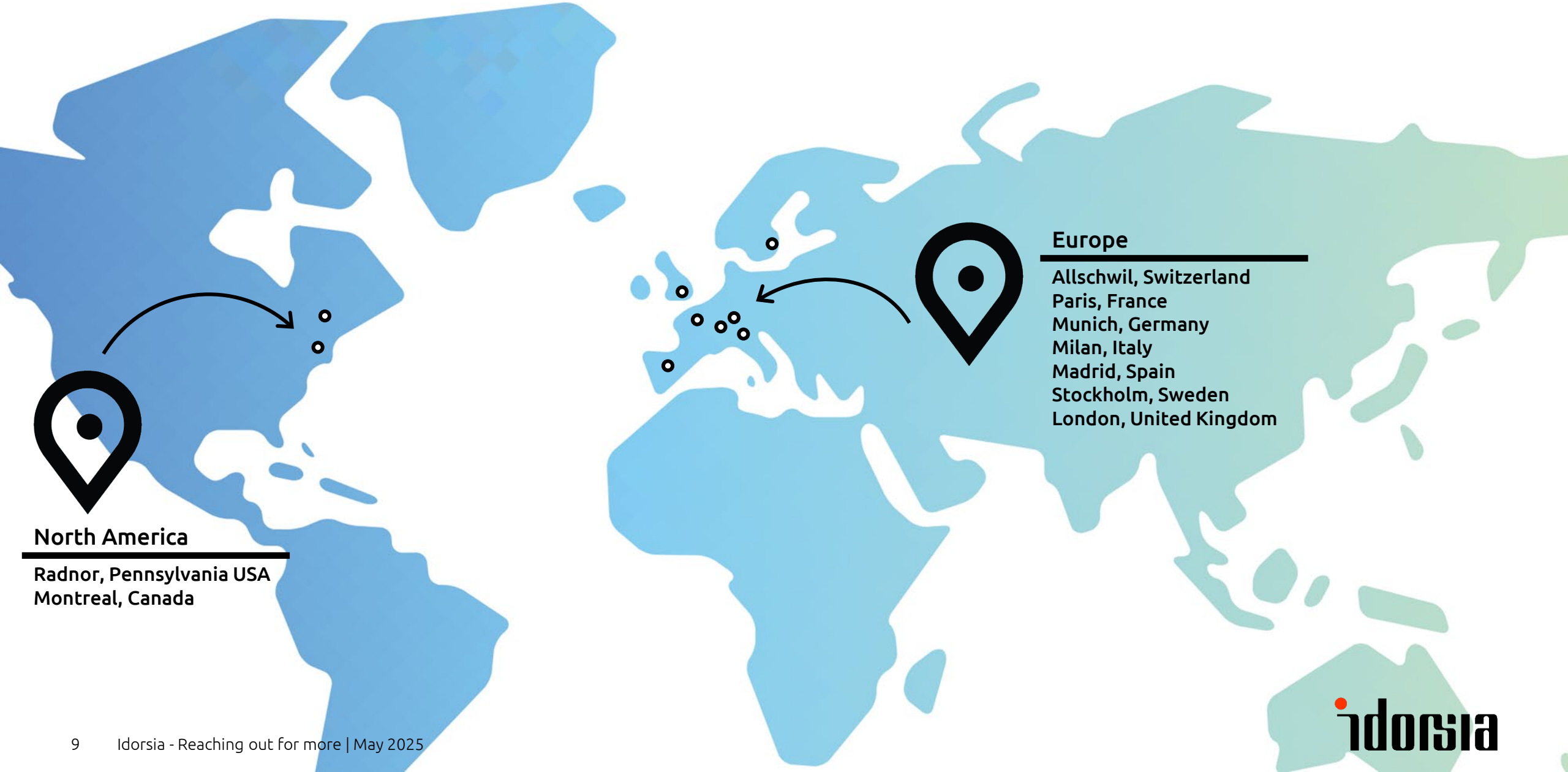
+ Skills

Specialized Drug Discovery engine

Our Strategic Priorities

- Making the money last
- Targeting our drug discovery
- Leveraging our innovative pipeline
- Nurturing our existing alliances
- Unlocking the value of QUVIVIQ

Our commercial reach



North America

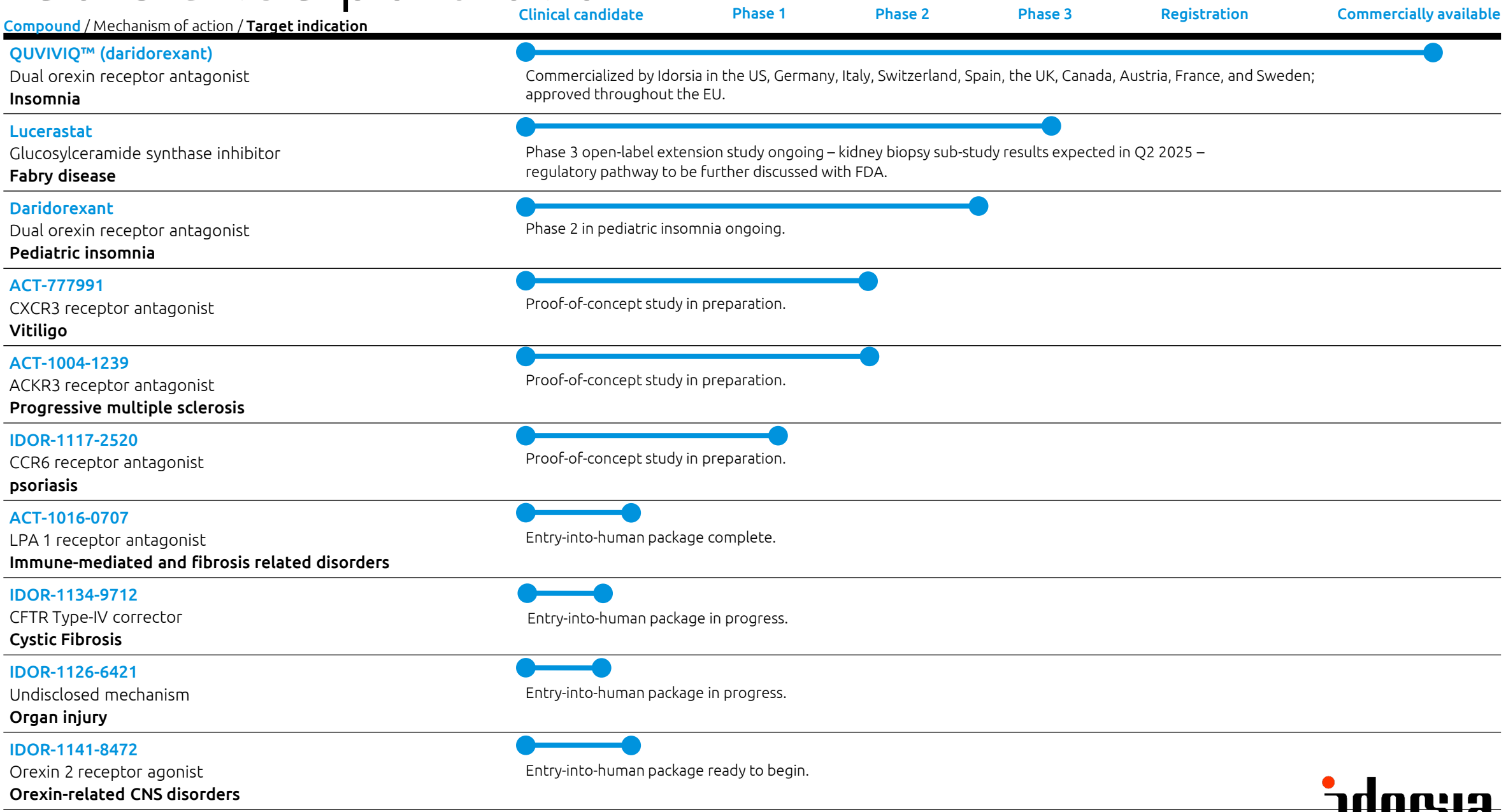
Radnor, Pennsylvania USA
Montreal, Canada

Europe

Allschwil, Switzerland
Paris, France
Munich, Germany
Milan, Italy
Madrid, Spain
Stockholm, Sweden
London, United Kingdom

Idorsia-led portfolio

The company will develop each asset to the next inflection point or seek a partner.



Idorsia-led portfolio

Synthetic Glycan Vaccine Platform

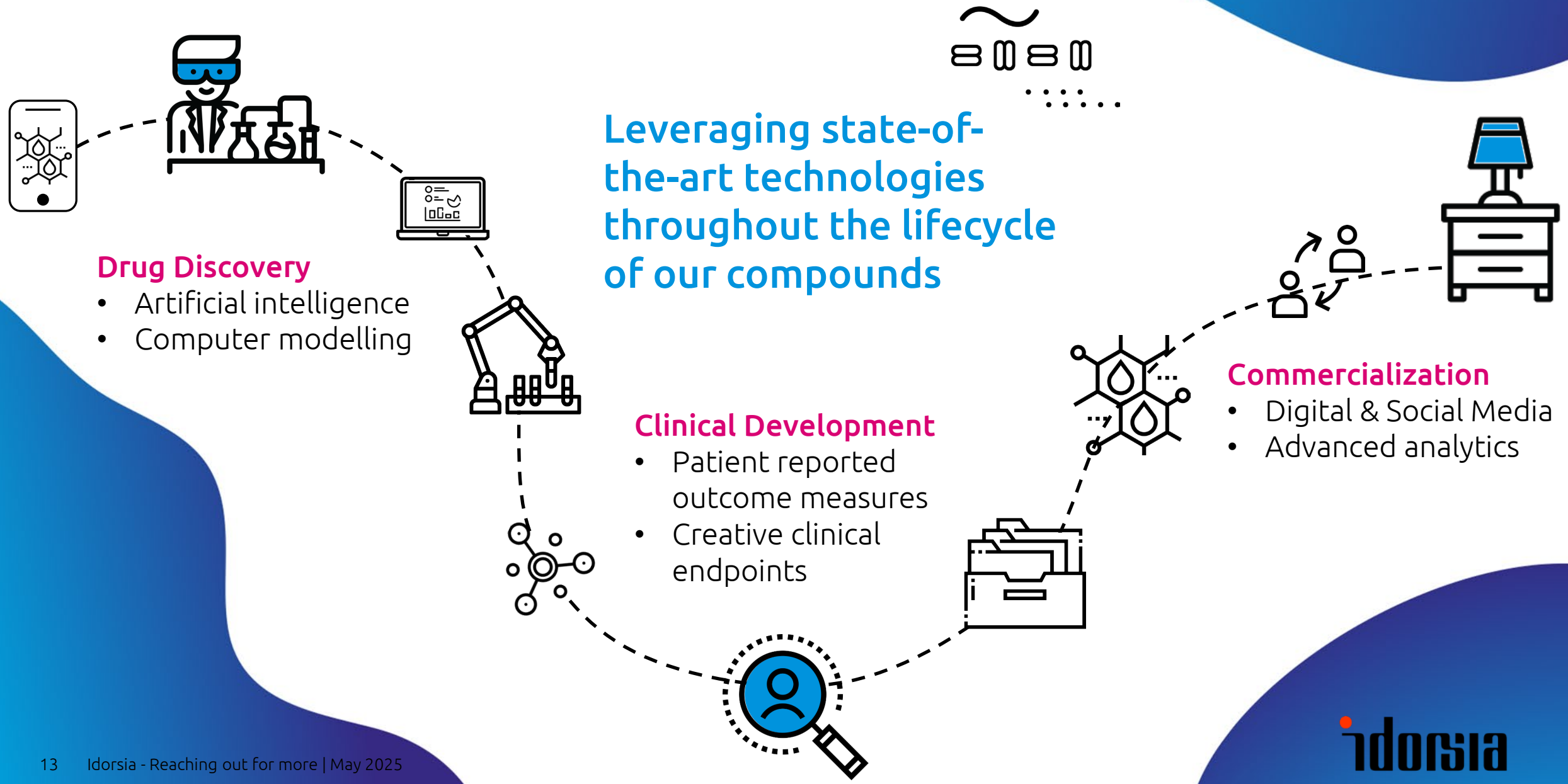
Compound / Mechanism of action / **Target indication**	Clinical candidate	Phase 1	Phase 2	Phase 3	Registration	Commercially available
IDOR-1134-2831 Synthetic glycan vaccine ***Clostridium difficile* infection**	Idorsia is conducting a Phase 1 clinical pharmacology study – results expected in Q2 2025.					
IDOR-1142-0810 Synthetic glycan vaccine ***Klebsiella pneumonia* infection**	Entry-into-human package in progress.					

- Idorsia will seek a partner for the platform or individual vaccines.

Partner-led portfolio

Compound / Mechanism of action / **Target indication**	Partner	Phase 1 / Phase 2 / Phase 3 / Registration / Commercially available
TRYVIO™ (aprocitentan) Dual endothelin receptor antagonist **Systemic hypertension in combination with other antihypertensives**	**To be defined**	Worldwide development and commercialization rights. Commercially available in the US.
JERAYGO™ (aprocitentan) Dual endothelin receptor antagonist **Resistant hypertension in combination with other antihypertensives**	**To be defined**	Worldwide development and commercialization rights. Approved in the EU and UK; Marketing authorization applications under review in Canada, and Switzerland.
QUVIVIQ™ (daridorexant) Dual orexin receptor antagonist **Insomnia**	Nxera	License to develop and commercialize for Asia-Pacific region (excluding China). Launched for the treatment of insomnia in Japan; Phase 3 ongoing in South Korea.
Daridorexant Dual orexin receptor antagonist **Insomnia**	Simcere	License to develop and commercialize for Greater China region. NDA submitted in Greater China; approved for the treatment of insomnia in Hong-Kong.
Selatogrel $P2Y_{12}$ inhibitor **Acute myocardial infarction**	VIATRIS	Worldwide development and commercialization rights. Phase 3 “SOS-AMI” program ongoing.
Cenerimod $S1P_1$ receptor modulator **Systemic lupus erythematosus**	VIATRIS	Worldwide development and commercialization rights. Phase 3 “OPUS” program ongoing.
Daridorexant Dual orexin receptor antagonist **Posttraumatic stress disorder (PTSD)**	**US Department of Defense (DOD)**	Idorsia is supporting a clinical study sponsored by the US DOD to develop new therapies to treat PTSD.
ACT-1002-4391 EP_2/EP_4 receptor antagonist **Immuno-oncology**	OWKIN	Global license to develop and commercialize. Phase 1 ongoing.

Innovation from bench to bedside



Leveraging state-of-the-art technologies throughout the lifecycle of our compounds

Drug Discovery
- Artificial intelligence
- Computer modelling

Clinical Development
- Patient reported outcome measures
- Creative clinical endpoints

Commercialization
- Digital & Social Media
- Advanced analytics

Nurturing strong alliances

Commercial and late-stage partnered assets

QUVIVIQ (daridorexant) 25mg, 50mg tablets

Nxera

Development and commercialization rights for Asia-Pacific region (excluding China)

Simcere

Development and commercialization rights for the Greater China region

Selatogrel

VIATRIS™

Worldwide development and commercialization rights

SOS AMI

Phase 3 study

Cenerimod

VIATRIS™

Worldwide development and commercialization rights

OPUS

Phase 3 program

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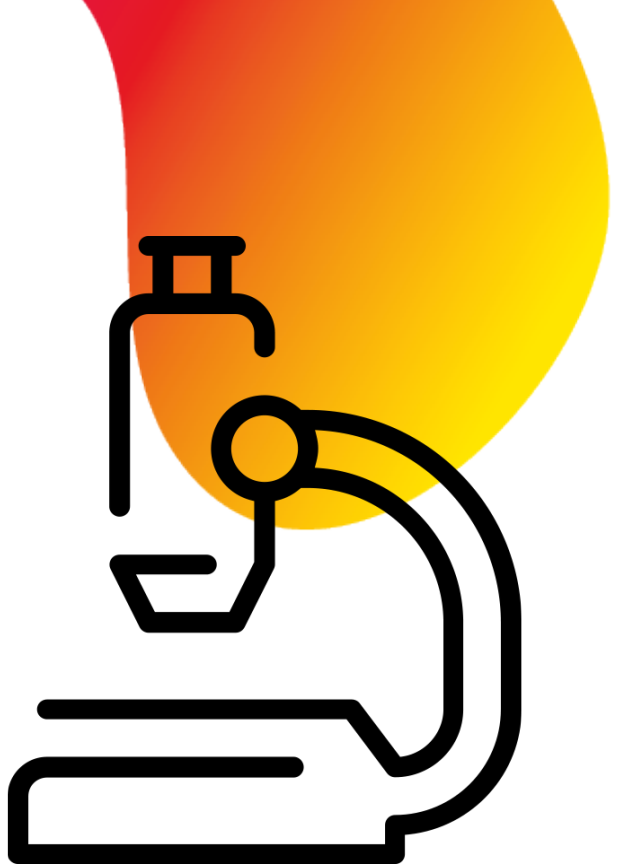
Find a comprehensive description of our pipeline assets as follows:

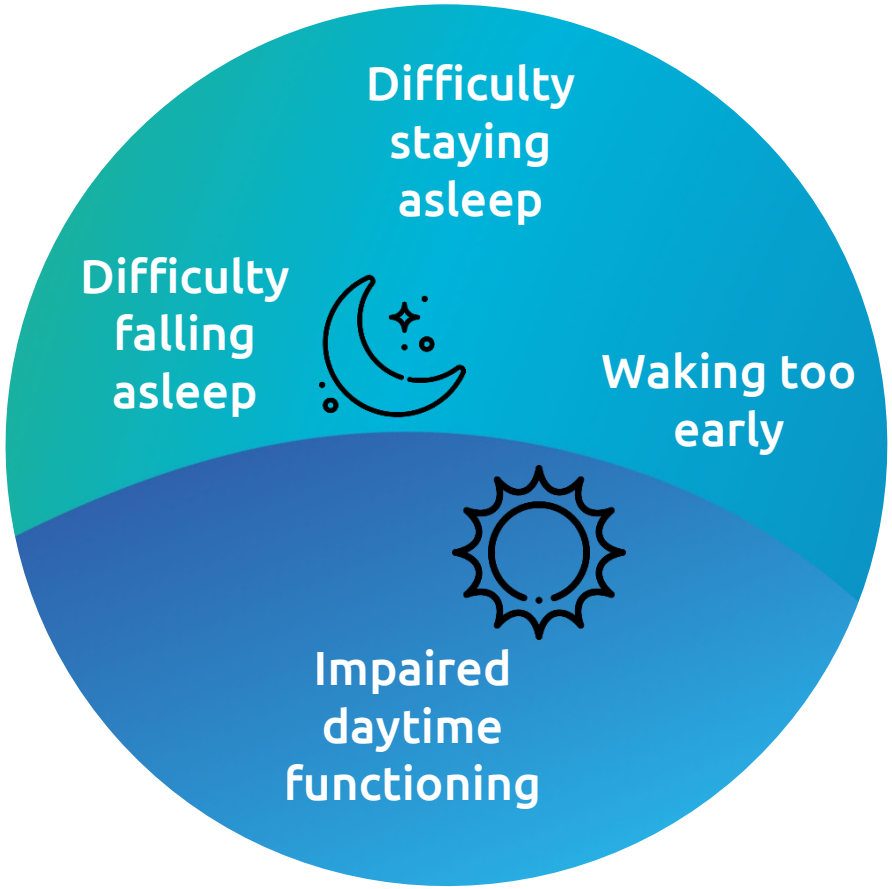


Daridorexant in insomnia

Idorsia makes daridorexant available in the US, Germany, Italy, Spain, Switzerland, the UK, Canada, Austria, France, and Sweden under the tradename QUVIVIQ. In addition, daridorexant is approved throughout the European Union.

Insomnia: A disease of the night and the day

High unmet need for effective, safe medications to treat insomnia



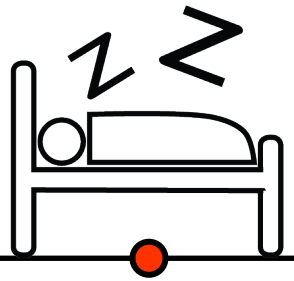
- Combination of difficulty obtaining sufficient sleep and dissatisfaction with sleep **combined with a significant negative impact on daytime functioning**

  Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5®)

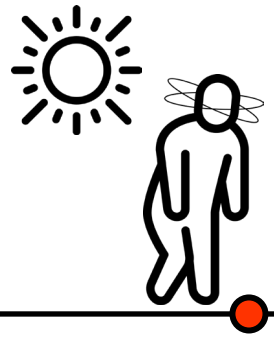
- Estimated approximately 25 million (10%[1]) adults in the US suffer from chronic insomnia

1 Morin CM, et al. Insomnia disorder. Nat Rev Dis Primers 2015;1:15026

Insomnia and the importance of sleep

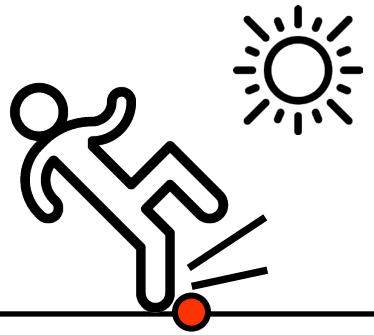


Sleep is an essential pillar for good physical and mental health to ensure optimal functioning throughout the day.

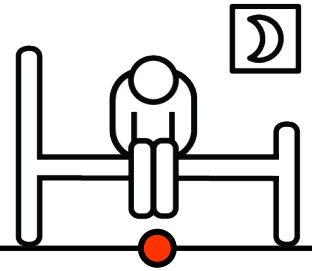


A key symptom of insomnia disorder is the **impairment of daytime functioning**, which is **linked to significant decrements in health status**, such as fatigue, reduced energy, mood alteration and cognitive difficulties.

Therefore, **without adequate, quality sleep**, one can face many issues that will impact day-to-day life.



Poor management of insomnia is associated with **increased risk of motor vehicle accidents, falls, and costly workplace errors**.



Insomnia disorder, the most common sleep-wake disorder, is **defined by difficulties in initiating or maintaining sleep, and early-morning awakening** with the inability to return to sleep, for **at least 3 months or longer.**

Improving daytime functioning is a critical unmet need that has not been addressed in a rigorous manner.

How is insomnia treated, what are the limitations?

Sleep hygiene

- Active patient participation required

Cognitive behavioral therapy

- Recommended first-line therapy but inconsistently practiced
- Not easily accessible
- Often not reimbursed
- Active patient participation required

Pharmacological therapy

- Many have significant limitations
- Insufficient acute effect:
  lack of sustained effect through the night
- Insufficient long-term effect:
  lack of continued benefit over time
- Next morning residual effect
- Abuse potential, withdrawal effect, and rebound
- May have significant adverse effects

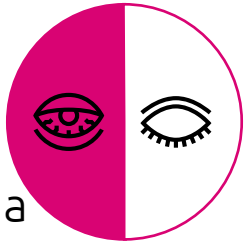
Prevalence and impact of insomnia across Europe

With respect to global burden, insomnia is ranked by the World Health Organization as the

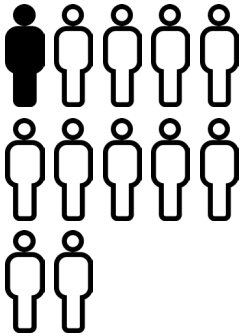
11th

most important brain disorder*

Across Europe, approximately half of all adults are expected to experience some insomnia symptoms, and



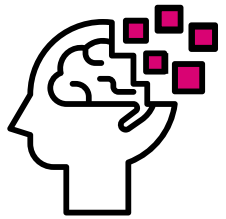
1 in 12 (8.2%) of adults live with chronic insomnia disorder (CID)



CID is associated to **11/18 days of absenteeism** and

39-45 days of presenteeism (showing up at work but less productive) leading to an overall, yearly

45-54 days of loss of productivity*



* Source: Roth, Thomas; Insomnia: Definition, Prevalence, Etiology, and Consequences; Journal of Sleep Medicine; Published Online: November 14, 2019; https://jcsm.aasm.org/doi/10.5664/jcsm.26929

** *Hafner M., Romanelli R.J., Yerushalmi E. & Troxel W.M. *The Societal and Economic Burden of Insomnia in Adults: An International Study.* Santa Monica, CA: RAND Corporation, 2023.

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Hidden economic burden of CID (working-age adults)

Who's affected?		Estimated "hidden" annual financial burden across working-age population suffering from CID
% of adults suffering from CID	Number of adults	
 7.6%	18.6 million	€92bn
 8.8%	2.2 million	Can$ 10.7bn
 7.7%	16.6 million	$127.1bn

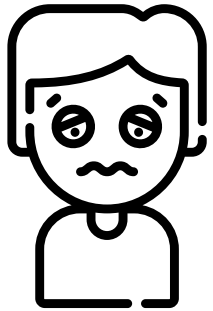
The US insomnia market is large, highly dissatisfied, and ripe for disruption

Who's affected?

~25M

Total insomnia patients

(~10% of US adults)



12M

Treated insomnia patients

Dissatisfaction

In a recent poll of 1001 Americans who struggle with sleep

70%

say they are desperate to find a solution to get quality sleep and fully function the next day

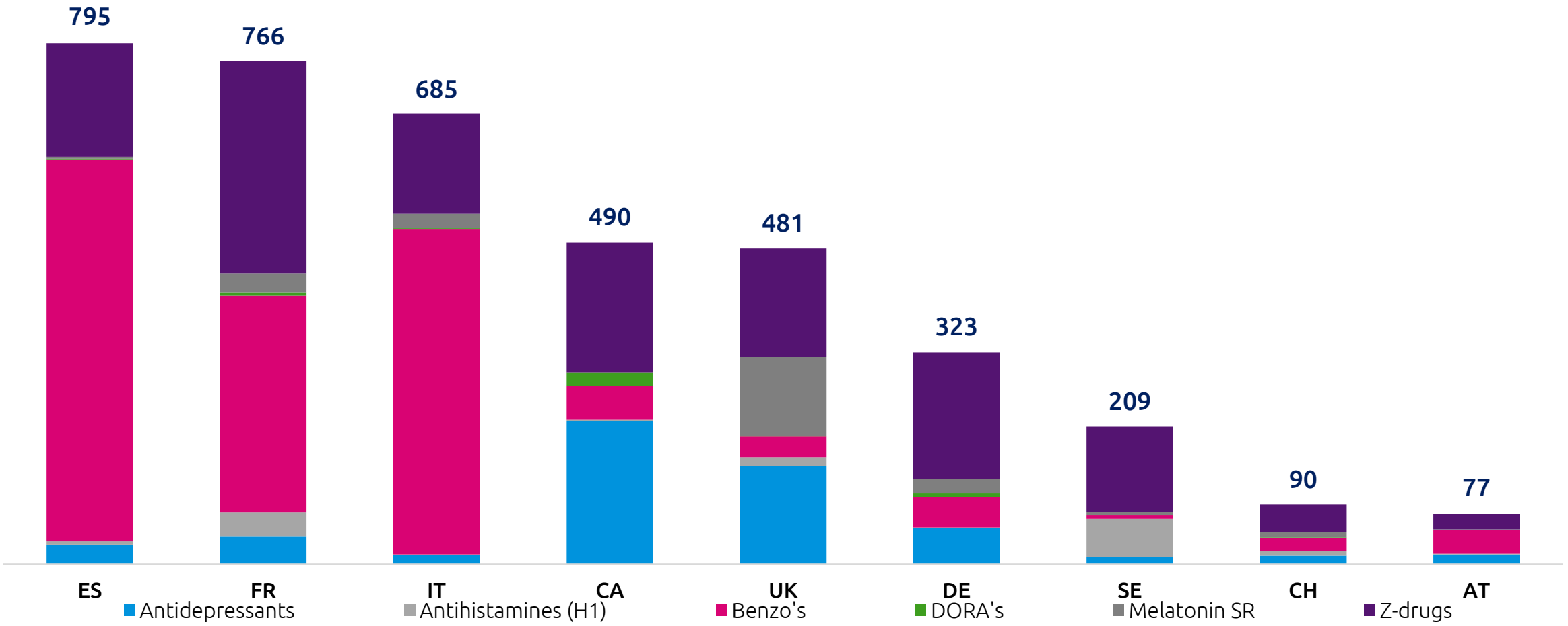
What are the costs?

$100B+

Insomnia related costs per year alone in the US

High unmet need in EU insomnia market

Estimated insomnia market volume*, standard units, millions

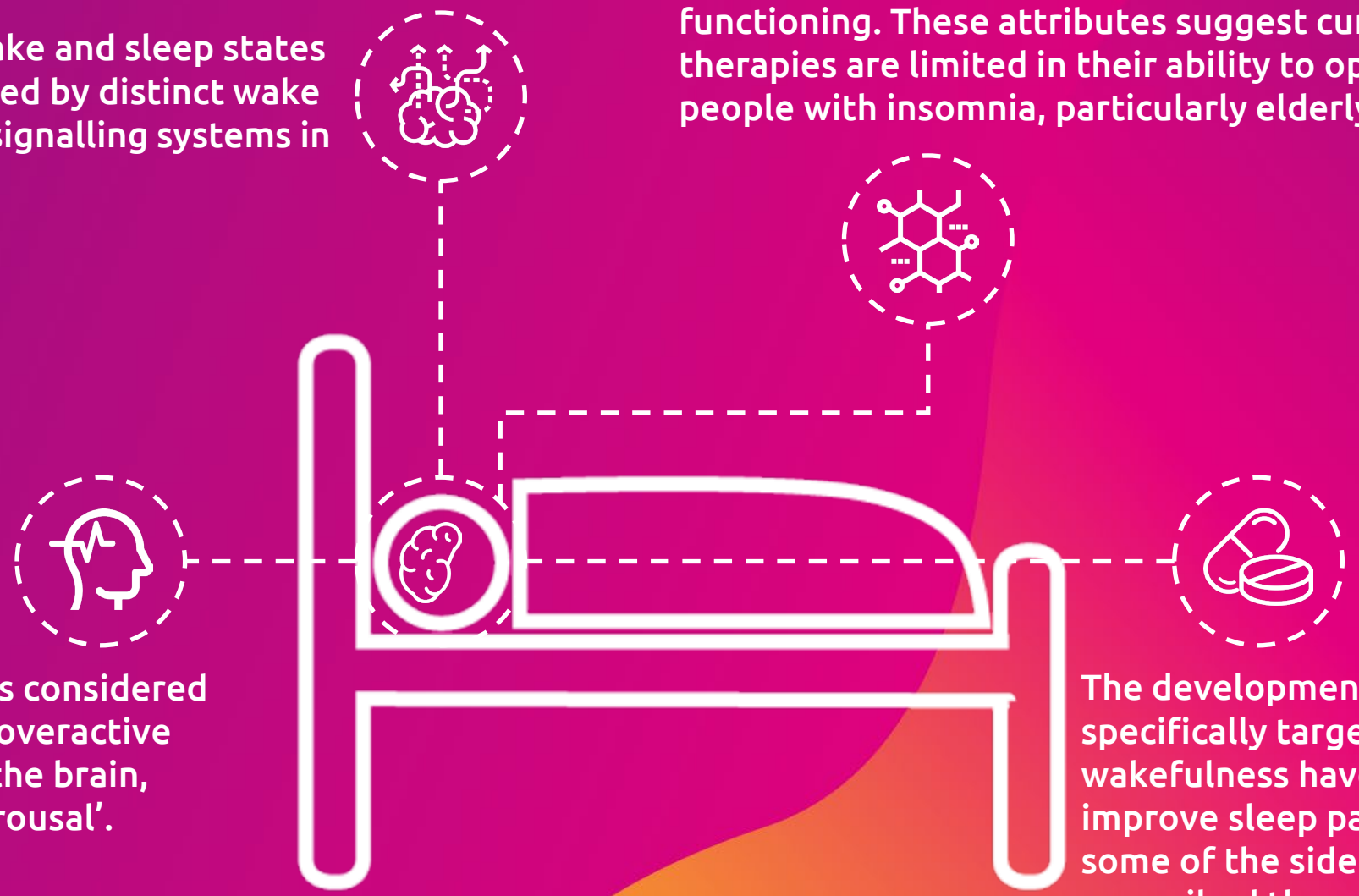


Sources:
1) IQVIA MIDAS - Monthly Volume in M SU, MAT/Sep/2024 (EU5-CA-CHAT); Sweden MAT/SEP/2020
*Includes estimated off-label usage of anti-depressants, anti-histamines and benzos to treat insomnia

The science of sleep

Healthy wake and sleep states are governed by distinct wake and sleep signalling systems in the brain.

Some therapies may increase somnolence and impair functioning. These attributes suggest current therapies are limited in their ability to optimally treat people with insomnia, particularly elderly patients.



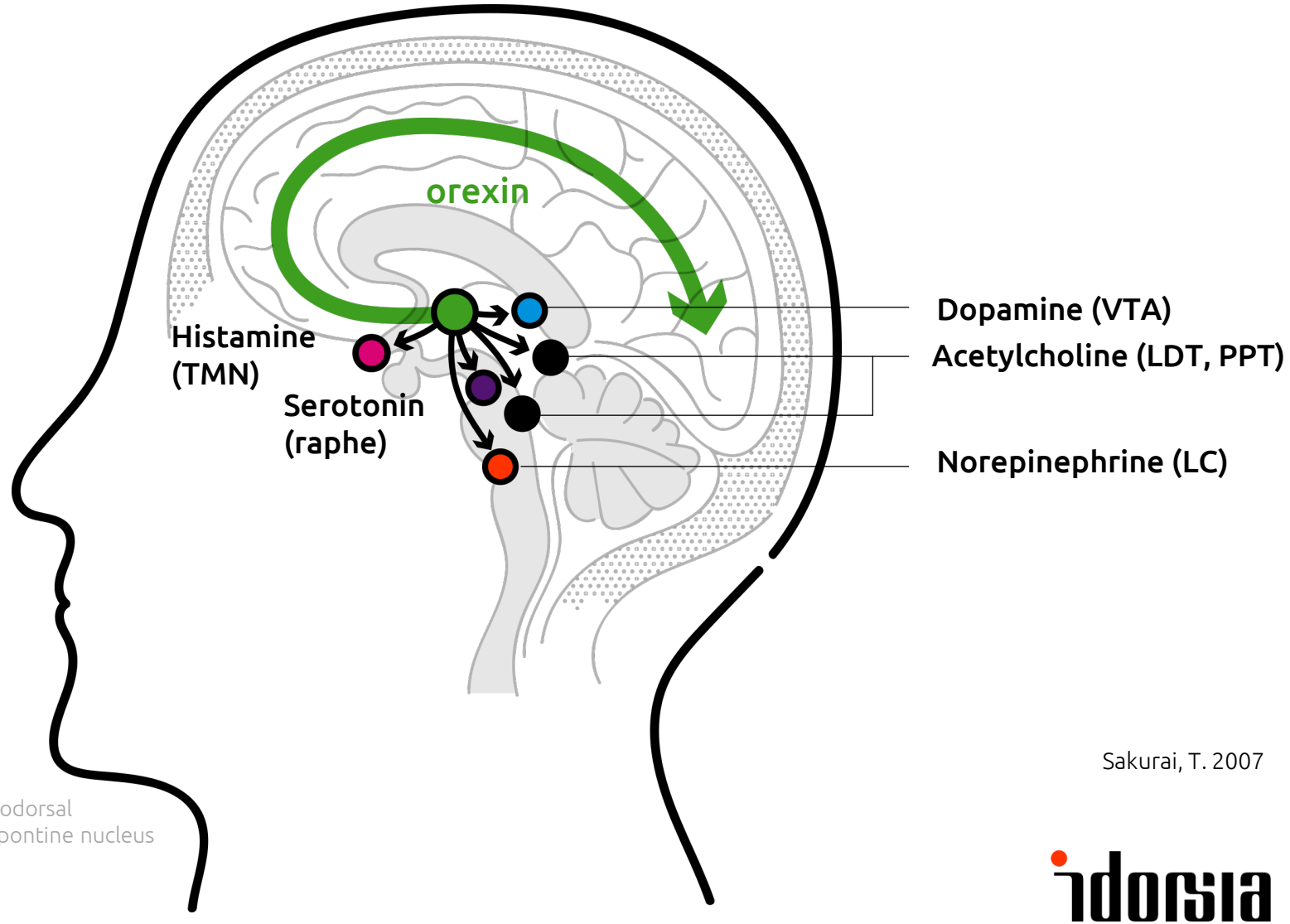
The underlying pathophysiological cause of insomnia is considered to be the result of overactive wake signalling in the brain, also called ‘hyperarousal’.

The development of medications that specifically target excessive wakefulness have been shown to improve sleep parameters without some of the side effects of commonly prescribed therapies for insomnia.

The orexin system is crucial for the regulation of wakefulness

Orexin stimulates many wake-promoting pathways

●	**LHA / PH**	**Orexin**
●	**LC**	OX_1R
●	**TMN**	OX_2R
●	**Raphe**	OX_1R and OX_2R
●	**LTD / PPT**	OX_1R and OX_2R
●	**VTA**	OX_1R and OX_2R



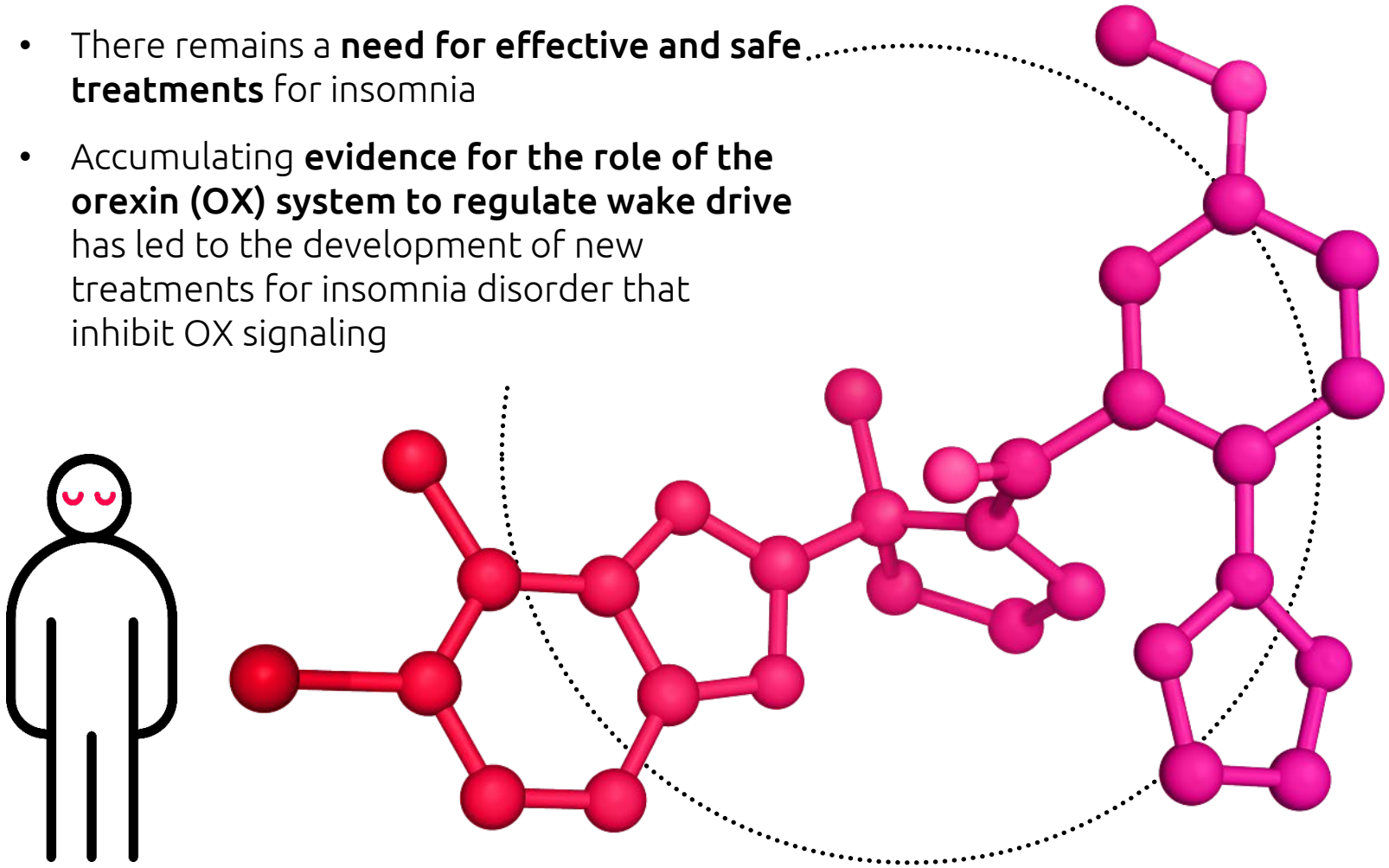
Sakurai, T. 2007

LHA = lateral hypothalamic area; PH = posterior hypothalamus
LC = locus coeruleus; TMN = tuberomammillary nucleus; LDT = laterodorsal tegmental nucleus; VTA = ventral tegmental area; PPT = pedunculopontine nucleus

Daridorexant in insomnia

Rationale

- There remains a **need for effective and safe treatments** for insomnia
- Accumulating **evidence for the role of the orexin (OX) system to regulate wake drive** has led to the development of new treatments for insomnia disorder that inhibit OX signaling



Daridorexant

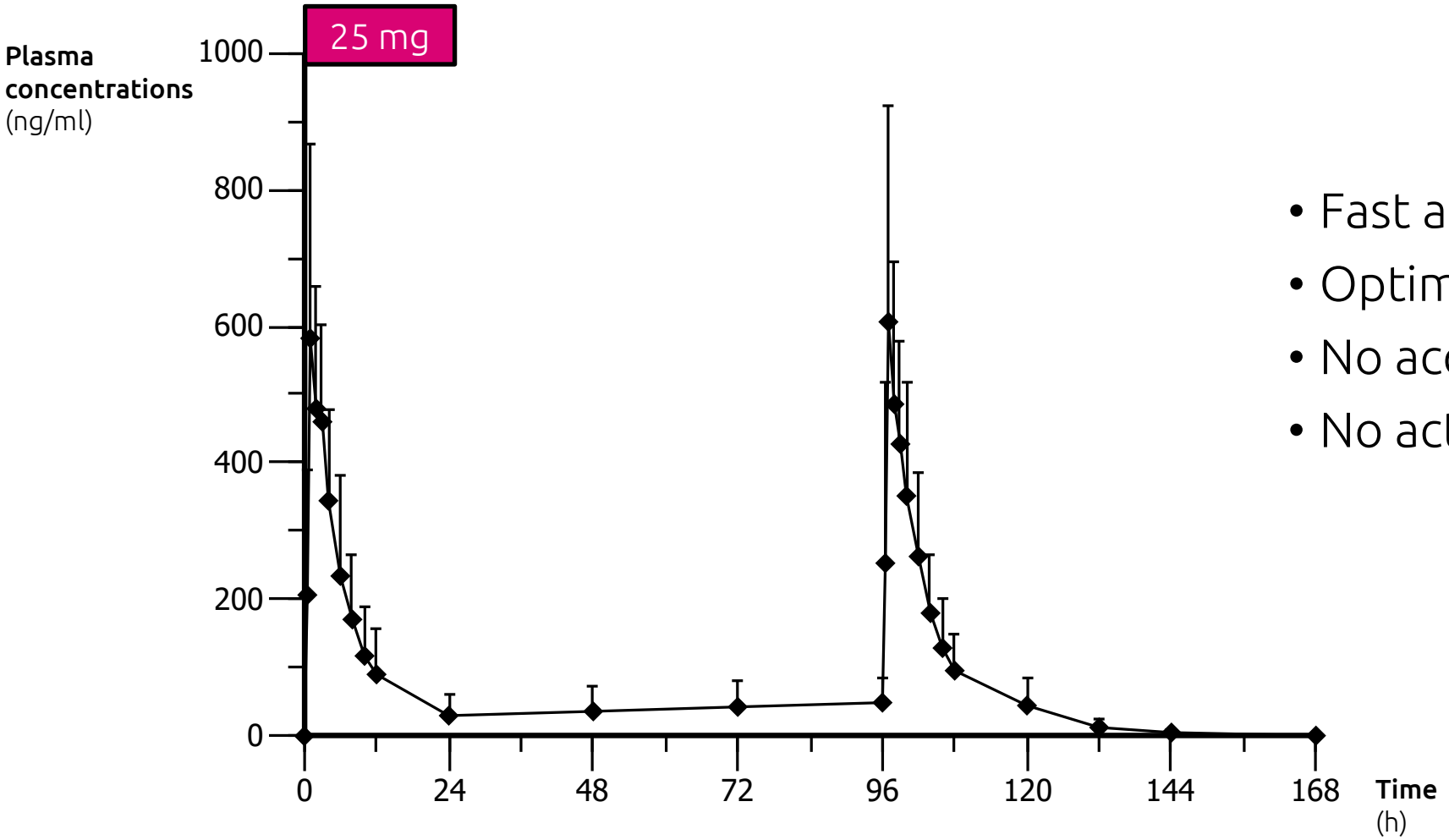
- a **potent and selective** dual orexin receptor antagonist (DORA)
- selected to **promote sleep onset and sleep maintenance, without impairing the next day**

Idorsia makes daridorexant available in the US, Germany, Italy, Spain, Switzerland, the UK, Canada, Austria, France, and Sweden under the tradename QUVIVIQ. In addition, daridorexant is approved throughout the European Union.

Different by design – next generation DORA

Optimized pharmacokinetic profile

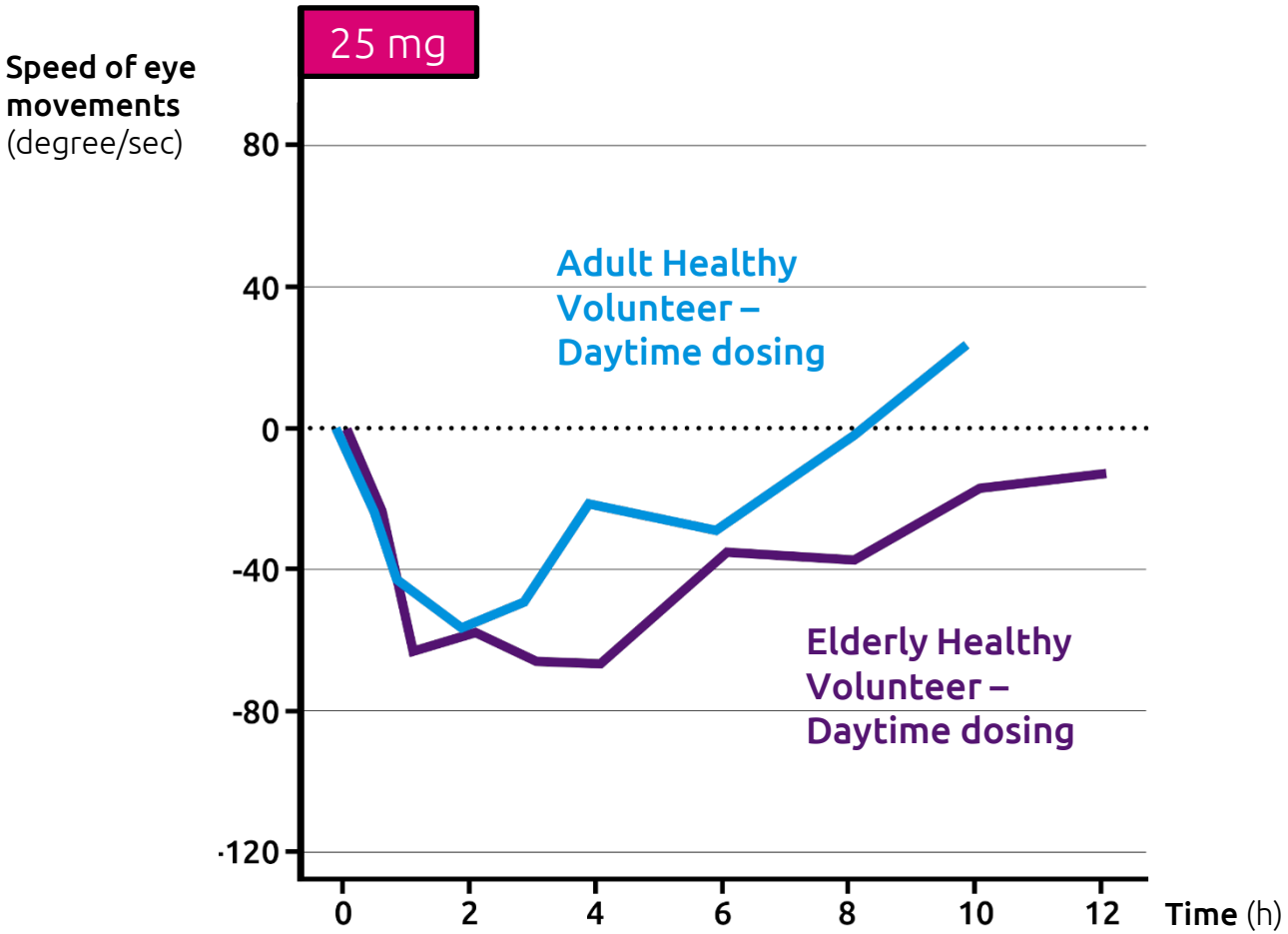
Entry into man studies

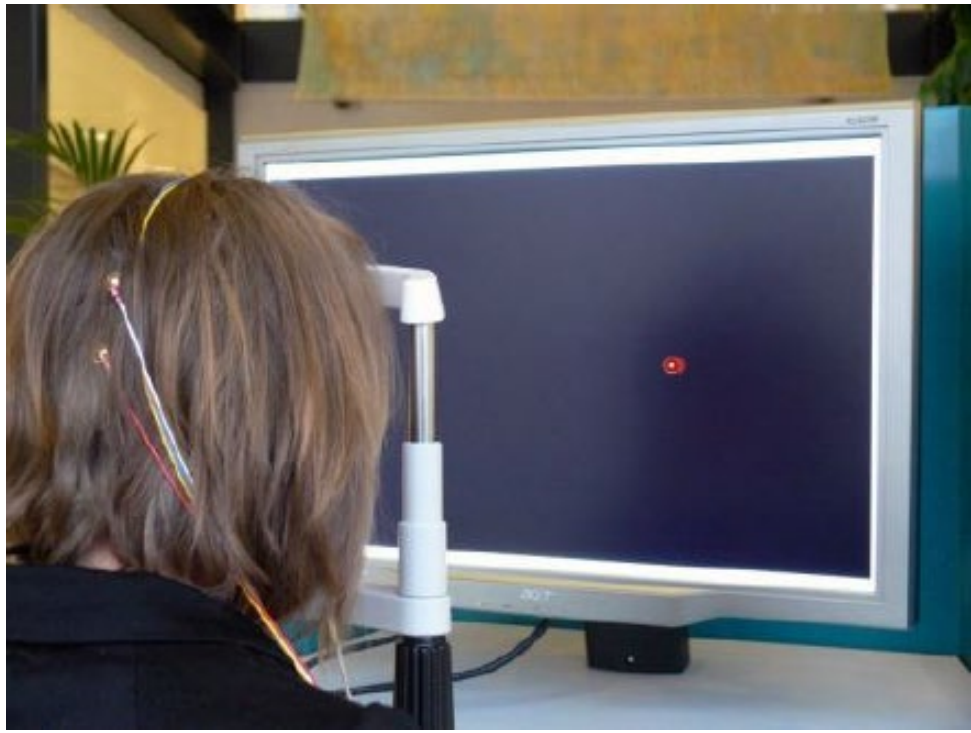


- Fast absorption
- Optimal half-life (8 h)
- No accumulation over time
- No active metabolites

Idorsia makes daridorexant available in the US, Germany, Italy, Spain, Switzerland, the UK, Canada, Austria, France, and Sweden under the tradename QUVIVIQ. In addition, daridorexant is approved throughout the European Union.

Fast and time limited pharmacodynamic effect





Person performing eye movement test

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No pharmacodynamic effect on next morning

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Daridorexant registration program

Robust program in adult and elderly insomnia patients

Following completion of Phase 2 studies, two similar pivotal studies of 3-month duration in moderate and severe insomnia

Efficacy

- Objective and subject sleep parameters (onset and maintenance) by polysomnography (PSG) and sleep diary questionnaire (SDQ)
- Daytime functioning assessed by insomnia daytime symptoms and impact questionnaire (IDSIQ)
- Replicated in two confirmatory studies

Safety

- Adverse events, vital signs, biochemistry and hematology
- Next morning residual “hang-over” effect
- Withdrawal/physical dependence, and rebound insomnia

Comprehensive clinical pharmacology program including:

- Driving performance, interaction (medicines, alcohol), Safety in specific population (COPD, obstructive sleep apnea, liver and renal impairment), drug abuse potential

Idorsia makes daridorexant available in the US, Germany, Italy, Spain, Switzerland, the UK, Canada, Austria, France, and Sweden under the tradename QUVIVIQ. In addition, daridorexant is approved throughout the European Union.

Study objectives

1st study, 50, 25 mg; 2nd study, 25, 10 mg

Primary objective

- To evaluate the efficacy of daridorexant on objective sleep parameters in patients with insomnia.

Secondary objective

- To evaluate the efficacy of daridorexant on subjective sleep parameters and daytime functioning in patients with insomnia.

Safety objective

- To assess the safety and tolerability of daridorexant in patients with insomnia during treatment and upon treatment discontinuation.

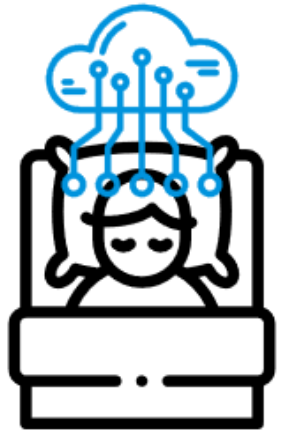
Idorsia makes daridorexant available in the US, Germany, Italy, Spain, Switzerland, the UK, Canada, Austria, France, and Sweden under the tradename QUVIVIQ. In addition, daridorexant is approved throughout the European Union.

Objective sleep assessments

Repeated polysomnography recordings in a sleep lab in all patients

Phase 3 program

- Assess insomnia objectively
- Ensure well-characterized insomnia patients are randomized
- Establish solid baseline during placebo run-in
- Measure primary endpoint at Month 1 and Month 3
  - **Latency to persistent sleep**
  - **Wakening after sleep onset**
- Asses the potential for rebound
- Collect comprehensive information on total sleep time and sleep architecture

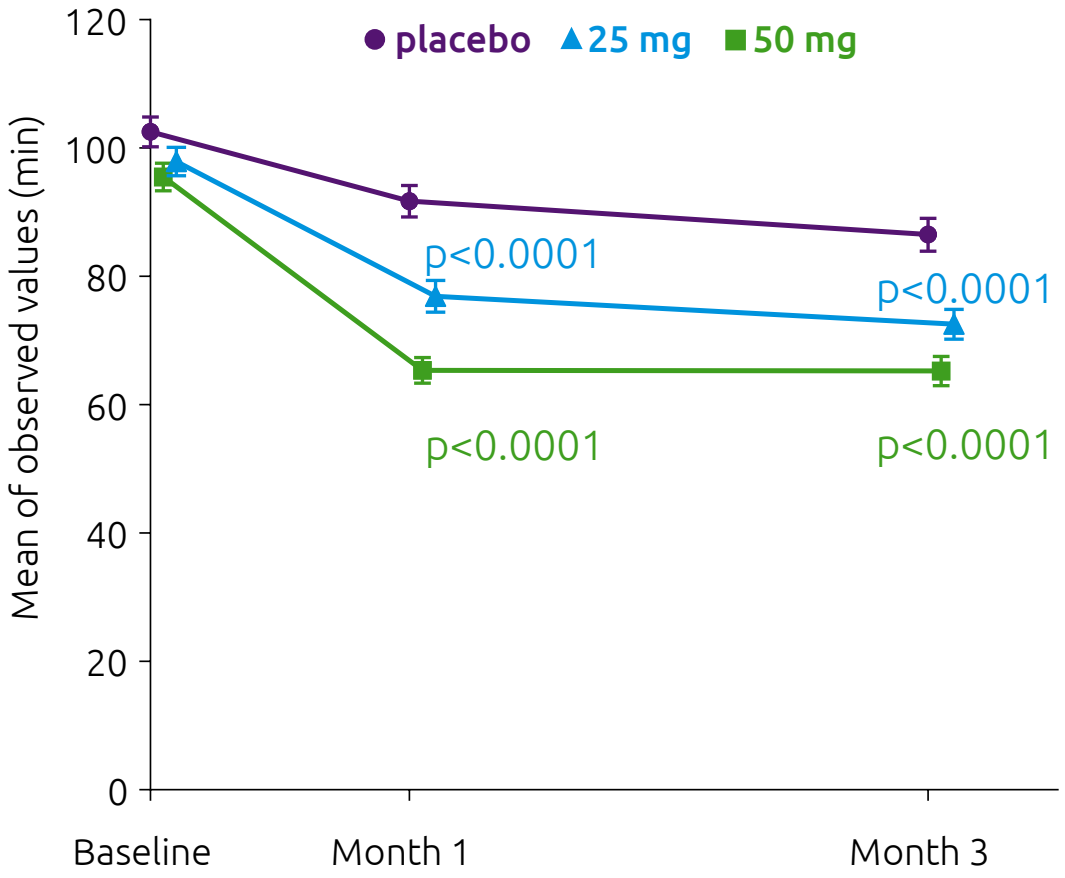


Sensors measure brain activity, eye movements, muscle tone, respiratory, and heart parameters.

Idorsia makes daridorexant available in the US, Germany, Italy, Spain, Switzerland, the UK, Canada, Austria, France, and Sweden under the tradename QUVIVIQ. In addition, daridorexant is approved throughout the European Union.

1º endpoint: Wake after sleep onset (WASO)

A measure of sleep maintenance



Daridorexant 25 mg and 50 mg **significantly improved WASO** compared to placebo at months 1 and 3

LSM change from baseline (95% CI)

	Month 1	Month 3
Placebo	**–6.2** (–9.9 to –2.5)	**–11.1** (–15.1 to –7.1)
Daridorexant 25 mg	**–18.4** (–22.1 to –14.7)	**–23.0** (–27.0 to –19.0)
LSM difference compared with placebo (95% CI)	**–12.2** (–17.4 to –7.0)	**–11.9** (–17.5 to –6.2)
Daridorexant 50 mg	**–29.0** (–32.7 to –25.3)	**–29.4** (–33.4 to –25.4)
LSM difference compared with placebo (95% CI)	**–22.8** (–28.0 to –17.6)	**–18.3** (–23.9 to –12.7)

CI = confidence interval; LSM = least squares mean

Mignot E, et al. *Lancet Neurol* 2022; 21: 125–39

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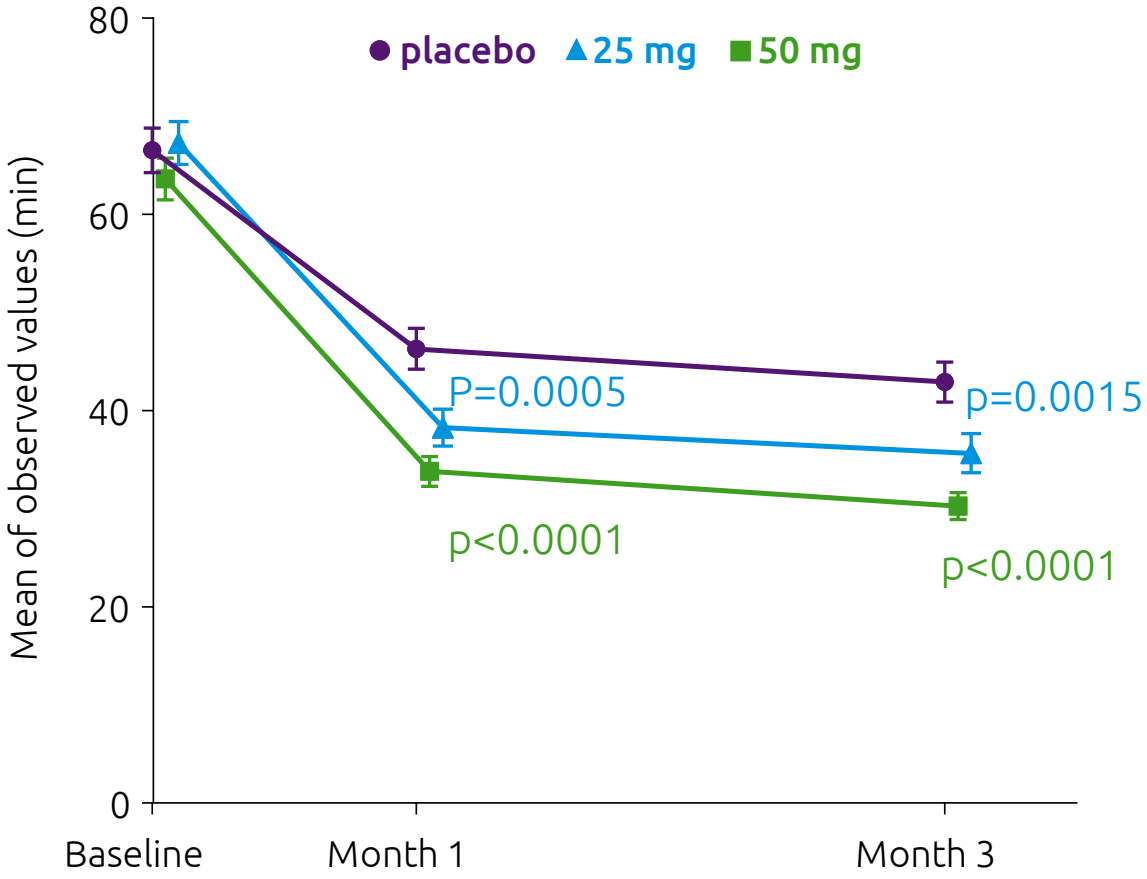
1º endpoint: Latency to persistent sleep (LPS)

A measure of sleep onset



Daridorexant 25 mg and 50 mg **significantly improved LPS** compared to placebo at months 1 and 3

LSM change from baseline (95% CI)

	Month 1	Month 3
Placebo	**–19.9** (–23.2 to –16.5)	**–23.1** (–26.5 to –19.8)
Daridorexant 25 mg	**–28.2** (–31.5 to –24.8)	**–30.7** (–34.0 to –27.4)
LSM difference compared with placebo (95% CI)	**–8.3** (–13.0 to –3.6)	**–7.6** (–12.3 to –2.9)
Daridorexant 50 mg	**–31.2** (–34.5 to –27.9)	**–34.8** (–38.1 to –31.5)
LSM difference compared with placebo (95% CI)	**–11.4** (–16.0 to –6.7)	**–11.7** (–16.3 to –7.0)

CI = confidence interval; LSM = least squares mean

Mignot E, et al. *Lancet Neurol* 2022; 21: 125–39

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Sleep diary questionnaire (SDQ)

Daily recording

Morning questionnaire

- 10 questions related to medication, quantification of sleep, awakenings
- 3 visual analog scales related to quality and deepness of sleep and sleepiness in the morning

Total sleep time
Secondary endpoint

Evening questionnaire

- 2 questions related to napping
- 2 visual analog scales related to alertness and ability to perform

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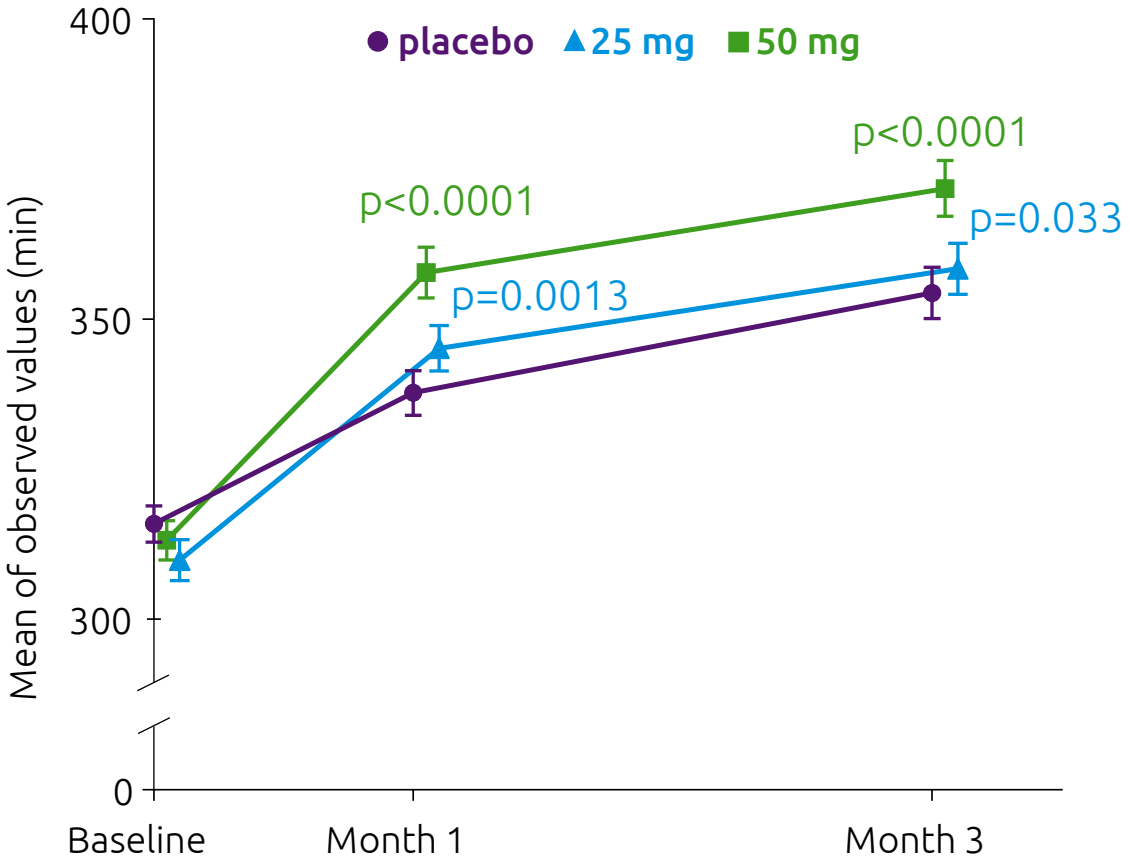
2º endpoint: Subjective Total Sleep Time (sTST)

A measure of how the patient think they slept



Daridorexant 25 mg and 50 mg **significantly improved sTST** compared to placebo at months 1 and 3

LSM change from baseline (95% CI)

	Month 1	Month 3
Placebo	**21.6** (16.1 to 27.0)	**37.9** (31.4 to 44.4)
Daridorexant 25 mg	**34.2** (28.7 to 39.6)	**47.8** (41.3 to 54.3)
LSM difference compared with placebo (95% CI)	**12.6** (5.0 to 20.3)	**9.9** (0.8 to 19.1)
Daridorexant 50 mg	**43.6** (38.2 to 49.1)	**57.7** (51.2 to 64.2)
LSM difference compared with placebo (95% CI)	**22.1** (14.4 to 29.7)	**19.8** (10.6 to 28.9)

CI = confidence interval; LSM = least squares mean

Mignot E, et al. *Lancet Neurol* 2022; 21: 125–39

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Subjective assessment of daytime functioning

Insomnia Daytime Symptoms and Impacts Questionnaire (IDSIQ)

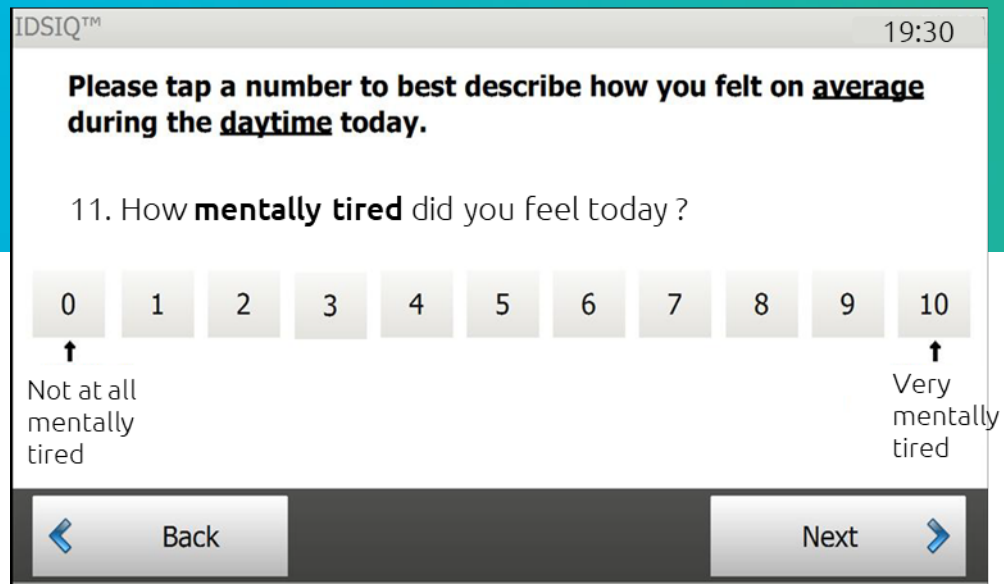
Measures
Item 1. How **clear-headed** did you feel today?
Item 2. How well were you able to **concentrate** today?
Item 3. How **forgetful** did you feel today?
Item 4. How **worried** did you feel today?
Item 5. How **frustrated** by your lack of sleep did you feel today?
Item 6. How **irritable** did you feel today?
Item 7. How **stressed** did you feel today?
Item 8. How **energetic** did you feel today?
Item 9. How **much of an effort** was it to perform daily activities (i.e. reading, cleaning, work, school) today?
Item 10. How **refreshed** did you feel today?
Item 11. How **mentally tired** did you feel today?
Item 12. How **physically tired** did you feel today?
Item 13. How **sleepy** did you feel today?
Item 14. How **awake** did you feel today?

"Alert/cognition" domain score (0-60)

"Mood" domain score (0-40)

"Sleepiness" domain score (0-40)

Items are ranked on a numeric rating scale from 0-10



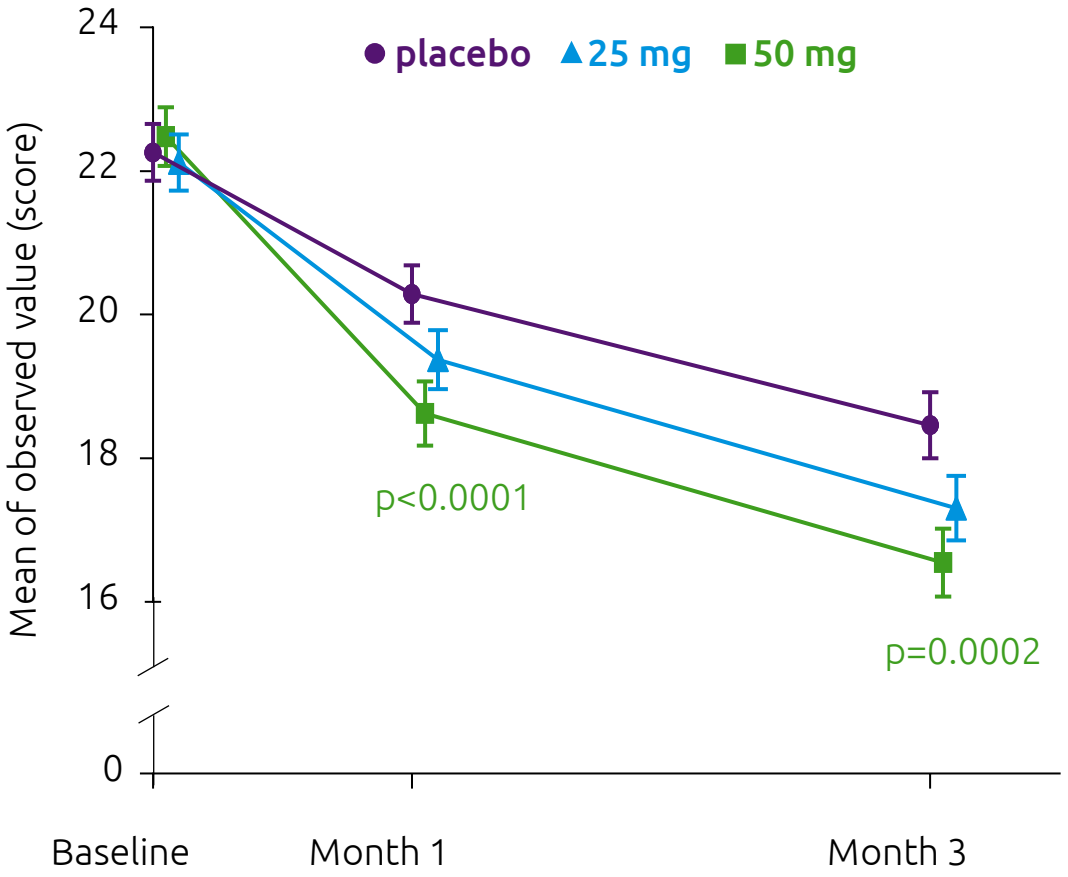
Daytime functioning measured by sleepiness domain score
Secondary endpoint

Idorsia makes daridorexant available in the US, Germany, Italy, Spain, Switzerland, the UK, Canada, Austria, France, and Sweden under the tradename QUVIVIQ. In addition, daridorexant is approved throughout the European Union.

2º endpoint: IDSIQ sleepiness domain

A measure of daytime functioning

How **energetic** did you feel today?
How **mentally tired** did you feel today?
How **physically tired** did you feel today?
How **sleepy** did you feel today?



Daridorexant 50 mg **significantly improved IDSIQ sleepiness domain** score compared to placebo at months 1 and 3

LSM change from baseline (95% CI)

	Month 1	Month 3
Placebo	**–2.0** (–2.6 to –1.5)	**–3.8** (–4.5 to –3.1)
Daridorexant 25 mg	**–2.8** (–3.3 to –2.2)	**–4.8** (–5.5 to –4.1)
LSM difference compared with placebo (95% CI)	**–0.8** (–1.5 to 0.01)	**–1.0** (–2.0 to 0.01)
Daridorexant 50 mg	**–3.8** (–4.3 to –3.2)	**–5.7** (–6.4 to –5.0)
LSM difference compared with placebo (95% CI)	**–1.8** (–2.5 to –1.0)	**–1.9** (–2.9 to –0.9)

CI = confidence interval; LSM = least squares mean

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Exploratory endpoints: IDSIQ other scores

A measure of daytime functioning

IDSIQ mood domain, alert/cognition domain, and total scores at both timepoints were reduced (improved) (all nominal p-values for daridorexant 50 mg versus placebo ≤0.0005; not adjusted for multiplicity)

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Adverse events

In the safety analysis population (n=1847)

	Study 1			Study 2		
	Dari 50 mg (n = 308)	Dari 25 mg (n = 310)	Placebo (n = 309)	Dari 25 mg (n = 308)	Dari 10 mg (n = 306)	Placebo (n = 306)
Participants with ≥1 adverse event*	116 (38%)	117 (38%)	105 (34%)	121 (39%)	117 (38%)	100 (33%)
Adverse events* leading to treatment discontinuation	3 (1%)	7 (2%)	10 (3%)	4 (1%)	6 (2%)	7 (2%)
Participants with ≥1 serious adverse event	3 (1%)	2 (1%)	7 (2%)	3 (1%)	3 (1%)	4 (1%)
Participants with adverse event* (≥2% in any group)						
Nasopharyngitis	20 (6%)	21 (7%)	20 (6%)	13 (4%)	32 (10%)	16 (5%)
Headache	19 (6%)	16 (5%)	12 (4%)	15 (5%)	12 (4%)	11 (4%)
Accidental overdose	8 (3%)	4 (1%)	5 (2%)	4 (1%)	4 (1%)	1 (<1%)
Fatigue	7 (2%)	7 (2%)	2 (1%)	11 (4%)	7 (2%)	2 (1%)
Dizziness	7 (2%)	6 (2%)	2 (1%)	6 (2%)	4 (1%)	4 (1%)
Nausea	7 (2%)	1 (<1%)	3 (1%)	2 (1%)	3 (1%)	3 (1%)
Somnolence	5 (2%)	11 (4%)	6 (2%)	10 (3%)	6 (2%)	4 (1%)
Fall	1 (<1%)	1 (<1%)	8 (3%)	3 (1%)	4 (1%)	3 (1%)
Upper respiratory tract infection	1 (<1%)	1 (<1%)	3 (1%)	3 (1%)	5 (2%)	6 (2%)

Data are n (%). The safety analysis population included all participants who received at least one dose of double-blind treatment. *Adverse events that occurred during the double-blind treatment period in the safety population are included in the table and presented with their preferred terms.

Mignot E, et al. *Lancet Neurol* 2022; 21: 125–39

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Adjudicated adverse events

In the safety analysis population (n=1847)

	Study 1			Study 2		
	Dari 50 mg (n = 308)	Dari 25 mg (n = 310)	Placebo (n = 309)	Dari 25 mg (n = 308)	Dari 10 mg (n = 306)	Placebo (n = 306)
Adjudicated adverse events†						
Excessive daytime sleepiness	1 (<1%)	2 (1%)	1 (<1%)	4 (1%)	1 (<1%)	1 (<1%)
Sleep paralysis	1 (<1%)	1 (<1%)	0	2 (1%)	0	0
Hallucinations	0	1 (<1%)	0	1 (<1%)	0	0
Suicidal ideation or self-injury‡	0	0	0	1 (<1%)	1 (<1%)	0

Data are n (%). The safety analysis population included all participants who received at least one dose of double-blind treatment. †Adjudicated adverse events were reported during the double-blind treatment up to 30 days after the end of treatment or date of enrolment into the extension trial and were adjudicated blindly by an independent safety board. ‡Adjudicated adverse events belonging to the category suicidal ideation or self-injury (preferred term: suicidal ideation) were reported in two participants, one in each daridorexant group in study 2; both patients had pre-existing medical conditions (paranoid schizophrenia or depression) and the independent safety board adjudicated both adverse events as potentially related to trial treatment.

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Further safety observations

No adverse events suggested that **drug misuse** might have occurred

No withdrawal symptoms were observed during the placebo run-out period, as assessed by adverse events or the Benzodiazepine Withdrawal Symptom Questionnaire (BWSQ)

During the placebo run-out period, WASO and LPS were numerically lower, and mean self-reported total sleep time was higher than respective baseline values, indicating **absence of rebound insomnia**

Mignot E, et al. *Lancet Neurol* 2022; 21: 125–39

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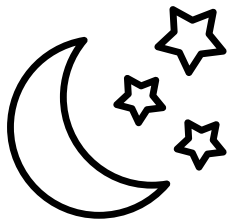
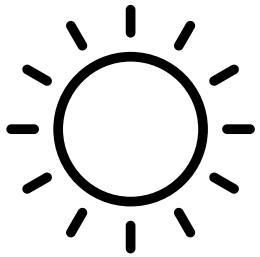
The daridorexant clinical program provides a wealth of evidence



Comprehensive sleep efficacy perceived by patients (25 mg & 50 mg)

- Fall asleep faster
- Stay asleep longer
- Time in each sleep stage preserved

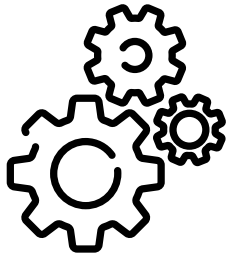


Daytime functioning perceived by patients (50 mg)

- Improved sleepiness
- Consistent effect on mood and alertness / cognition on exploratory endpoints
- Progressive improvement over time

Documented safety

- A low overall incidence of adverse events (AE), comparable between treatment groups
- Most common AEs (>5%): nasopharyngitis and headache
- No evidence of tolerance or dependence
- No rebound insomnia or withdrawal effects



Precision MOA & intrinsic properties of daridorexant

- Targets only the part of the brain that keeps you awake, without broad sedation
- Ideal pharmacological profile

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Unlocking the value of QUVIVIQ

Advance the science of sleep and insomnia

QUVIVIQ™ daridorexant 25mg, 50mg tablets

- Positive results in Phase 4 study in patients with insomnia and comorbid nocturia
- Phase 4 studies in patients with insomnia and comorbid psychiatric and neurological disease
- Phase 2 in pediatric insomnia expected to read out results in Q3 2025
- >10 investigator-initiated studies in preparation or recruiting as a treatment for:
  - mild cognitive impairment and mild to moderate **Alzheimer disease**
  - active-duty service members and veterans with **PTSD**
  - enhancing sleep and **reducing substance use** in patients **dependent on alcohol and opioids**
  - enhancing sleep during **smoking withdrawal**
  - **menopause-related insomnia** symptoms
  - improving **CPAP adherence** in subjects with **co-morbid insomnia and sleep apnea**
  - among others…

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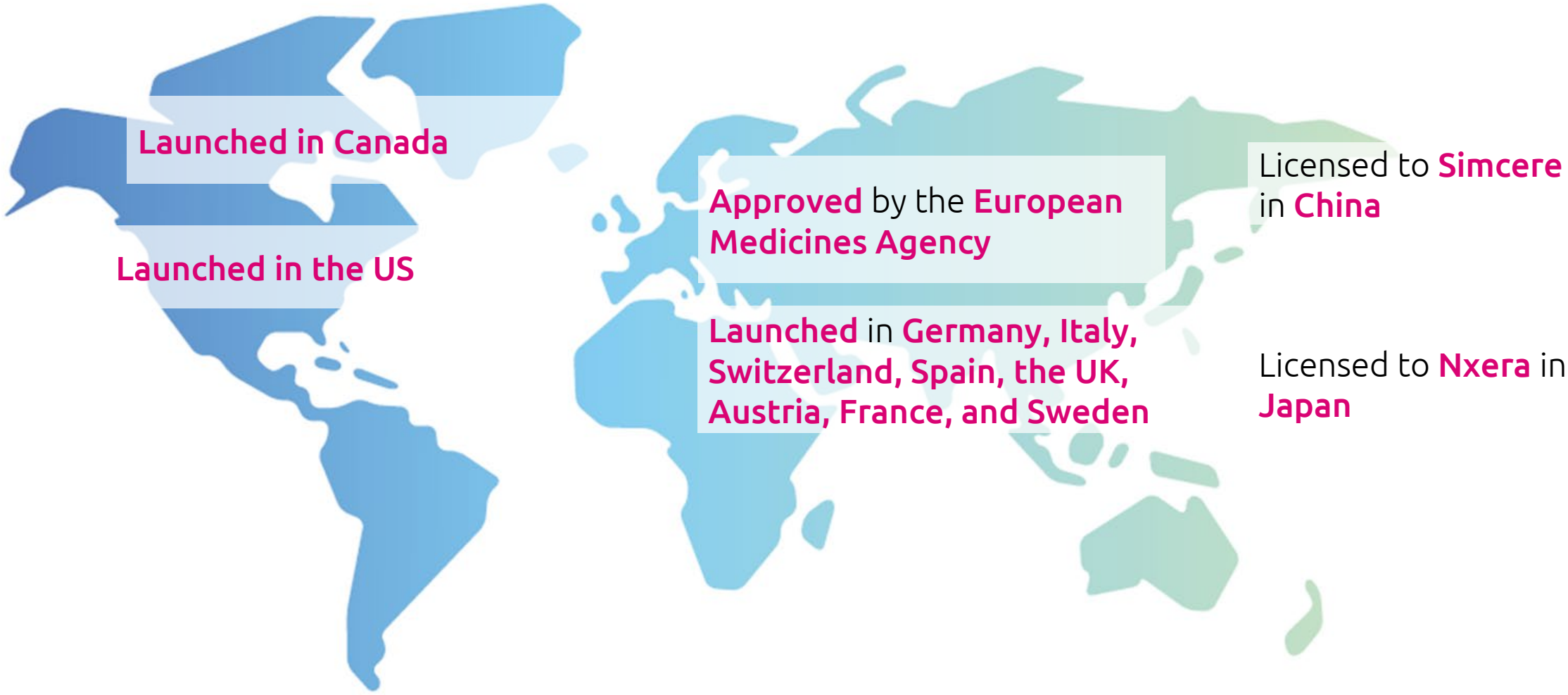
On track to become a global brand

QUVIVIQ daridorexant 25mg, 50mg tablets



Launched in Canada

Launched in the US

Approved by the **European Medicines Agency**

Launched in **Germany, Italy, Switzerland, Spain, the UK, Austria, France, and Sweden**

Licensed to **Simcere** in **China**

Licensed to **Nxera** in **Japan**

Idorsia makes daridorexant available in the US, Germany, Italy, Spain, Switzerland, the UK, Canada, Austria, France, and Sweden under the tradename QUVIVIQ. In addition, daridorexant is approved throughout the European Union.

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Collaboration with Syneos Health

Commercialization partner to launch daridorexant in the US, Europe, and Canada

- Syneos Health selected as commercialization partner in order to effectively reach the primary care market, which accounts for a large volume of insomnia prescriptions, in the US, Europe, and Canada
- Syneos Health brings a robust customer-facing sales expertise and proven track record in launching new products in these regions
- An innovative, revenue-driven agreement to accelerate and maximize reach to patients
- Together we will lead the transformation and modernization of the insomnia market

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License agreements with Nxera

Nxera Pharma

Co-exclusive license granted to Nxera for daridorexant in Australia, Brunei, Cambodia, Indonesia, Japan, Laos, Malaysia, Myanmar, New Zealand, Philippines, Singapore, South Korea, Thailand, Taiwan, and Vietnam

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License agreement with Simcere

Development and commercialization of daridorexant in the Greater China region

- Simcere has an exclusive right to develop and commercialize daridorexant in the Greater China region (Mainland China, Hong Kong, and Macau), one of the world's largest pharmaceutical markets
- Simcere is responsible for the local development program with Chinese patients
- Idorsia receives a US$ 30 million upfront payment and will be eligible to receive an additional milestone payment of US$ 20 million upon regulatory approval by the National Medical Products Administration, as well as commercial milestone payments and low double-digit tiered royalties based upon future sales.

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QUVIVIQ® (daridorexant) launched in the US in May 2022

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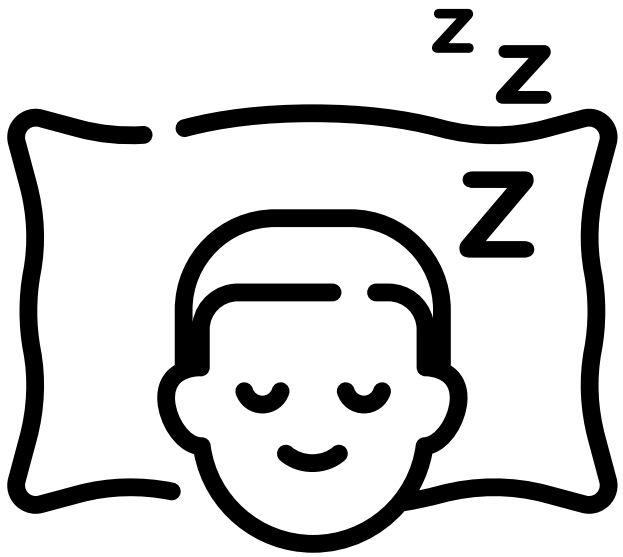
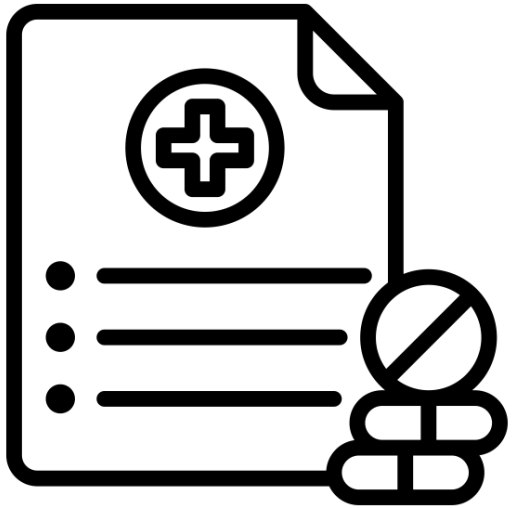
QUVIVIQ® (daridorexant) IV 25mg, 50mg tablets

CHF 5.9 million net sales in Q1 2025 in the US

>180K
patients treated



>600K
prescriptions dispensed



>50K
prescribers

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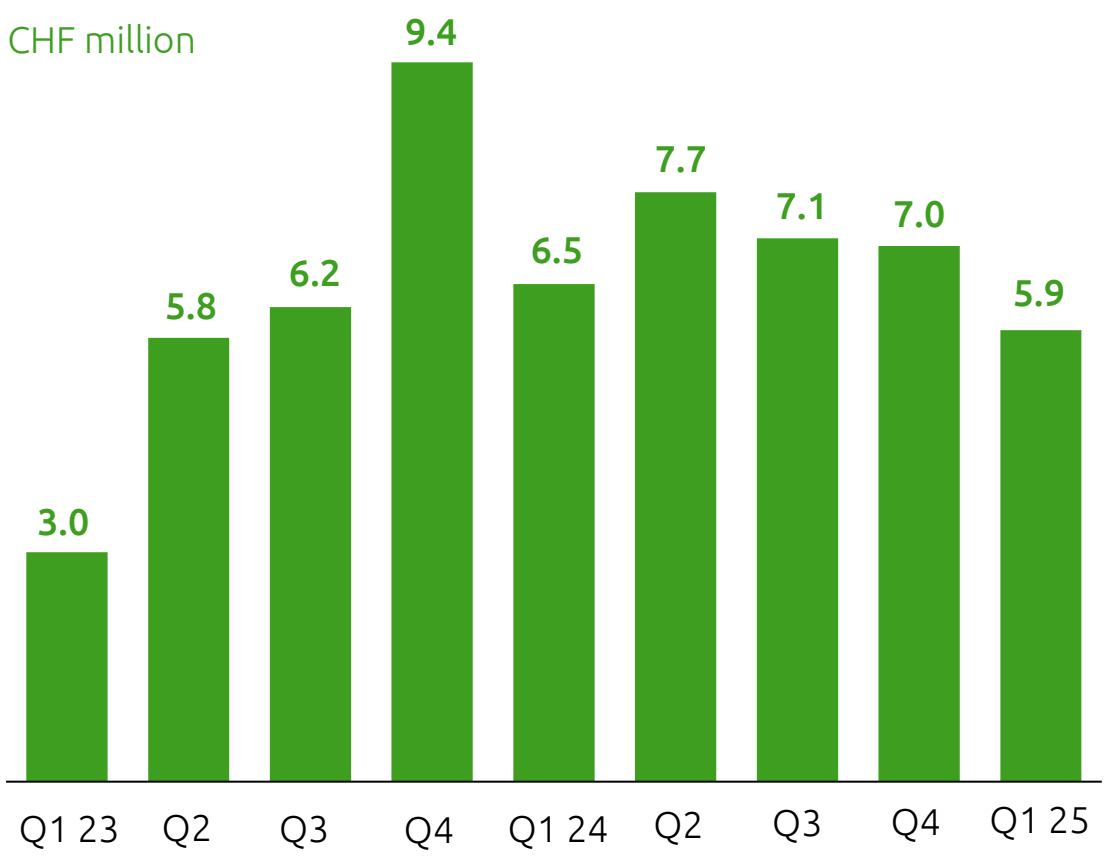
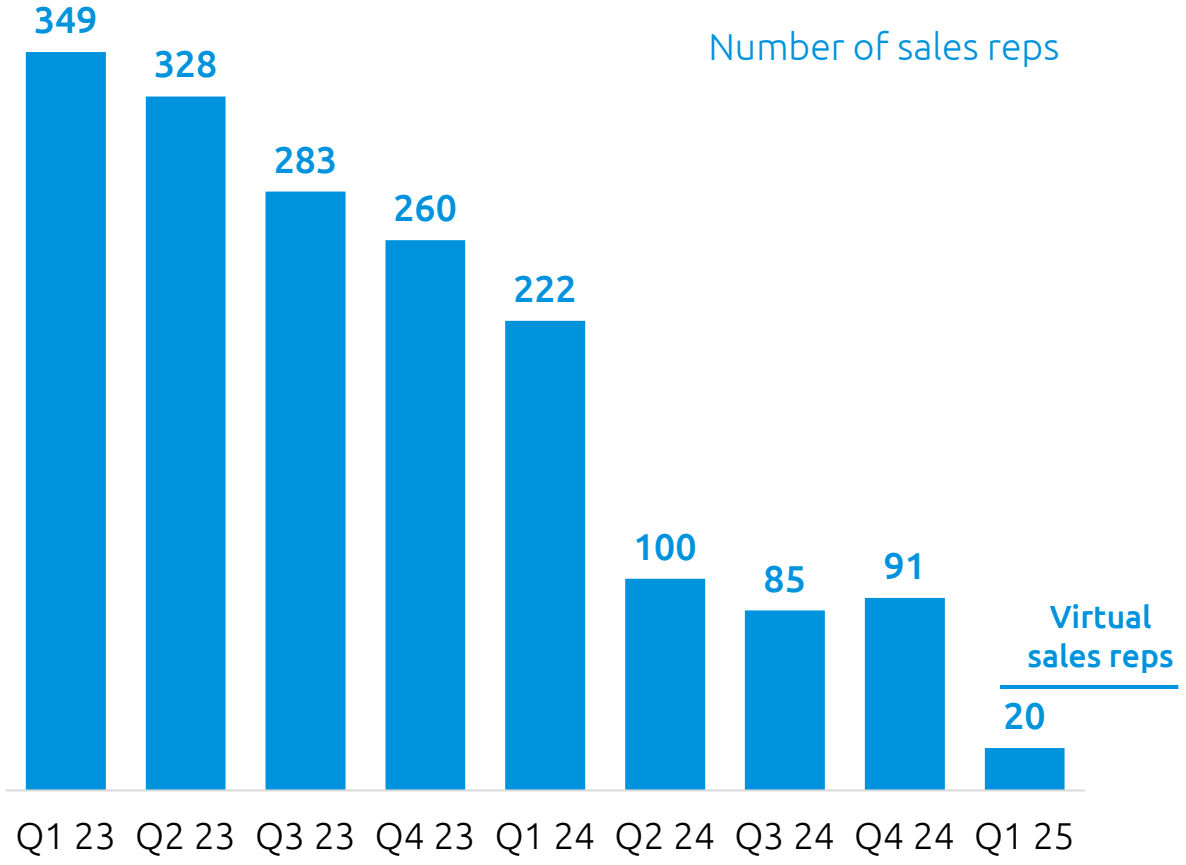
Unlocking the value of QUVIVIQ

US sales maintained despite field force and OPEX reduction

US net sales



QUVIVIQ field force



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QUVIVIQ (daridorexant) IV 25mg, 50mg tablets

"We are still hopeful that descheduling of the DORA class can be achieved and the real value of QUVIVIQ in the US market can be unlocked."

Michael Moye
President Idorsia US

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Scheduling under discussion

Citizen's Petition
requesting descheduling
of the DORA class
of medicines
progressing

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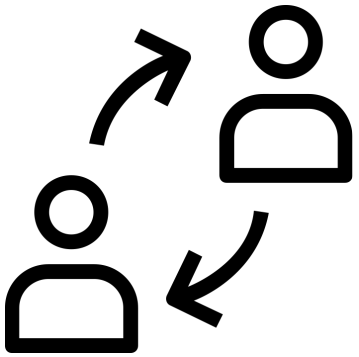
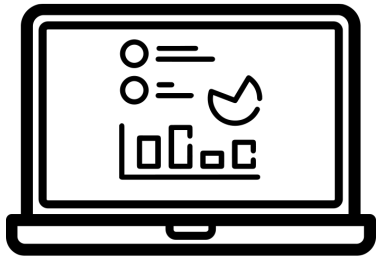
Collaboration with Syneos Health



Switched to 20 virtual sales reps operating remotely instead of the around 100 field force sales reps



Marketing, digital media, data analytics and market access activities in support of the virtual reps

“Demand has grown by an impressive 50% quarter on quarter, mainly driven by reimbursed markets. Across the EUCAN region, more than 10 million nights of sleep have been prescribed in the first quarter of 2025.”

Benjamin Limal

President of Europe and Canada region

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The European Insomnia Guideline: An update on the diagnosis and treatment of insomnia 2023

“The introduction of DORAs has probably been the most significant recent development in the pharmacological treatment of insomnia…”

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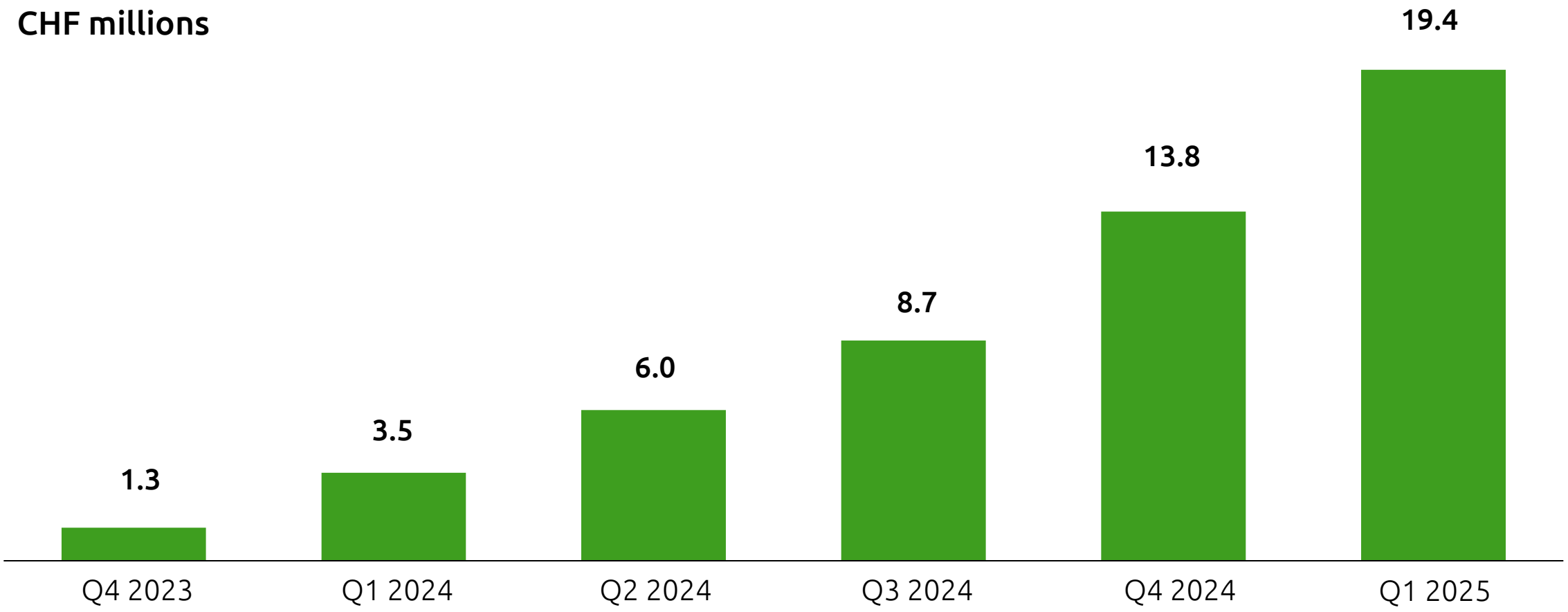
Accelerating QUVIVIQ sales

Europe & Canada



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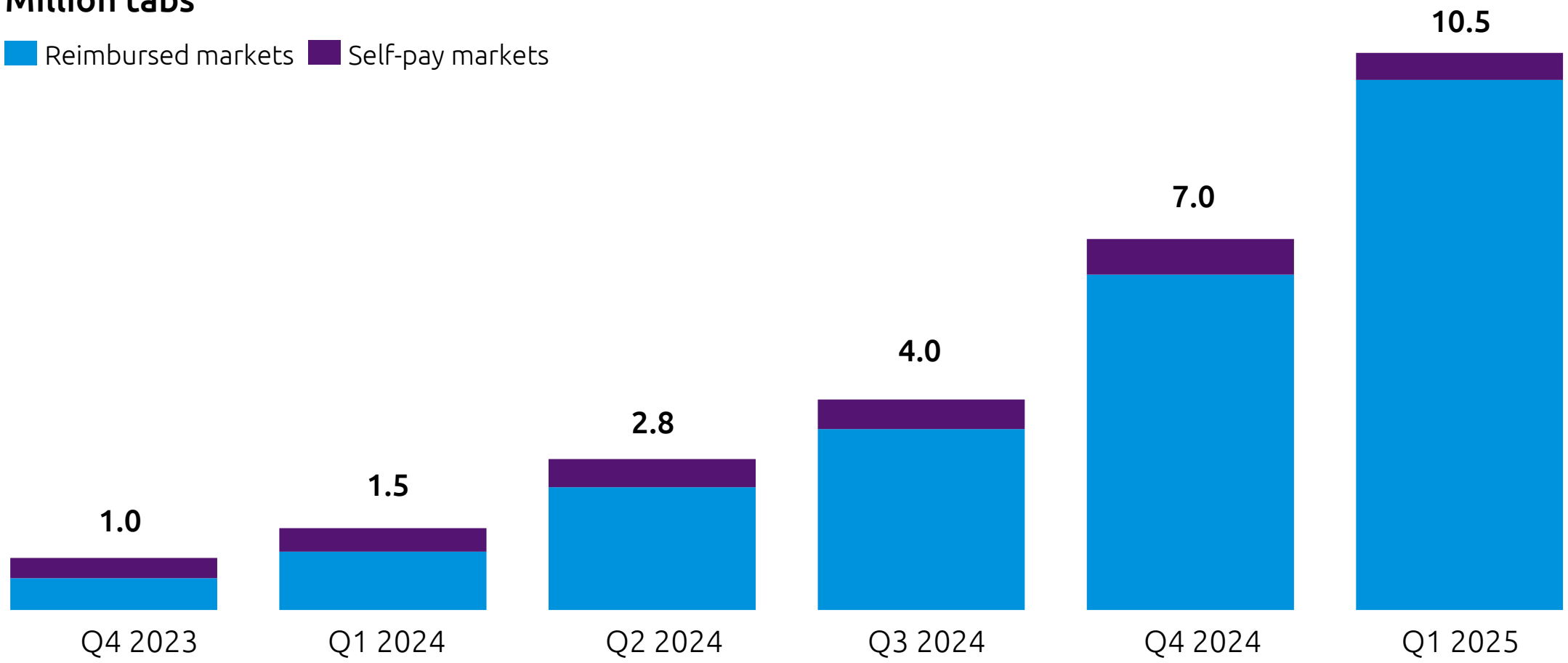
Accelerating QUVIVIQ demand

Europe & Canada

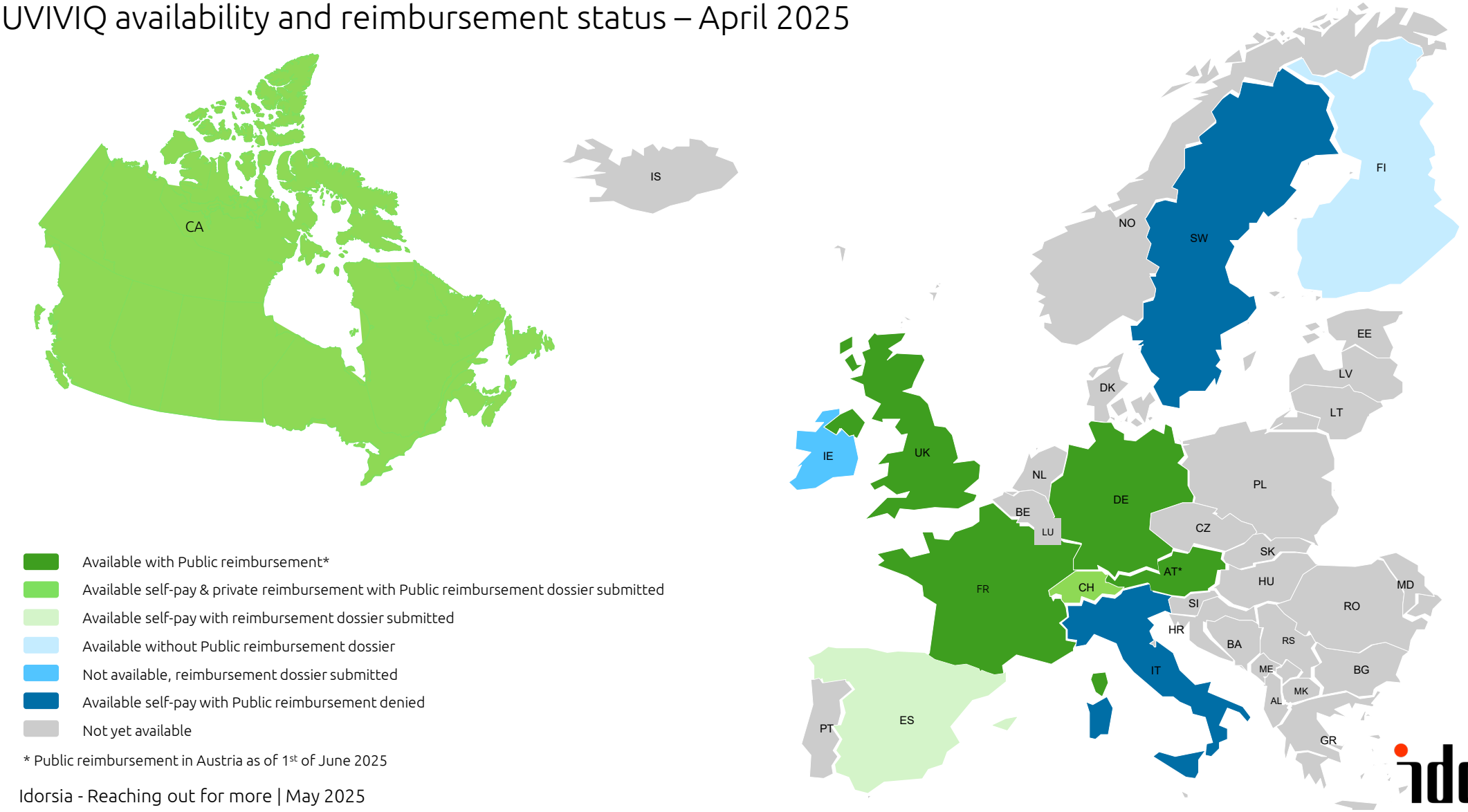
Million tabs



Daridorexant is available in the US, Germany, Italy, Spain, Switzerland, the UK, Canada, Austria, France, and Sweden under the tradename QUVIVIQ. In addition, daridorexant is approved throughout the European Union.

We have secured reimbursement in 6 Countries and are focused to expand public access in EUCAN

QUVIVIQ availability and reimbursement status – April 2025

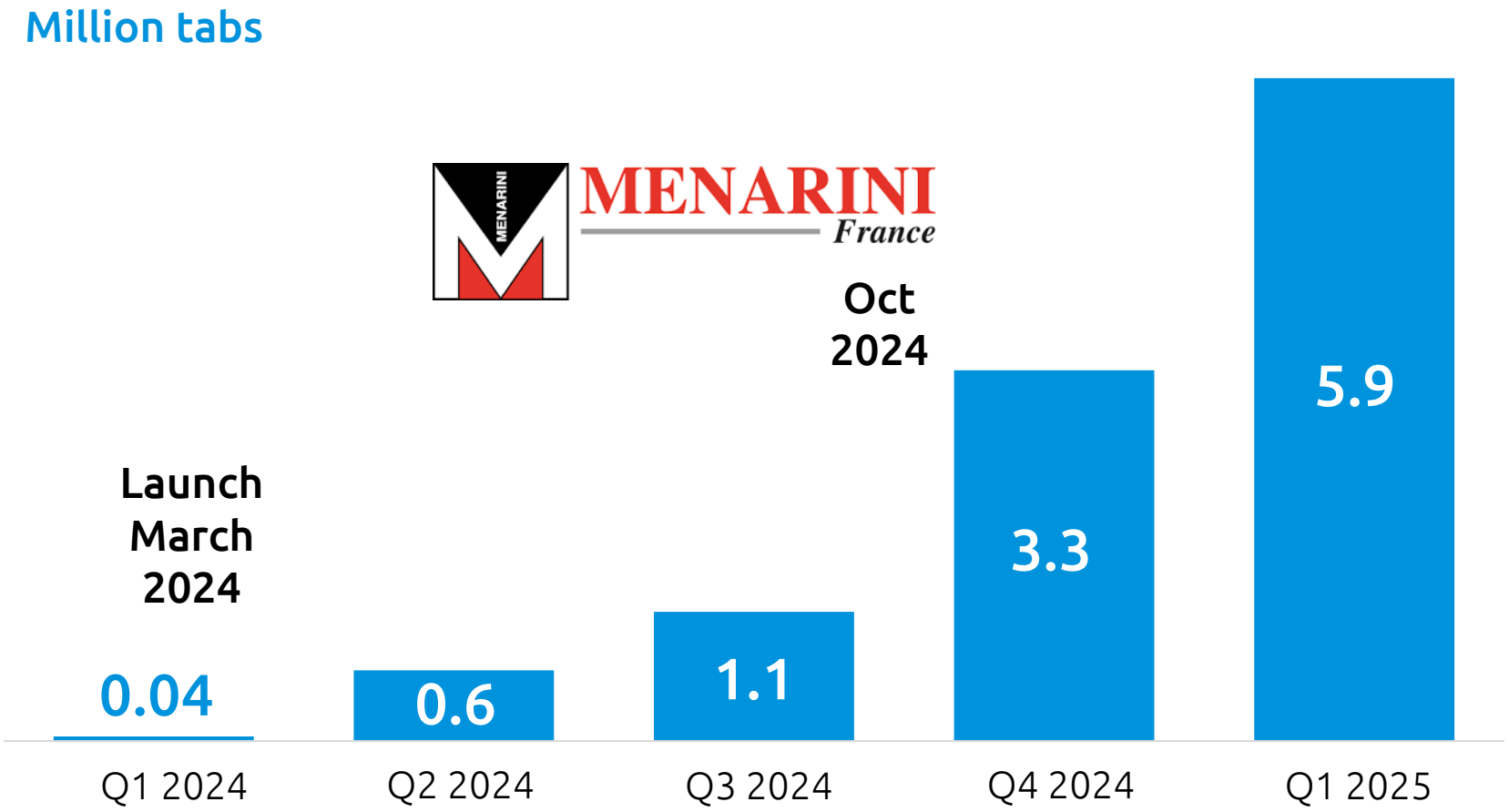


- Available with Public reimbursement*
- Available self-pay & private reimbursement with Public reimbursement dossier submitted
- Available self-pay with reimbursement dossier submitted
- Available without Public reimbursement dossier
- Not available, reimbursement dossier submitted
- Available self-pay with Public reimbursement denied
- Not yet available

* Public reimbursement in Austria as of 1st of June 2025

Expanding our commercial reach to GP prescribers

Immediate impact of commercial partnership with Menarini in France



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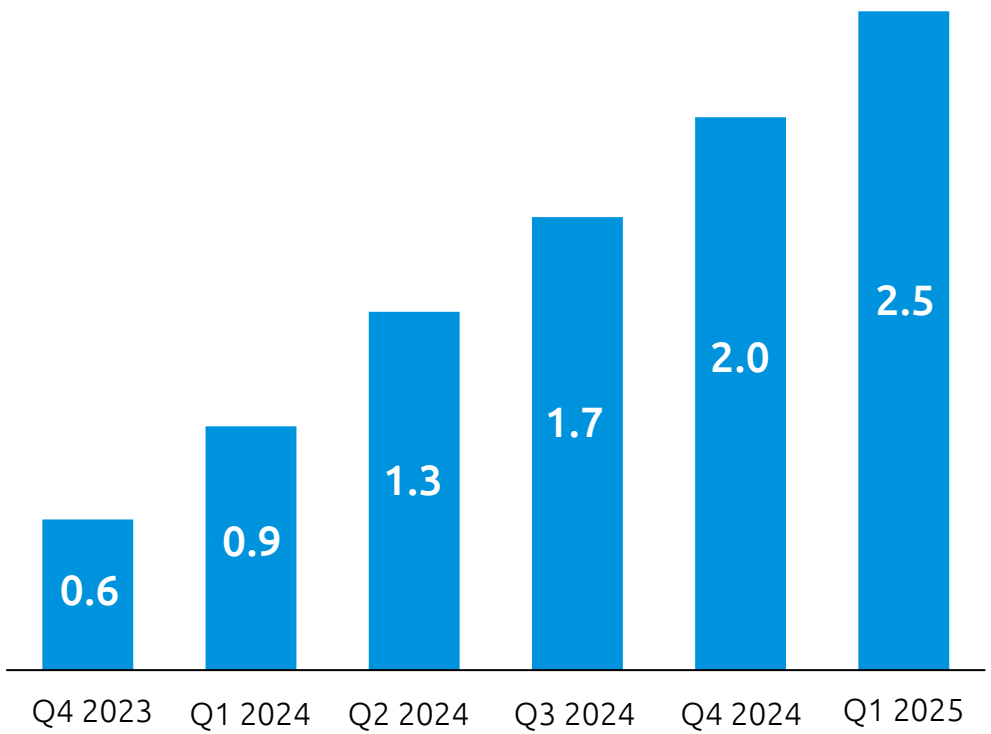
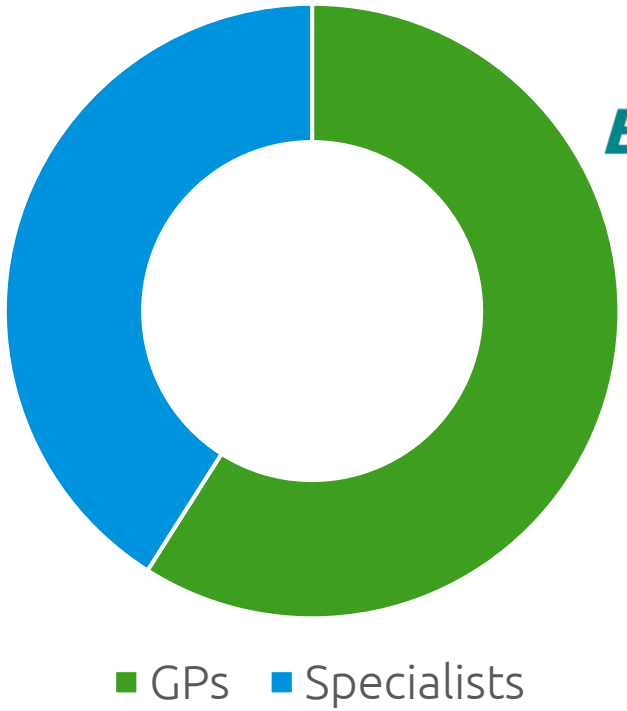
Expanding our commercial reach to GP prescribers

Solid sales growth set to accelerate with new commercial partnership with Berlin-Chemie

Million tabs



Volume share by specialty of the German insomnia market

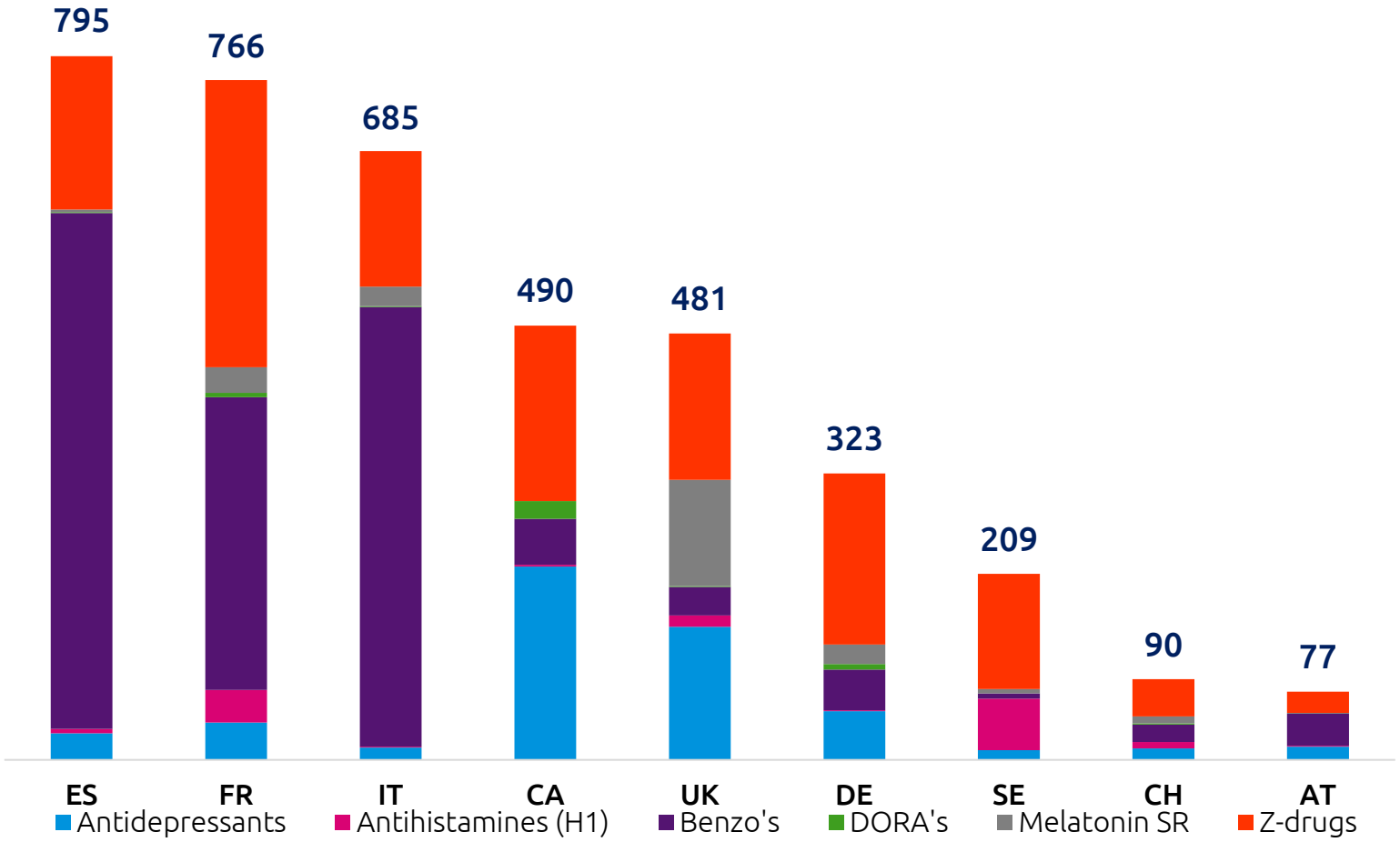


BERLIN-CHEMIE MENARINI

…beginning in early April 2025

EUCAN represents a massive market opportunity

Estimated insomnia market volume*, standard units, millions

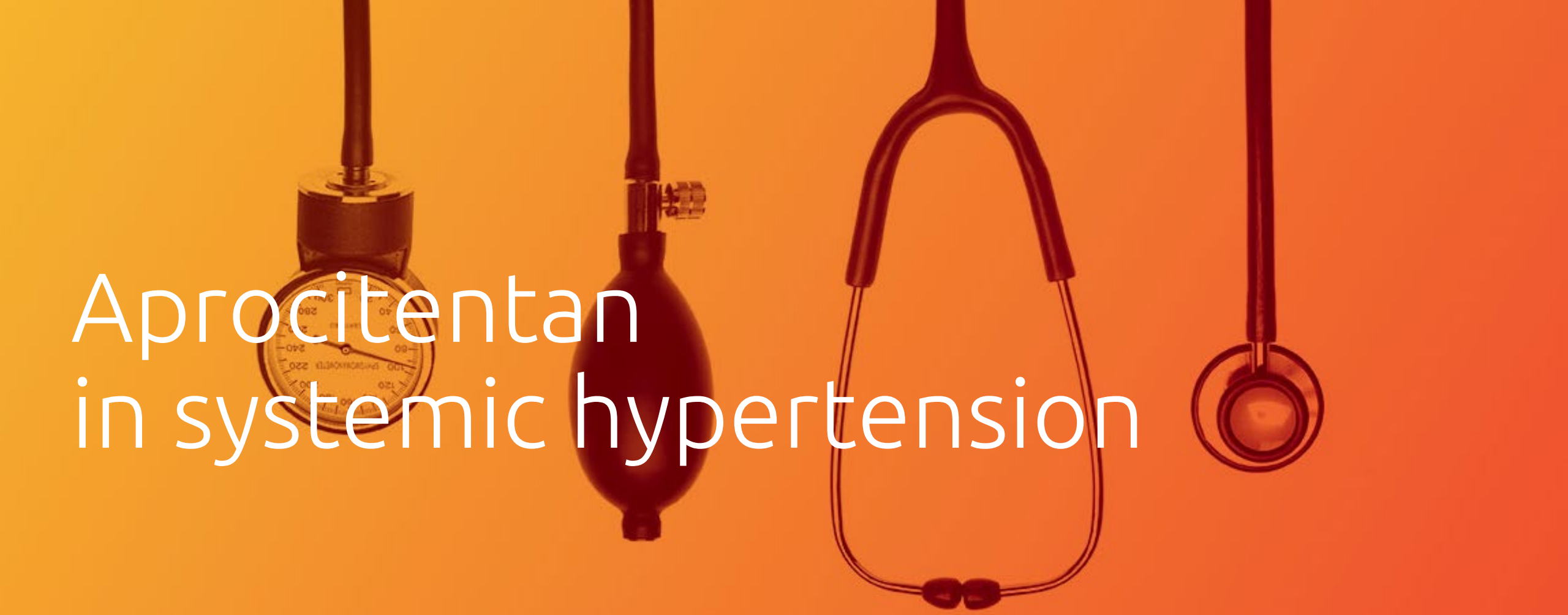


QUVIVIQ patient NBRx**

- 8%
- 8% Specialty only
- 4%
- 3.5%
- 2%
- 2%

** LRx - Nov 2024 for FR, IT, DE & CA. Oct 2024 for CH

Sources:
1) IQVIA MIDAS - Monthly Volume in M SU, MAT/Sep/2024 (EU5-CA-CHAT); Sweden MAT/SEP/2020
*Includes estimated off-label usage of anti-depressants, anti-histamines and benzos to treat insomnia



Aprocitentan in systemic hypertension

Aprocitentan is only available in the US under the tradename TRYVIO™ and is approved in the European Union and the UK under the tradename JERAYGO™. Market authorization is under review in Canada and Switzerland.

Aprocitentan: Innovative and highly differentiated drug for uncontrolled hypertension

TRYVIO™
(aprocitentan) **12.5mg tablets**

TRYVIO™ (aprocitentan)
12.5 mg **approved** in
March 2024

JERAYGO™
aprocitentan

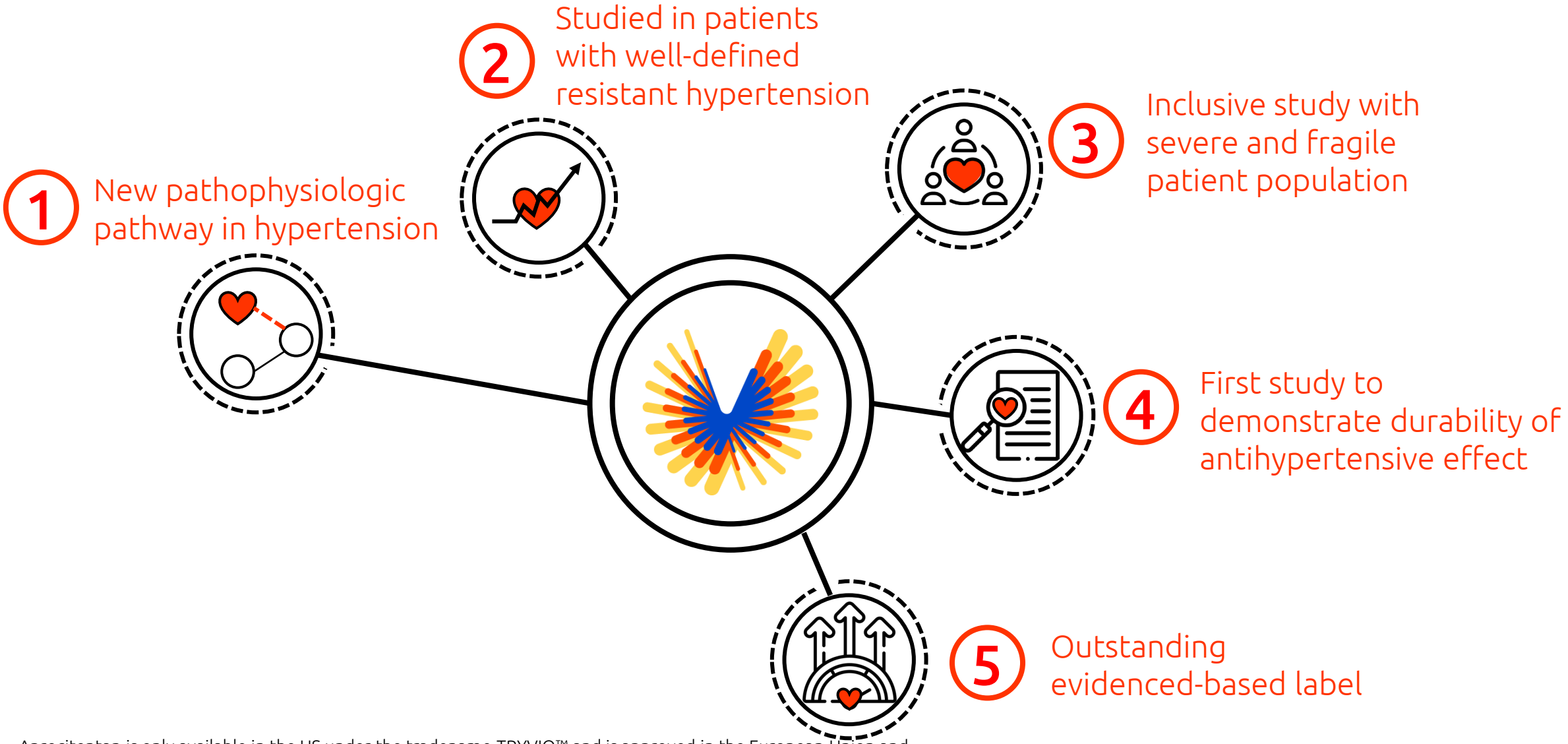
JERAYGO™ (aprocitentan)
12.5 mg & 25 mg **approved** in the EU
in July 2024 and UK in January 2025

Idorsia makes aprocitentan available in the US under the tradename TRYVIO. In addition, aprocitentan is approved throughout the European Union and in the UK under the tradename JERAYGO. Marketing authorization applications are under review in Canada and Switzerland.

"Today, there are millions of Americans whose blood pressure is not well-controlled despite existing therapy. This is a major public health issue leading to a high incidence of cardiovascular events."

Jean-Paul Clozel
Chairman of the Board of Directors

A unique compound with unique data



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“Since the endothelin pathway was not yet tackled, we selected aprocitentan, an endothelin receptor antagonist with the ideal properties for use with patients whose hypertension is not adequately controlled with other antihypertensives.”

Martine Clozel
Chief Scientific Officer

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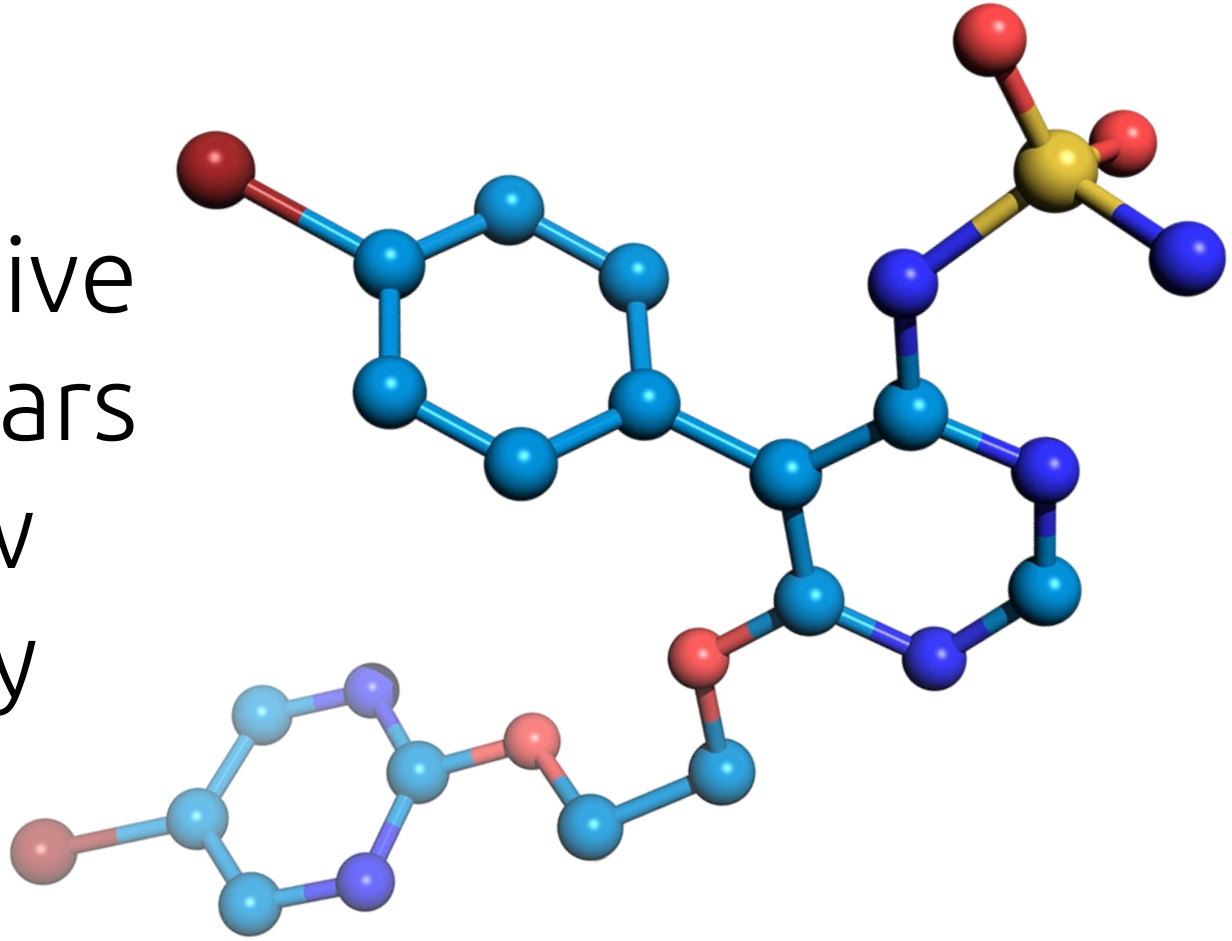
TRYVIO™
(aprocitentan) 12.5mg tablets

JERAYGO™
aprocitentan

The first anti-hypertensive therapy in almost 40 years which works on a new physiological pathway



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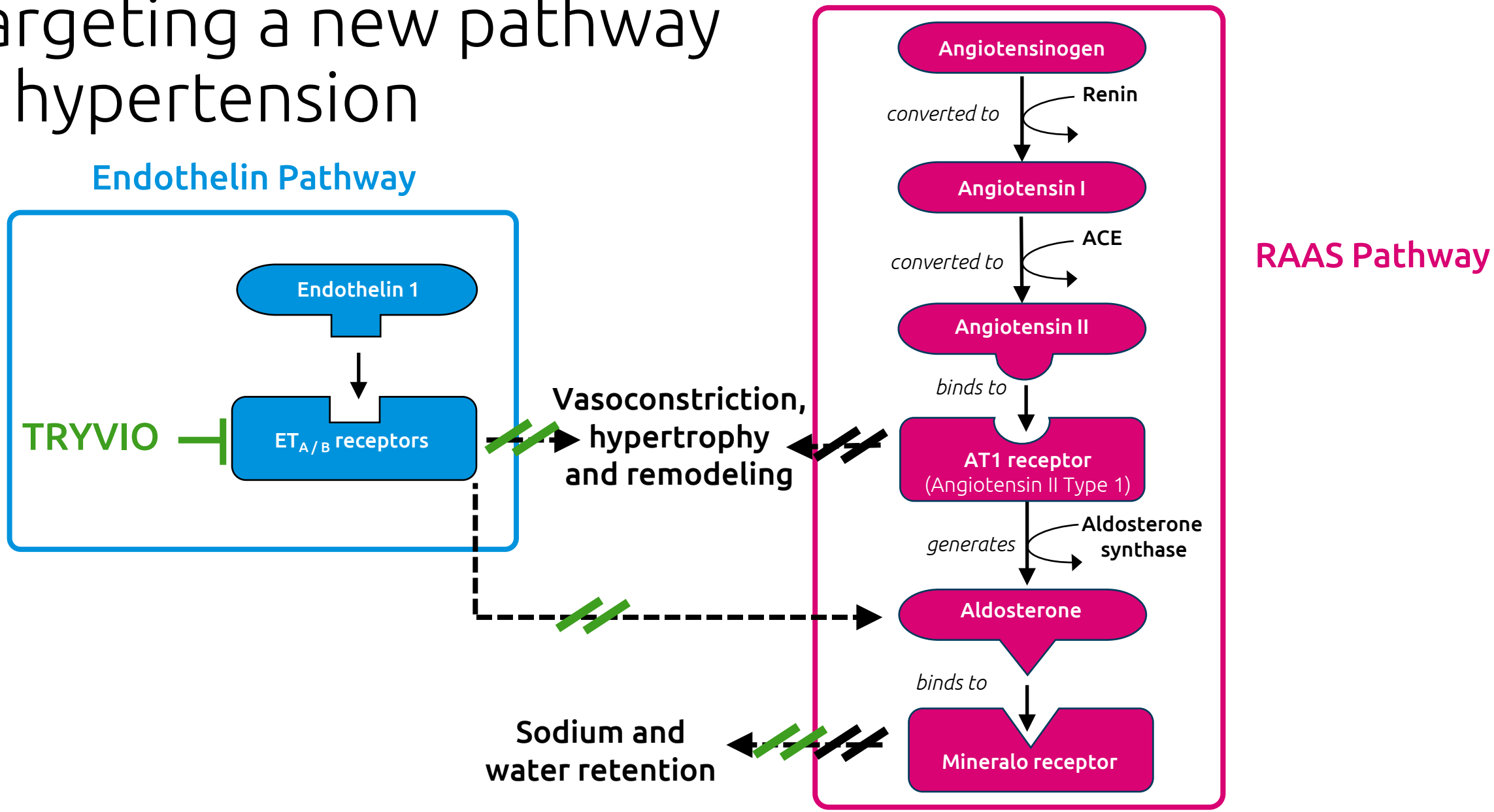
Targeting a new pathway in hypertension



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>30 years of researching the endothelin system

1988

Endothelin-1 identified

1990

ET_A and ET_B receptors identified

1993

First proof of the role of ERA published in *Nature*

1998

First evidence of dual ERA effect in hypertension published in *New England Journal of Medicine*

2007

Failed attempt by competition in resistant hypertension with selective ERA

2022

Aprocitentan – positive Phase 3 in resistant hypertension

2024

TRYVIO™ (aprocitentan) approved by US FDA

JERAYGO™ (aprocitentan) approved by EMA

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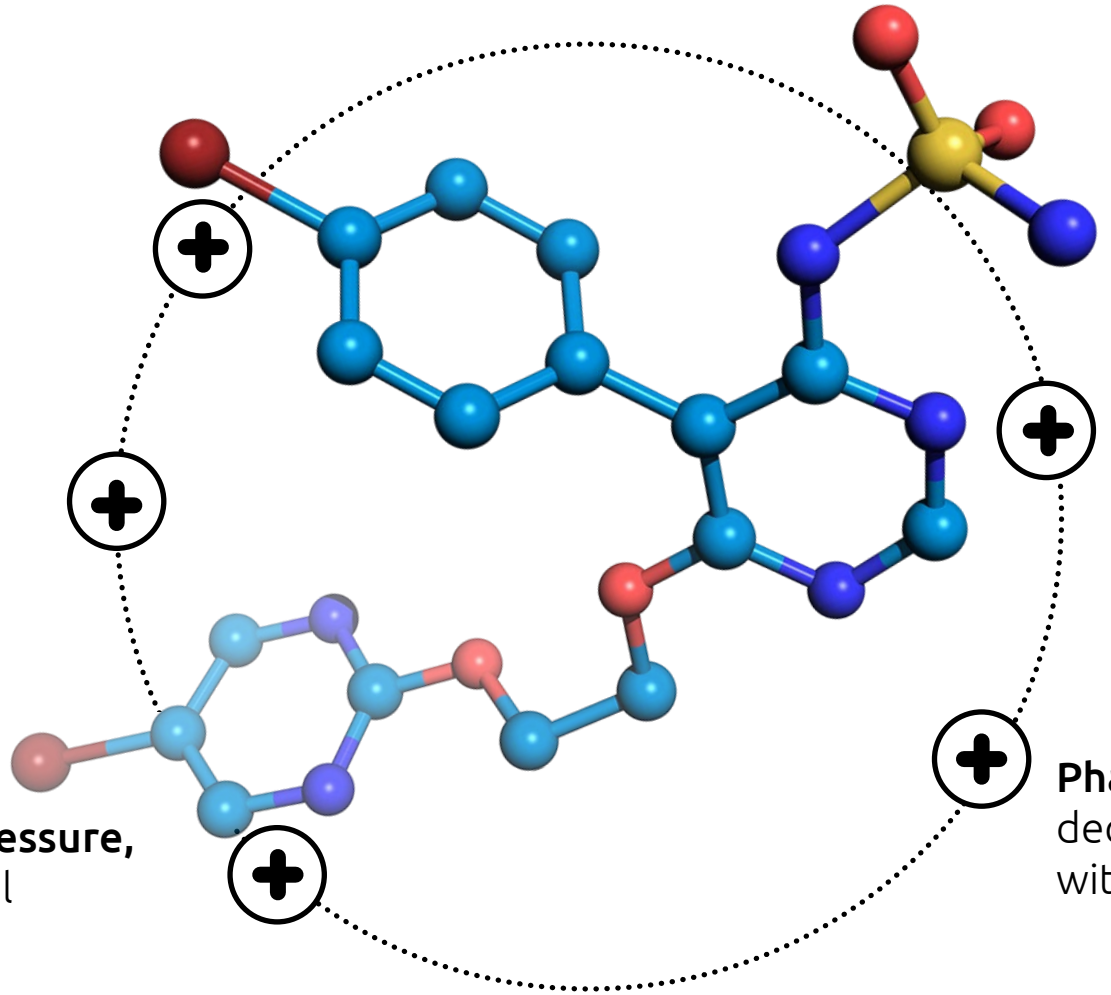
Aprocitentan selected for its ideal properties

Orally-active, potent dual ET_A and ET_B receptor antagonist

Synergistic effect with other antihypertensive drugs (RAAS blockers) in animal models

Demonstrated efficacy on blood pressure, renal and cardiac protection in animal models



Low potential for drug-drug interaction

Phase 2 study shows blood pressure decrease as monotherapy in patients with hypertension

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“Aprocitentan demonstrated a clear and consistent effect across all endpoints of blood pressure measurement and in key sub-populations.”

Alberto Gimona
Head of Global Clinical Development

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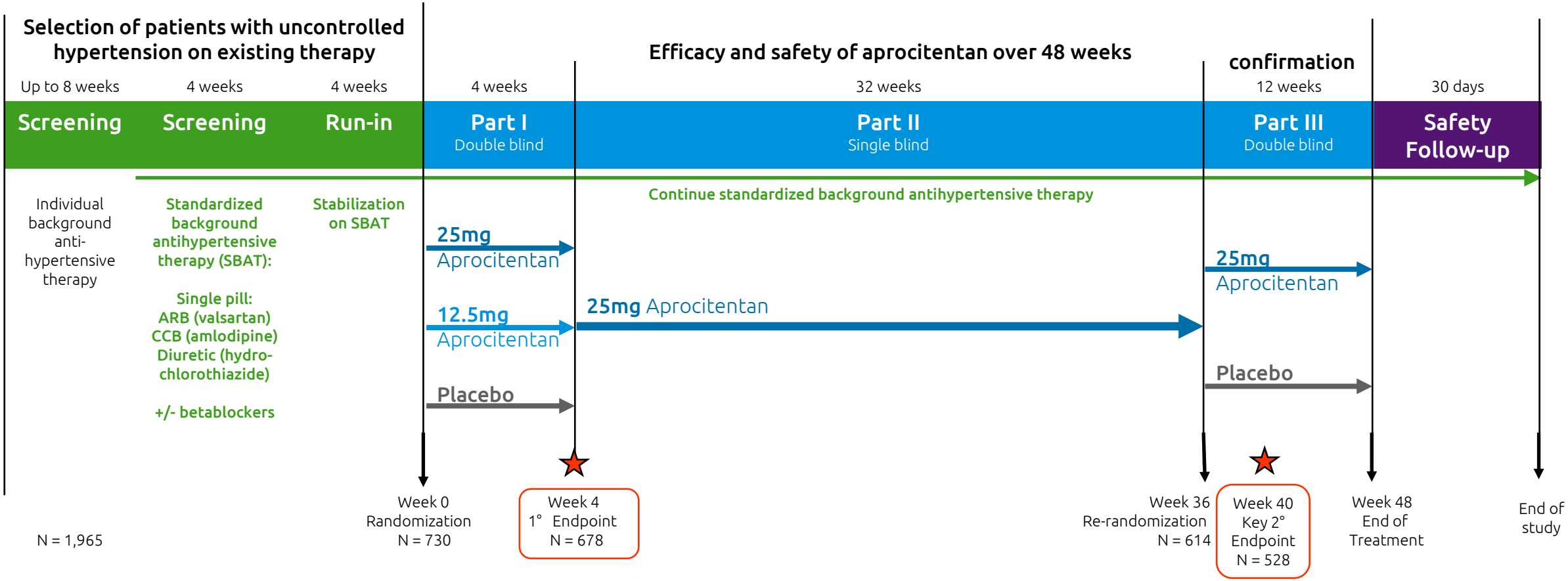
PRECISION investigated durability of BP reduction



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Frail population with multiple co-morbidities

Total: N = 730 [n (%)]

Age (years)		
Mean (SD)	61.7	(10.6)
18 to <65	409	(56.0)
65 - <75	**249**	**(34.1)**
≥75	**72**	**(9.9)**
Race		
White	605	(82.9)
Black or African American	**82**	**(11.2)**
Asian	38	(5.2)
Other	5	(0.7)
BMI# (kg/m^2)		
Mean (SD)	**33.7**	**(6.2)**
SiSBP / SiDBP (mmHg)*		
Mean (SD)	153.3 (8.9) / 87.6 (9.7)	

Antihypertensive therapies#		
3	269	(36.8)
4	337	(46.2)
≥ 5	123	(16.8)
UACR [mg/g]*		
< 30	453	(63.2)
30–300	**174**	**(24.3)**
> 300	**90**	**(12.6)**
missing	13	
eGFR [mL/min]*		
< 30	**21**	**(2.9)**
30 – < 45	**48**	**(6.6)**
45 – < 60	**93**	**(12.7)**
≥ 60	568	(77.8)

Medical history		
Diabetes mellitus	**395**	**(54.1)**
Congestive heart failure	**143**	**(19.6)**
Sleep apnea syndrome	103	(14.1)
Stroke	57	(7.8)
Myocardial infarction	51	(7.0)

BMI: *body mass index*
eGFR: *estimated glomerular filtration rate*
RHT: *resistant hypertension*
SD: *standard deviation*
SiDBP: *sitting diastolic blood pressure*
SiSBP: *sitting systolic blood pressure*
UACR: *urine albumin-to-creatinine ratio*

**** at baseline***
 # at screening

Danaietash P et al., *J Clin Hypertens* 2022 Jul; 24(7):804-813

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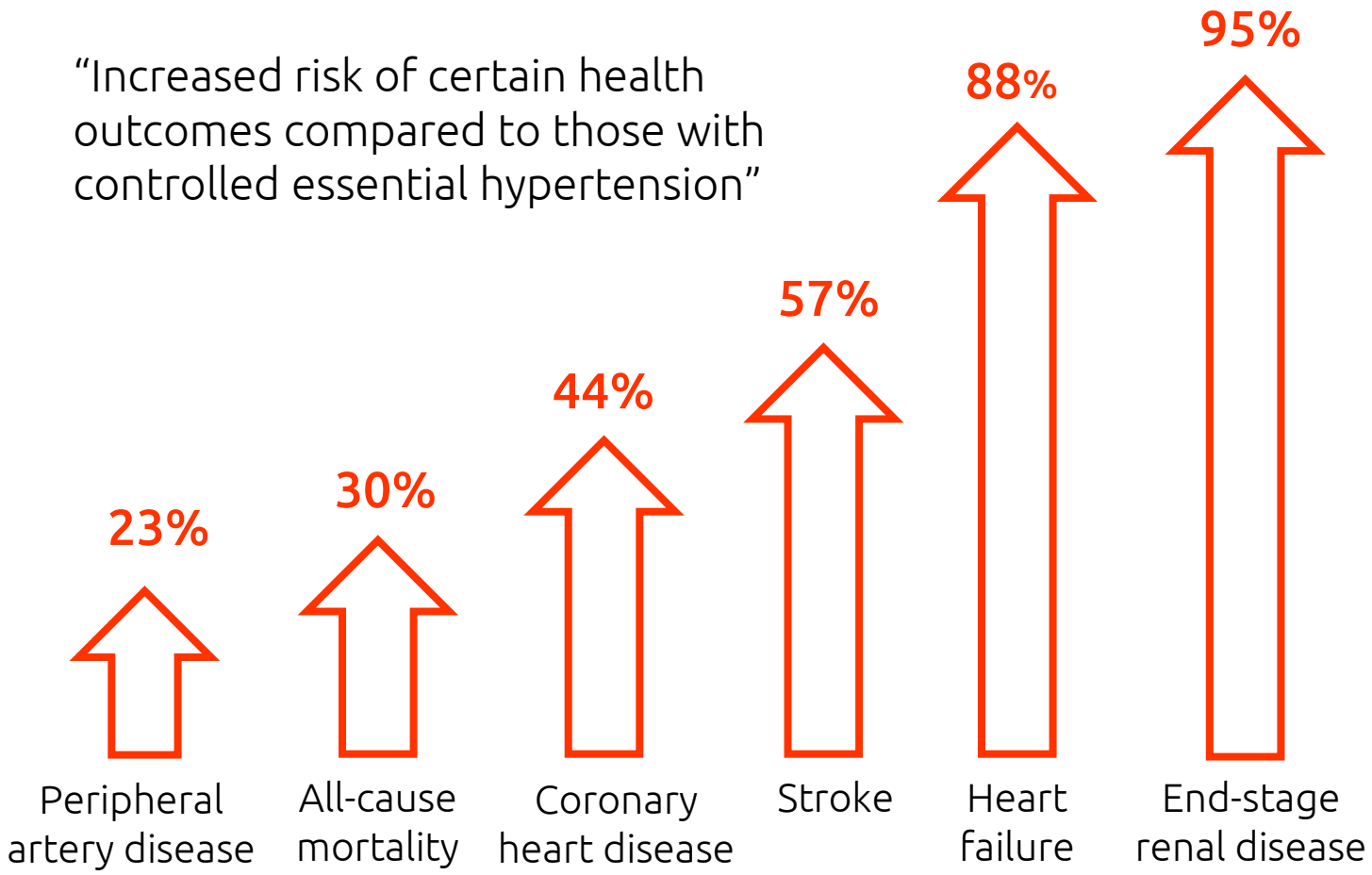
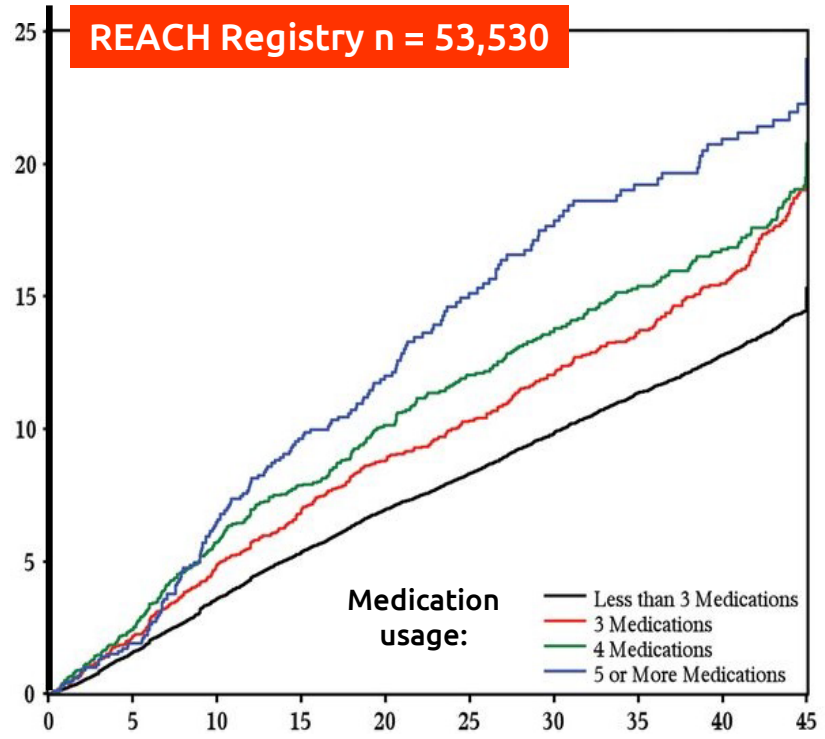
Disease burden when hypertension is uncontrolled

"Increased risk of certain health outcomes compared to those with controlled essential hypertension"



Muntner et al., 2014

Higher incidence of major cardiovascular events



European Heart Journal, 2013

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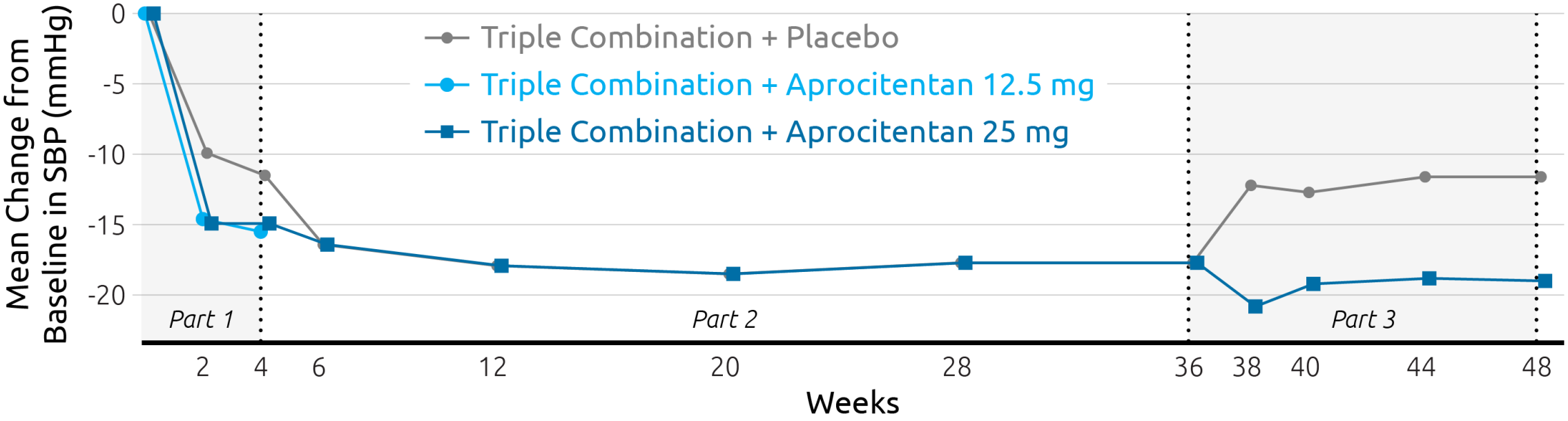
Significant and sustained BP reduction

Absolute BP reduction of 15 mmHg

TRYVIO™ (aprocitentan) 12.5mg tablets



Primary endpoint
12.5 mg vs placebo: -3.8 mmHg, P=0.0042
25 mg vs placebo: - 3.7 mmHg, P=0.0046

Key secondary endpoint
25 mg vs placebo: - 5.8 mmHg P<0.0001

Triple combination: single pill ARB (valsartan), CCB (amlodipine) , diuretic (hydrochlorothiazide) +/- beta blockers

Schlaich MP, et al. The Lancet, 2022; Dec 3;400(10367):1927-1937.

Aprocitentan is only available in the US under the tradename TRYVIO™ and is approved in the European Union and the UK under the tradename JERAYGO™. Market authorization is under review in Canada and Switzerland.

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USPI Highlights: Indication and Usage

TRYVIO™ (aprocitentan) 12.5mg tablets

----------INDICATIONS AND USAGE----------

TRYVIO is an endothelin receptor antagonist indicated for the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adult patients who are not adequately controlled on other drugs. Lowering blood pressure reduces the risk of fatal and non-fatal cardiovascular events, primarily strokes and myocardial infarctions. (1)

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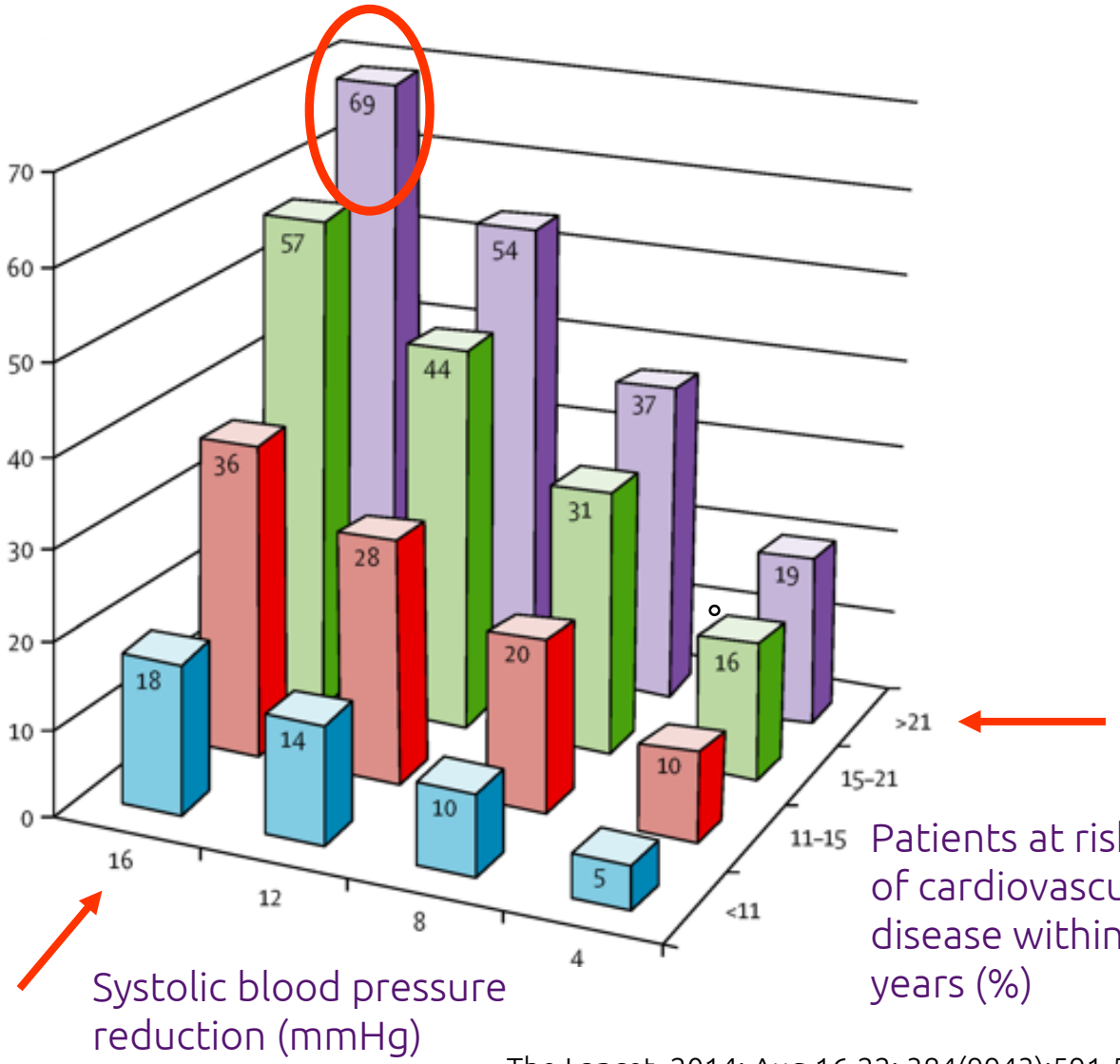
Reduction in BP will prevent CV events

16-mmHg (uAOBPM) reduction in SBP vs baseline would avoid approximately 70 CV events per 1000 patients over the following 5 years



NB: There are no controlled trials demonstrating reduction of risk of these events with TRYVIO

The Lancet, 2014; Aug 16-22; 384(9943):591-598.

Aprocitentan is only available in the US under the tradename TRYVIO™ and is approved in the European Union and the UK under the tradename JERAYGO™. Market authorization is under review in Canada and Switzerland.

USPI Highlights: Dosage and Administration

TRYVIO™ (aprocitentan) 12.5mg tablets

----------DOSAGE AND ADMINISTRATION----------

- The recommended dosage of TRYVIO is 12.5 mg orally once daily, with or without food. (2.1)

USPI Section 14: Clinical Studies

TRYVIO **long-term sustained effect**

The persistence of the BP-lowering effect of TRYVIO was demonstrated in part 3 of the trial, in which patients on aprocitentan were re-randomized to placebo or 25 mg aprocitentan following a period during which all patients were treated with 25 mg. In patients re-randomized to placebo, the mean SiSBP increased, whereas in patients re-randomized to 25 mg aprocitentan the mean effect on SiSBP was maintained and was statistically superior to placebo at Week 40. The treatment effect was consistent for SiDBP.

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USPI Section 14: Clinical Studies

TRYVIO consistent **effect in subgroups** and across **measures**

TRYVIO™ (aprocitentan) 12.5mg tablets

Most of the BP-lowering effect occurred within the first two weeks of treatment with TRYVIO.

TRYVIO's BP-lowering effect appeared consistent among subgroups defined by age, sex, race, BMI, baseline eGFR, baseline UACR, medical history of diabetes, and between BP measurement methodologies (uAOBP and ambulatory BP measurements).

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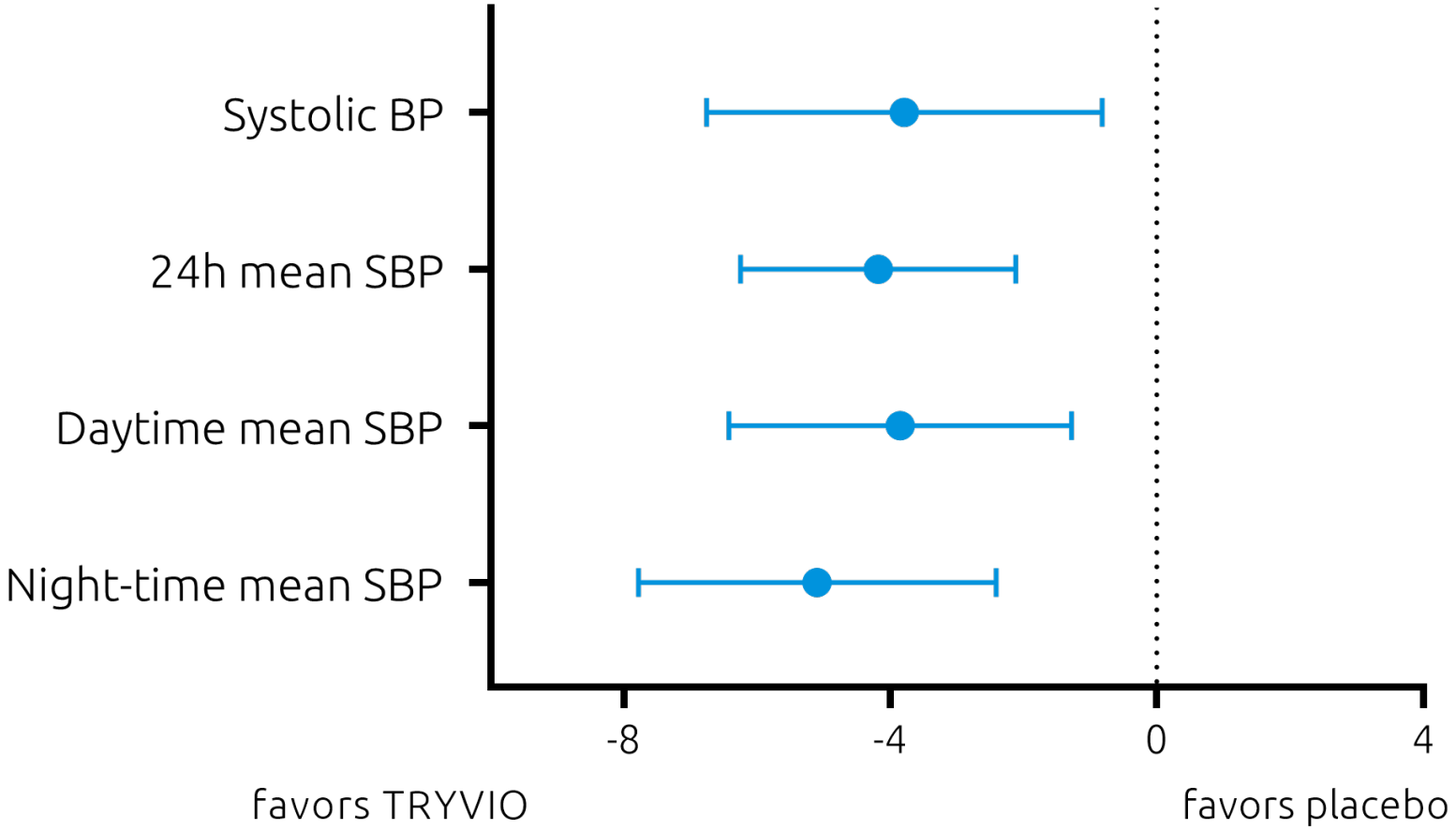
Consistent effect between BP measurement methodologies

TRYVIO™ (aprocitentan) 12.5mg tablets



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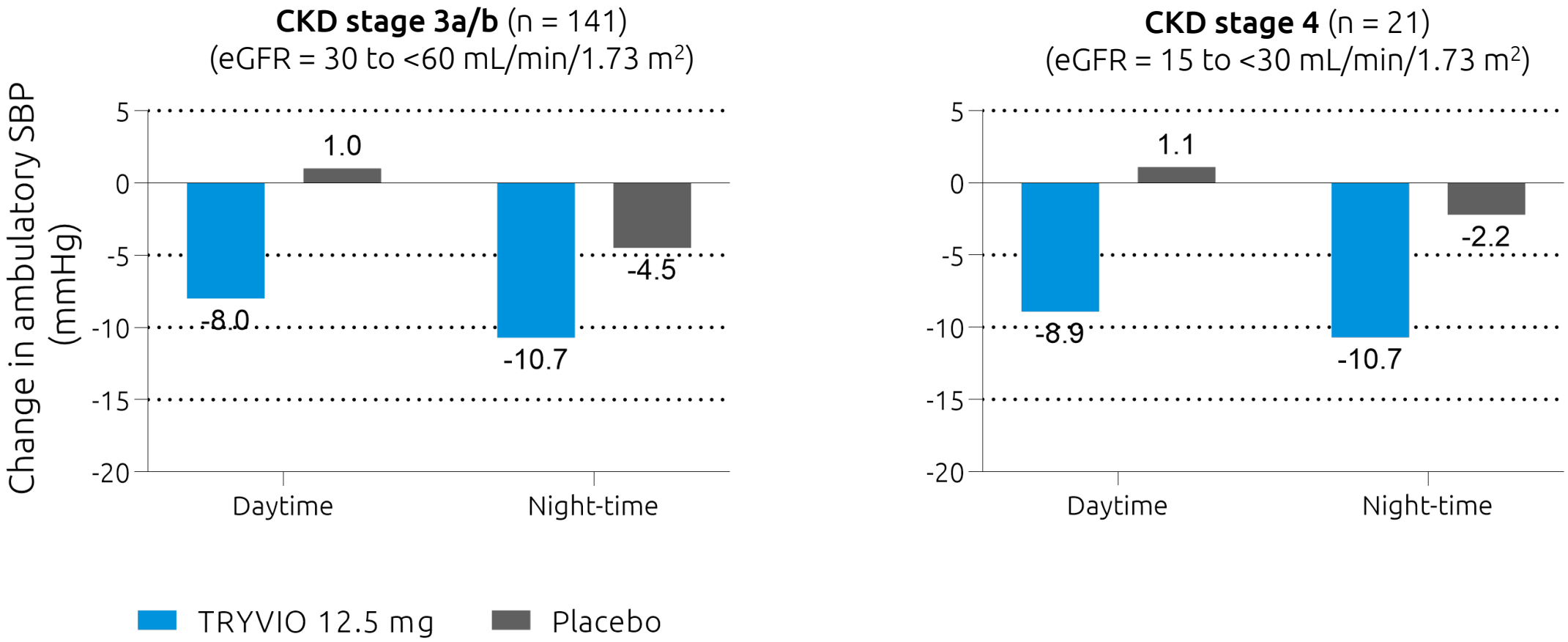
Consistent effect among subgroups: E.g., Patients with chronic kidney disease

TRYVIO™ (aprocitentan) 12.5mg tablets



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USPI Section 6: Adverse Reactions

TRYVIO™ (aprocitentan) 12.5mg tablets

Table 1 Adverse reactions reported with a frequency of ≥2% in TRYVIO-treated patients and greater (≥1%) than in placebo-treated patients during the initial 4-week double-blind placebo-controlled treatment (part 1)

Adverse Reaction	12.5 mg N = 243 %	Placebo N = 242 %
Edema/fluid retention	9.1	2.1
Anemia	3.7	0

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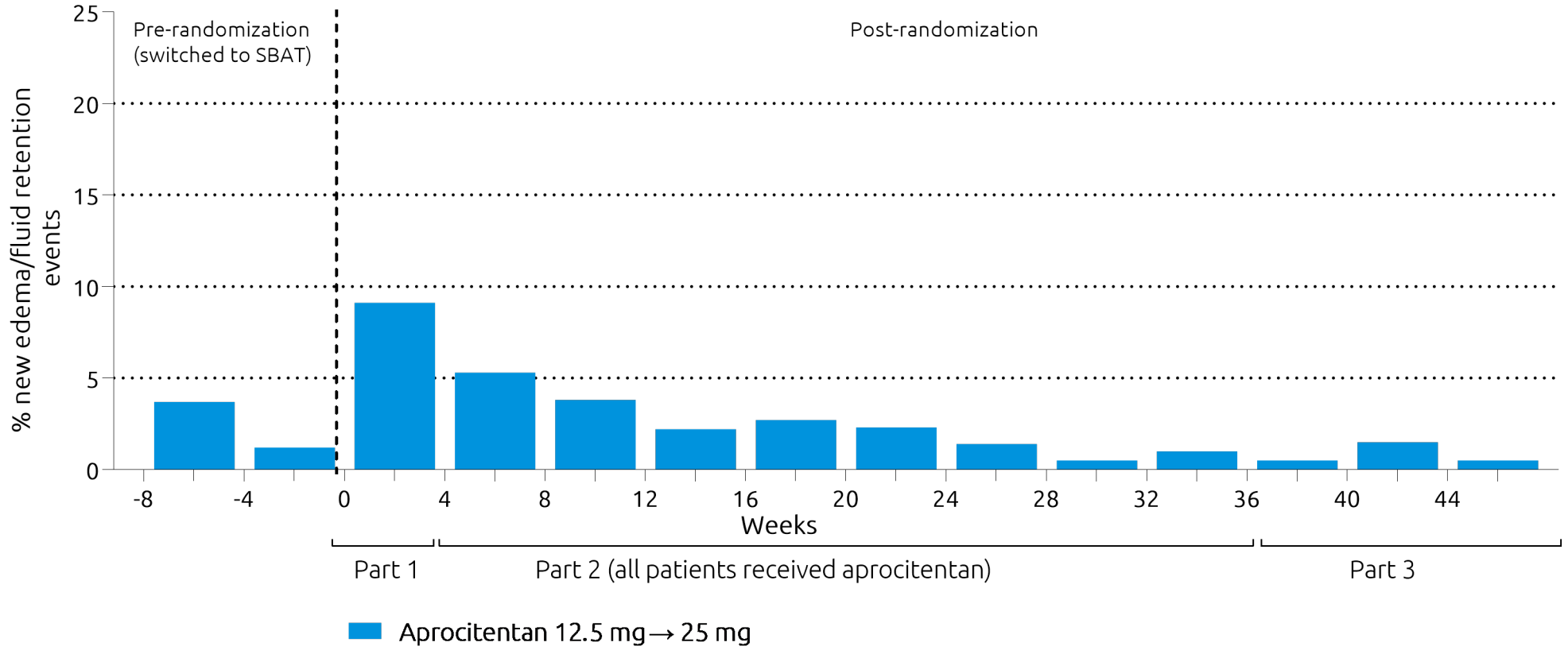
Incidence of edema

TRYVIO™ (aprocitentan) 12.5mg tablets

Returns to levels observed before randomization 8 weeks after treatment



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USPI Section 5.2: TRYVIO REMS

5.2 TRYVIO REMS

TRYVIO is available only through a restricted program und… the TRYVIO REMS because of the risk of embryo-fetal toxicity … *…ns (4.1), Warnings and Precautions (5.1), Use in Specific Pop…*

Important requirements of th… include the following:

- Prescrib… with the TRYVIO REMS by enrolling and completing tra…
- …that dispense TRYVIO must be certified with the TRYVIO REMS.

…rther information is available at www.TRYVIOREMS.com or 1-866-429-8964.

March 17, 2025: US FDA removes REMS requirement for TRYVIO (aprocitentan) – minimizing the burden on the healthcare delivery systems and patients

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“We are eager to provide physicians and patients with a novel medicine working in a new pathway in uncontrolled hypertension that can provide additional blood pressure control”

Michael Moye
President Idorsia US

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Hypertension is the leading modifiable risk factor for early death and disability

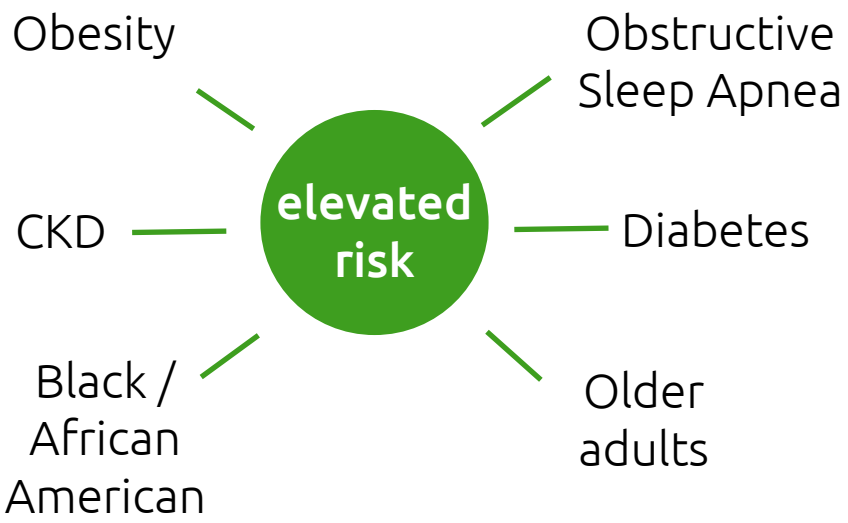
The importance of treating hypertension is well established

The risk of developing **uncontrolled hypertension is elevated in certain subgroups** of patients

2-6x
Greater Risk

especially for uncontrolled patients at high risk of cardio- and neurovascular events

5 mmHg reduction in SBP
= ~10% reduction in the risk of major cardiovascular events



Uncontrolled hypertension patients have a **greater risk** for CV events and end-stage renal disease

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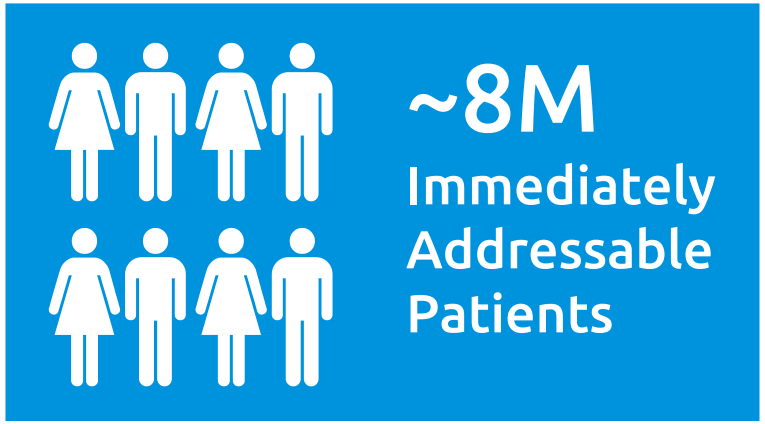
~8M patients immediately addressable at launch* – most with multiple comorbidities

TRYVIO™ (aprocitentan) 12.5mg tablets

3.5M Patients
on **3 meds for hypertension are not controlled**

4.6M Patients
on 4+ meds for hypertension



90% of these patients have comorbidities and are taking branded meds

* in line with Phase 3 criteria

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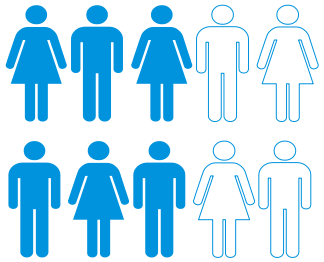
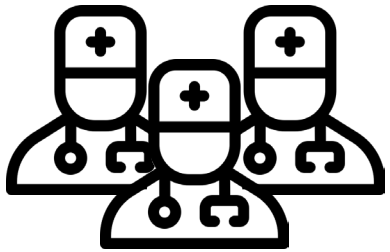
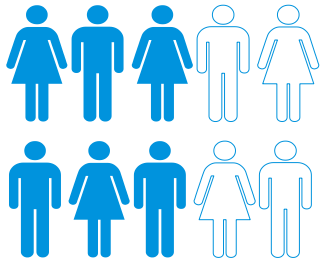
Prescribers span several specialties – often more than one HCP involved

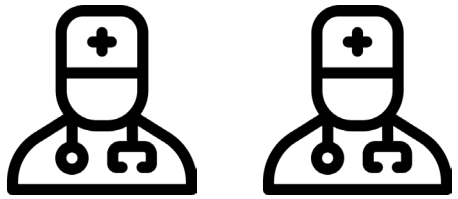


60% of Patients
on 3+ Meds were treated by 2 or more HCPs

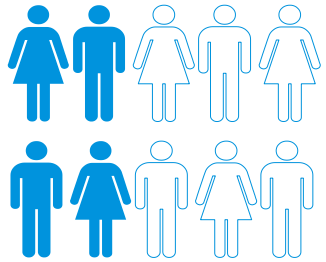




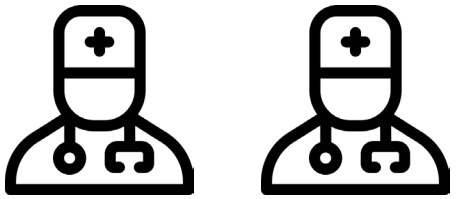
50-60% of patients
on 3+ Meds were treated by cardiologists and nephrologists



cardiologists nephrologist



30-40% of patients
on 3+ Meds were treated by primary care physicians (PCPs)/other



PCPs other

Source: Komodo claims; 3-Year Dx: Sep'20 - Aug'23; 1-Year Rx: Sep'22 - Aug'23

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Early dialogues with Payers suggest an overall favorable reaction to TRYVIO clinical profile

- Recognize the unmet patient need of uncontrolled hypertension
- Favorable reaction to Phase 3 trial design
- Perceive efficacy as favorable, highlighting BP differences vs placebo clinically meaningful
- Product available through med exception process until the NTM / NDC Blocks removed

NTM: New To Market; NDC: National Drug Code

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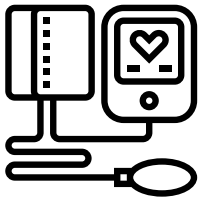
First to target the endothelin pathway bringing the power of an ERA to systemic hypertension

Easy for patients to **use**

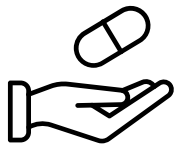


Easy for HCPs to **prescribe**

...even for **high-risk, frail** population

Broad indication, evidence-based label

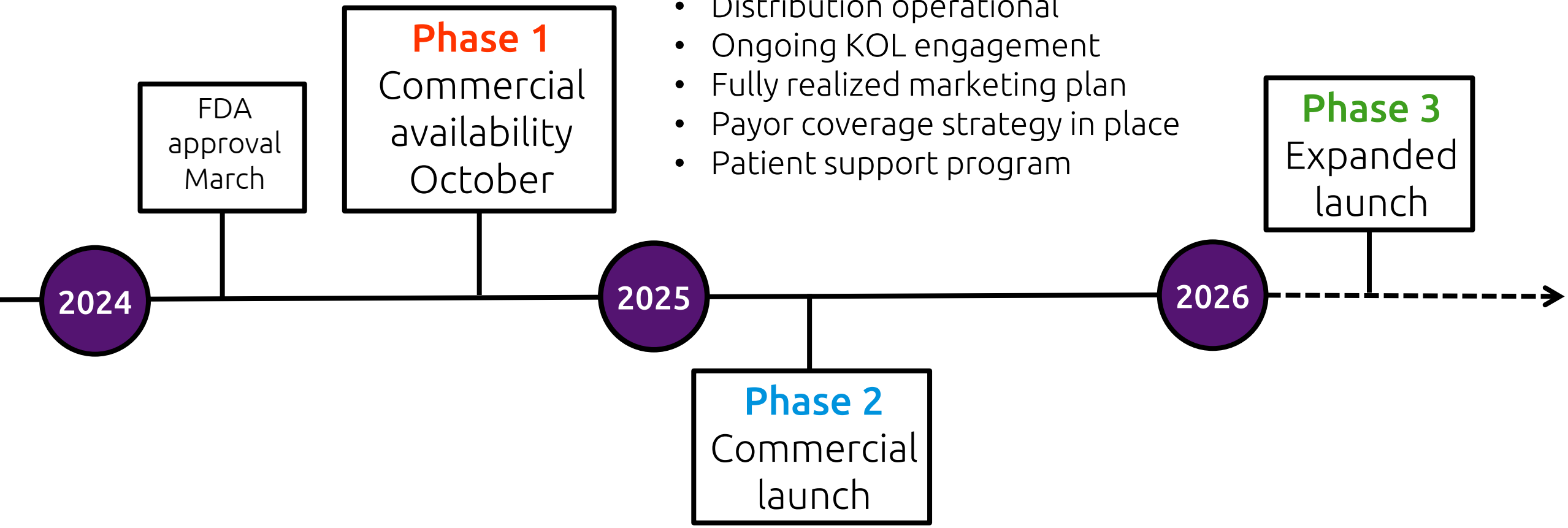
Strong and sustained efficacy with good safety and tolerability



Once-daily oral, single dose

Idorsia makes aprocitentan available in the US under the tradename TRYVIO. In addition, aprocitentan is approved throughout the European Union and in the UK under the tradename JERAYGO. Marketing authorization applications are under review in Canada and Switzerland.

TRYVIO™ (aprocitentan) 12.5mg tablets US launch



Idorsia makes aprocitentan available in the US under the tradename TRYVIO. In addition, aprocitentan is approved throughout the European Union and in the UK under the tradename JERAYGO. Marketing authorization applications are under review in Canada and Switzerland.

“The approval of TRYVIO heralds a new era of endothelin research beyond hypertension, where we intend to investigate the utility of aprocitentan for first-in-class applications in new indications.”

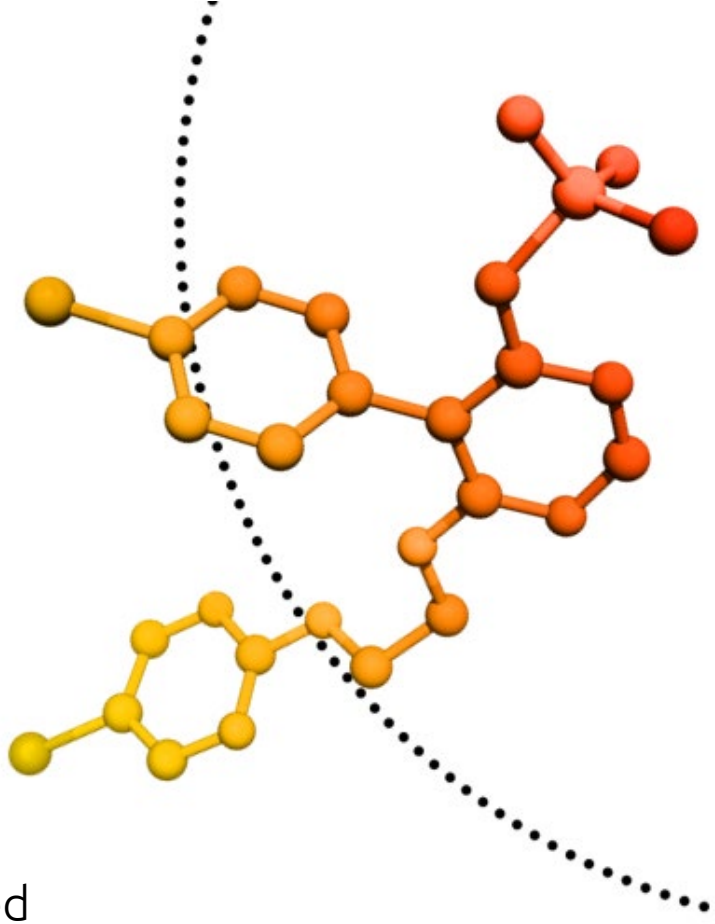
Martine Clozel
Chief Scientific Officer

Aprocitentan is only available in the US under the tradename TRYVIO™ and is approved in the European Union and the UK under the tradename JERAYGO™. Market authorization is under review in Canada and Switzerland.

JERAYGO™ (aprocitentan) for resistant hypertension in the EU

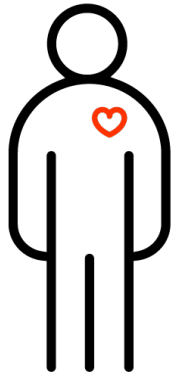
New mode of action in systemic hypertension

JERAYGO™
aprocitentan



Current status

- In June 2024, Idorsia received approval from the European Commission (EC) for JERAYGO™ (aprocitentan) as the first and only endothelin receptor antagonist (ERA) for the treatment of resistant hypertension in adult patients in combination with at least three antihypertensive medicinal products.
- The recommended dose is 12.5 mg orally once daily. The dose can be increased to 25 mg once daily for patients tolerating the 12.5 mg dose and in need of tighter blood pressure (BP) control.



Aprocitentan is only available in the US under the tradename TRYVIO™ and is approved in the European Union and the UK under the tradename JERAYGO™. Market authorization is under review in Canada and Switzerland.

Lucerastat in Fabry disease

Lucerastat is investigational, in development and not approved or marketed in any country.

Fabry disease

Fabry disease is a **rare inherited lysosomal storage disorder** in which a particular **lipid** (a fat-like substance) can't be broken down by the body, leading to its build-up in the cells of the body organs which results in cell and organ damage

Fabry disease is often undetected or misdiagnosed

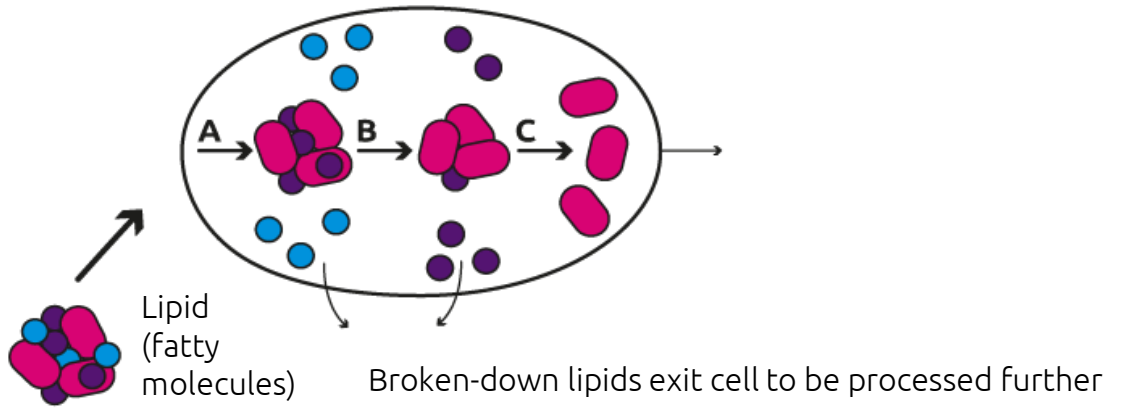
As the disease is progressive, **early diagnosis is essential** to manage the symptoms as soon as possible and reduce the risk of developing serious complications

What is the role of lipids in the body?

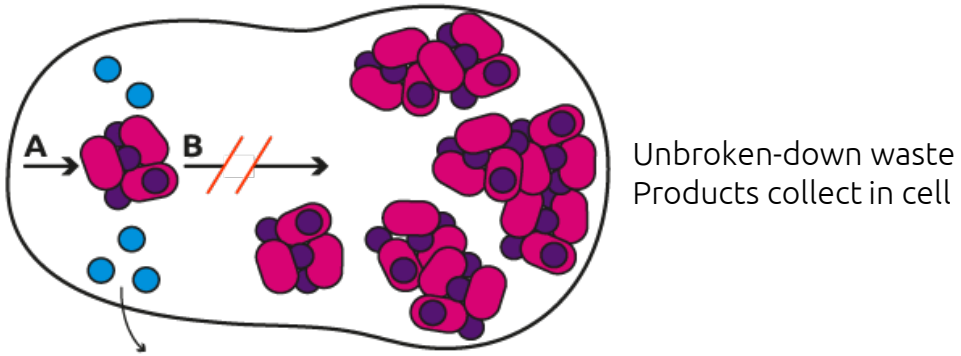
- Lipids are fat-like substances such as fatty acids, oils, waxes and steroids. A well-known example is cholesterol
- Lipids are stored naturally in the body's cells and organs and are vital to their healthy functioning
- Normally, the body is able to process lipids effectively, which keeps them within healthy levels

What happens in patients with lysosomal storage disorders?

Normal breakdown of lipids



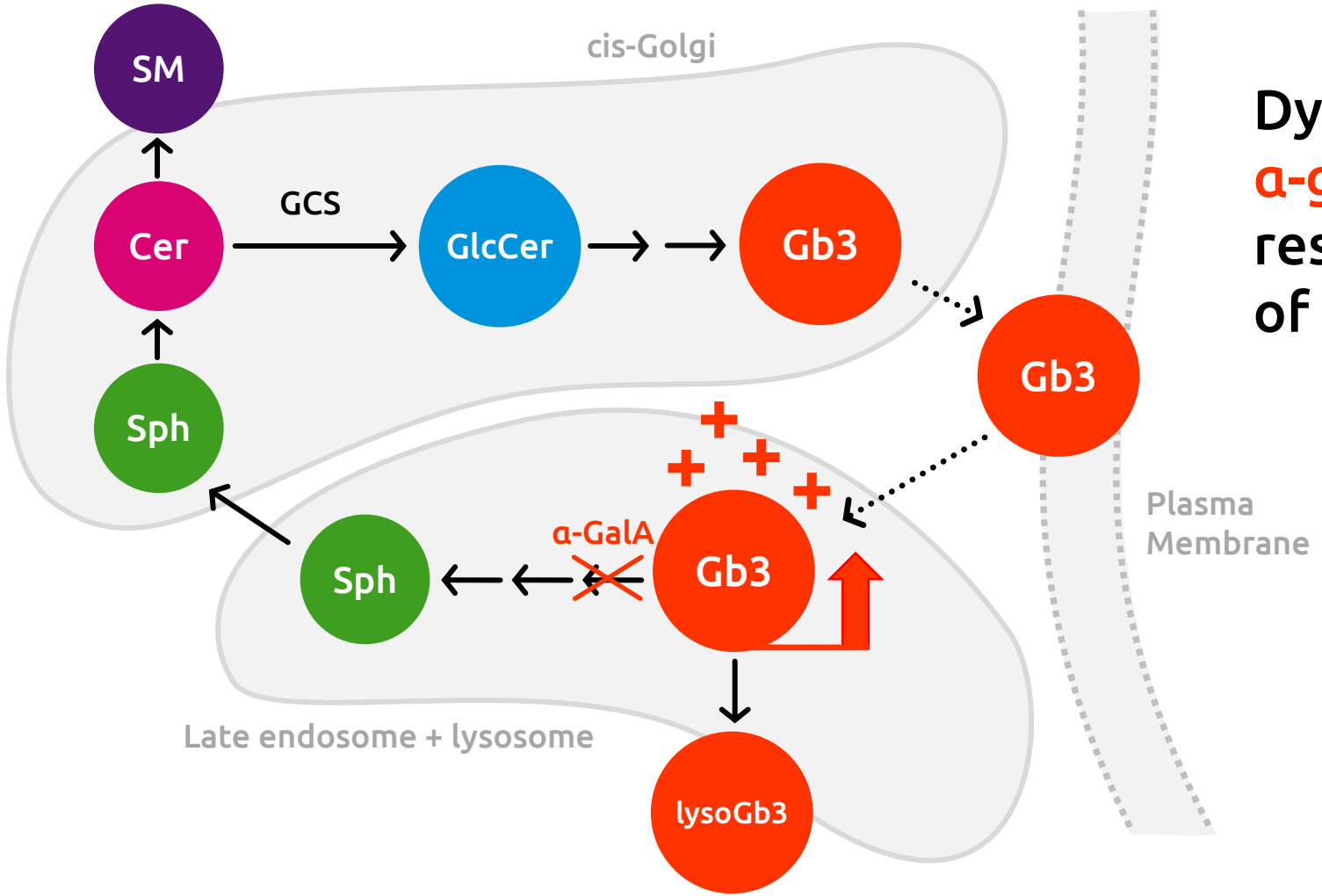
When enzyme to break down lipid is deficient



Lipids can't be processed and build up in cell

Fabry disease

Biochemical mechanism



Dysfunctional or absent α-galactosidase A results in accumulation of Gb3 in various organs

Cer	ceramide
GCS	glucosylceramide synthase
GlcCer	glucosylceramide
Gb3	globotriaosylceramide
lysoGb3	globotriaosylsphingosine
α-GalA	α-galactosidase A
SM	sphingomyelin
Sph	sphingosine

Inheritance pattern in Fabry disease

X-linked recessive genetic disease

- GLA gene mutation results in **defective lysosomal enzyme α-GalA**
- In turn, this results in **Gb3 accumulation**

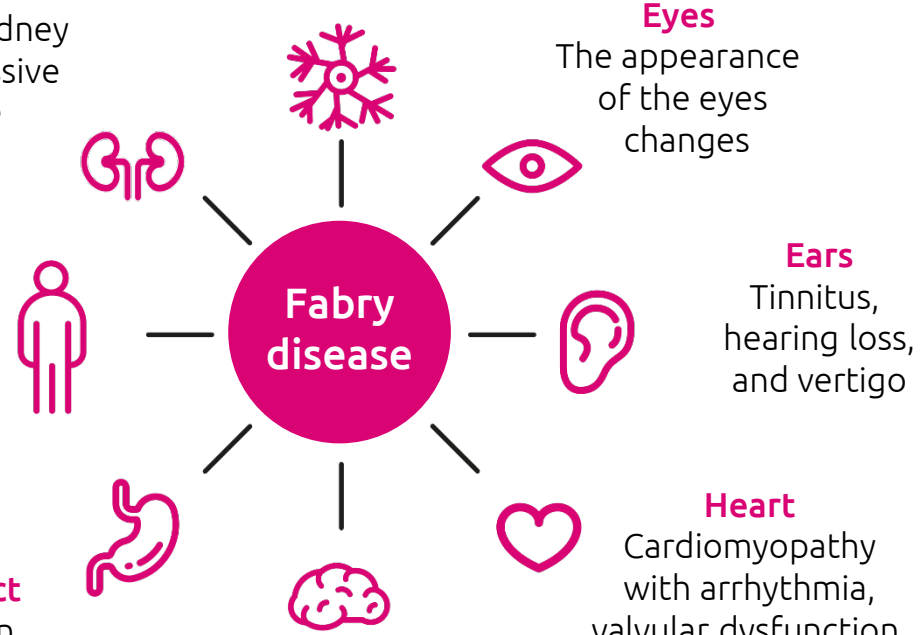
Random X-inactivation in Fabry female ‘carriers’: both genders affected

Male have generally classical phenotype

Females have higher residual level enzyme and
- are affected later
- progress slower
- have more variable phenotype

Clinical manifestations of Fabry disease

Large spectrum of clinical, heterogeneous manifestations



Neuropathic pain
Pain resulting from damage to or dysfunction of the nervous system

Kidneys
Cysts, reduced kidney function, progressive kidney failure

Eyes
The appearance of the eyes changes

Skin
Dark red spots or rashes, burning / tingling sensations, sensitivity to temperature and profuse sweating

Ears
Tinnitus, hearing loss, and vertigo

Digestive Tract
Abdominal pain, constipation, diarrhea, and nausea

Heart
Cardiomyopathy with arrhythmia, valvular dysfunction, ischemia, left heart failure

Brain
Strokes (in severe cases), and dizziness

- **Gradually progressing** in severity from childhood to adulthood
- **Major impact on quality of life**
- **Slow progressive damage** to vital organs over decades
- **Earlier death**

Diagnosis of Fabry disease

Clinical symptoms

Neuropathic pain, GI, hearing loss, hypohydrosis

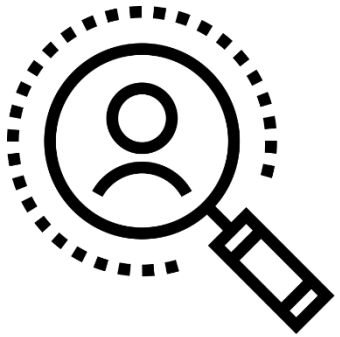
Clinical events

Stroke, cardiac and renal events

Pedigree analysis

Family members

(between children and parents)



Enzyme assay

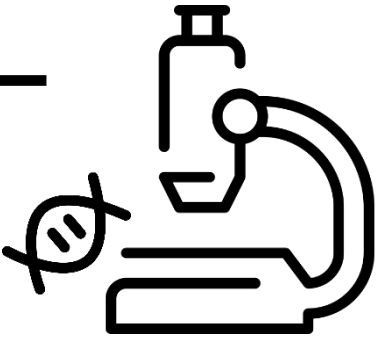
Leukocyte α-GalA

Genotyping

>830 mutations

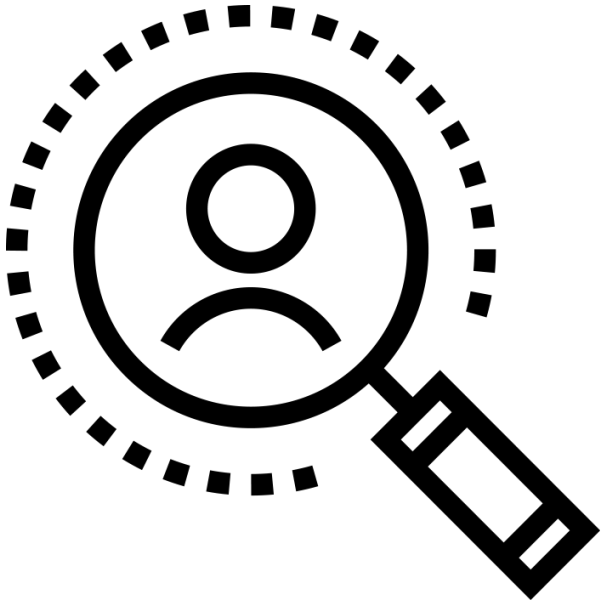
Biomarkers

Gb3 in plasma and urine



Epidemiology of Fabry disease

Patients diagnosed with Fabry disease in 7 major markets (US, EU-4 and UK, and Japan) in 2020 and forecasted out to 2034



	2020	2034
EU-4 + UK	**6,251**	**8,248**
UK	1,340	1,769
Italy	1,325	1,748
Germany	2,000	2,638
France	800	1,056
Spain	786	1,037
US	**8,288**	**11,710**
Japan	**1,658**	**1,778**
Total	**16,197**	**21,736**

Delveinsight, Fabry Disease – Market Insight, Epidemiology and Market Forecast – 2034 (March 2025)

Current therapies in Fabry disease

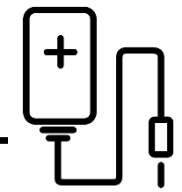
No curative therapy

Symptomatic treatments not satisfactory

Etiological therapies limited

Enzyme replacement therapy

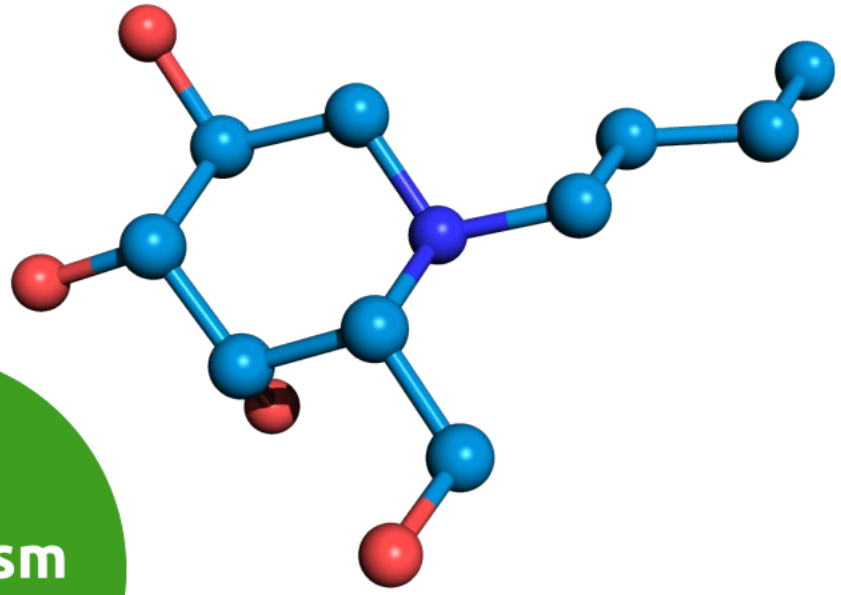
- Fabrazyme (agalsidase beta) (US and EU)
- Replagal (agalsidase alfa) (EU only)
- i.v. infusion, bi-weekly
- Immunogenicity
- Partial efficacy



Chaperone therapy

- Galafold (migalastat) for patients with amenable mutation
- 1 capsule orally, fasted, every other day

Lucerastat in Fabry disease



Novel mechanism of action

Bioavailability
Orally available, highly soluble small molecule with rapid and complete absorption

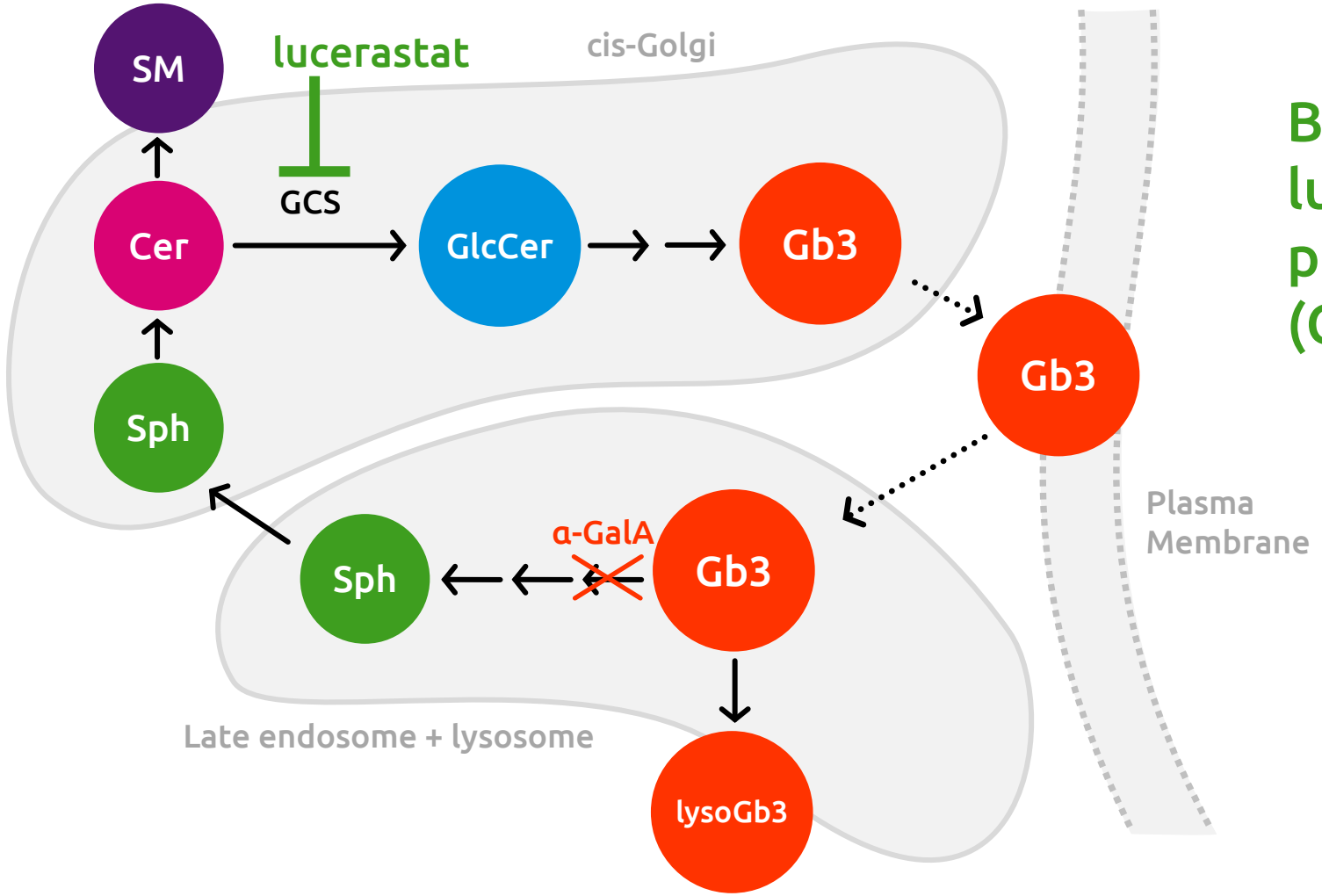
Tissue penetration
Access to most tissues, including peripheral and central nervous system

For all mutations
Potential to treat all Fabry patients irrespective of the underlying enzyme mutation

Lucerastat is investigational, in development and not approved or marketed in any country.

Lucerastat in Fabry disease

Mode of action



By inhibiting GCS, lucerastat reduces the precursor of Gb3 (GlcCer) and Gb3 itself

Cer	ceramide
GCS	glucosylceramide synthase
GlcCer	glucosylceramide
Gb3	globotriaosylceramide
lysoGb3	globotriaosylsphingosine
α-GalA	α-galactosidase A
SM	sphingomyelin
Sph	sphingosine

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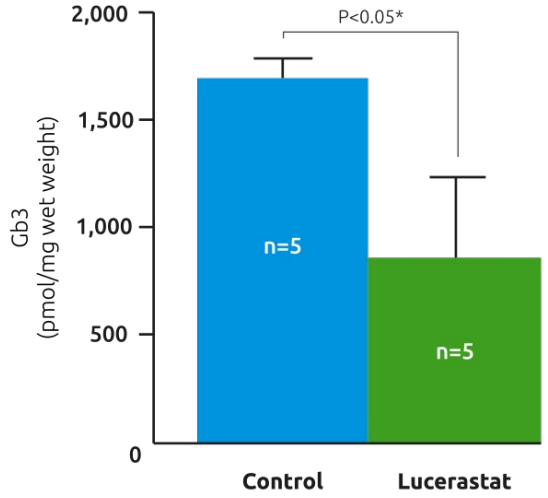
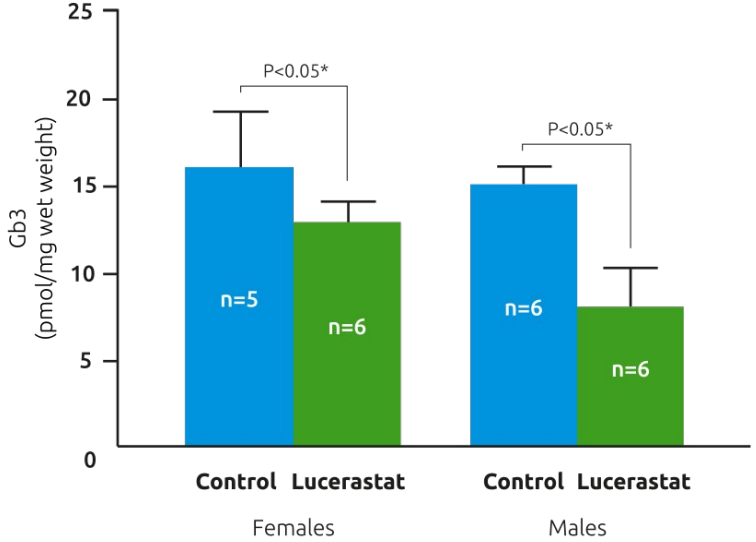
Lucerastat has the potential to reduce Gb3 levels in target organs

Dorsal root ganglia

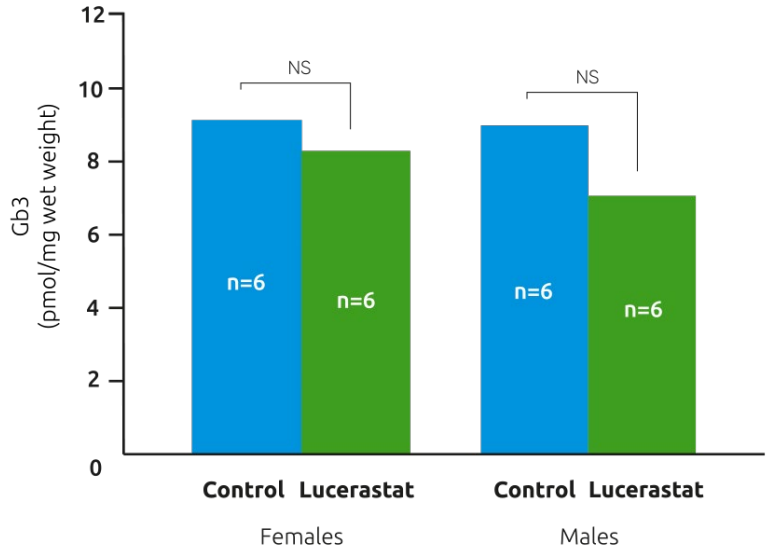


Kidneys



*ANOVA with Bonferroni's multiple testing correction.

Heart



Male and female Fabry mice treated for 20 weeks with lucerastat at 1200 mg/kg/day as food admix and compared to non-treated controls

Idorsia data on file. Data collected in animal models does not necessarily predict human clinical effect.

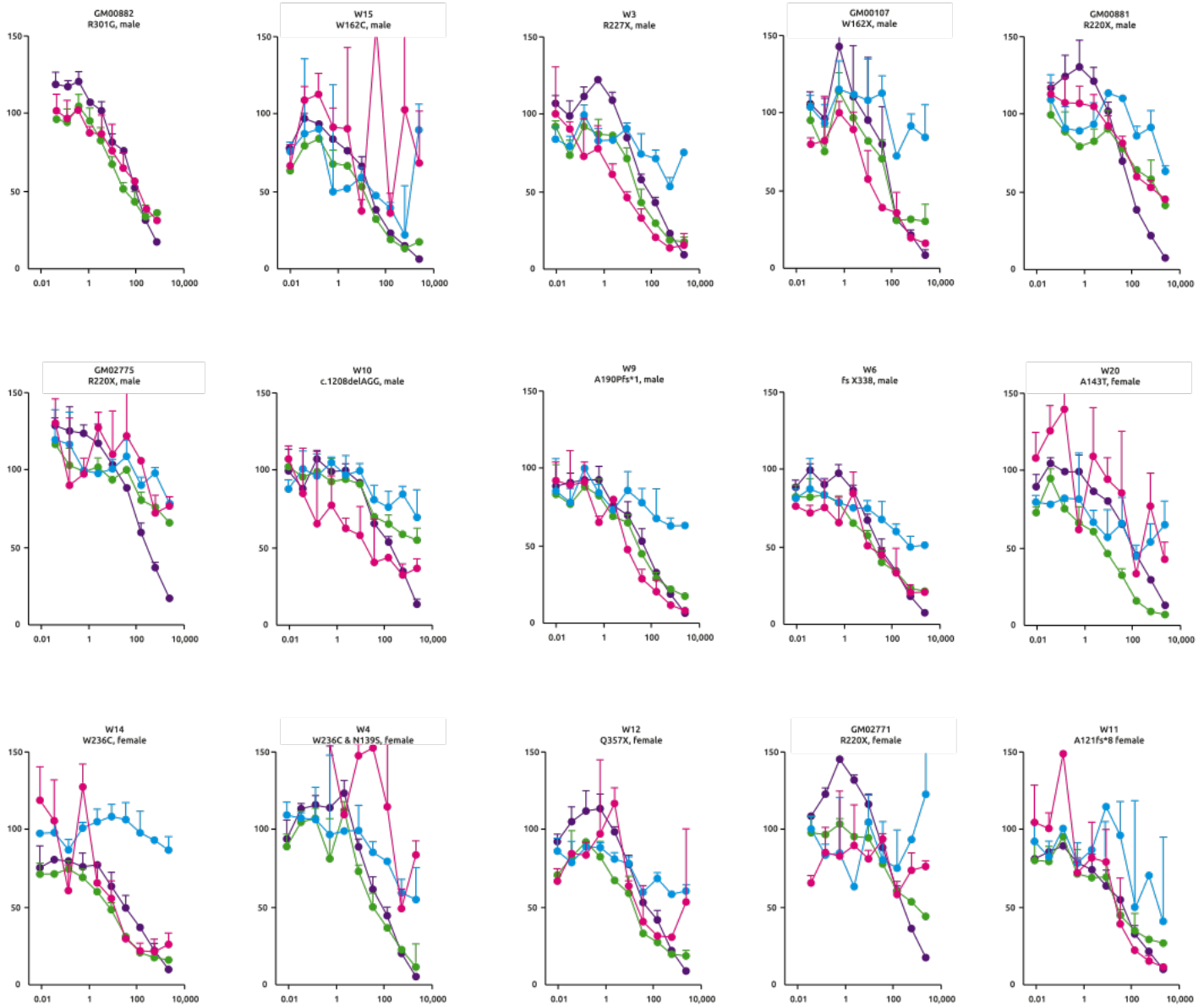
Lucerastat is investigational, in development and not approved or marketed in any country.

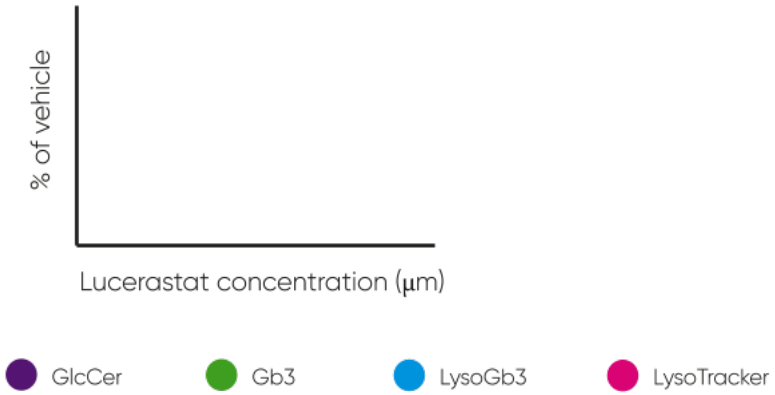
Mutation sensitivity

Proven reduction in Gb3 in all tested mutation types

Effect of different concentrations of lucerastat on GlcCer, Gb3, lysoGb3 lipid levels, and LysoTracker staining in cultured Fabry patients' fibroblasts after 9 days of treatment.

Each point is the mean of duplicates (±SD)





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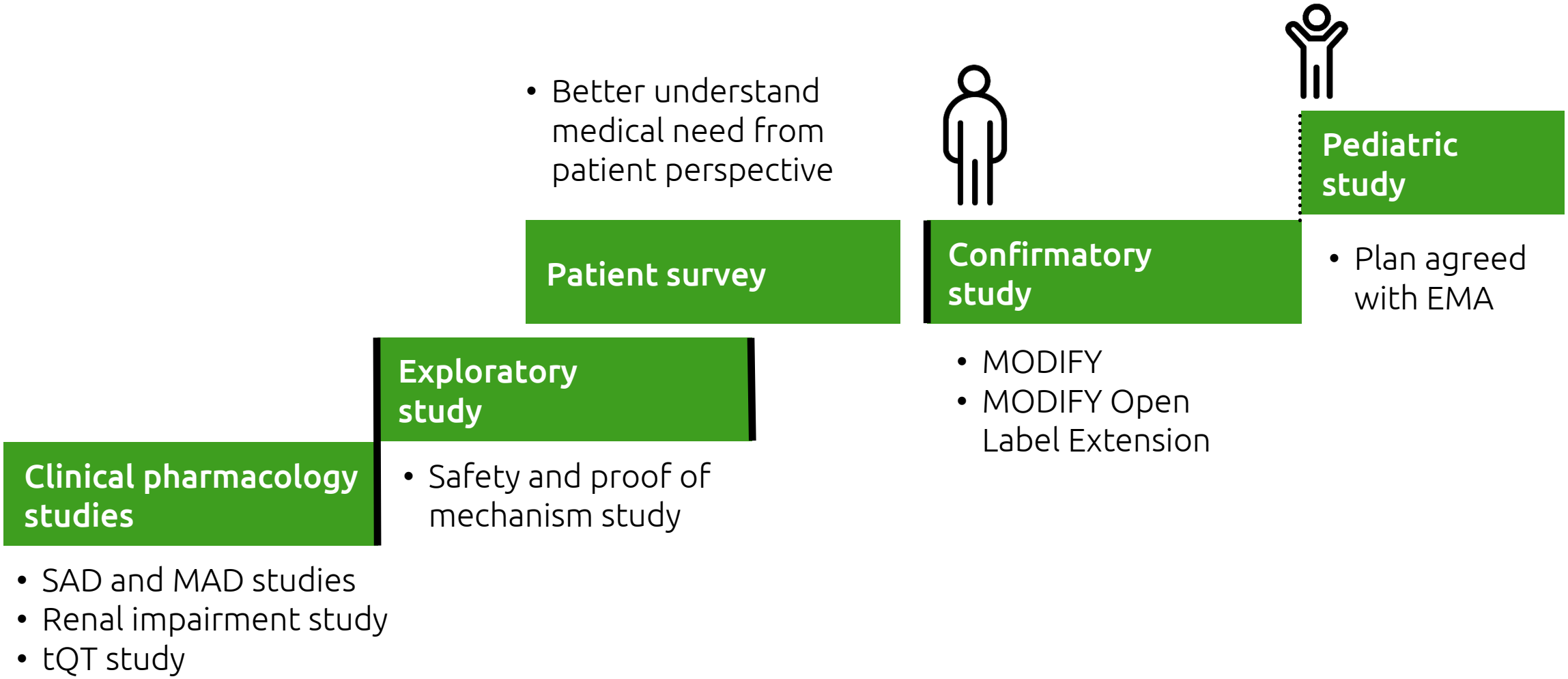
Lucerastat clinical development plan



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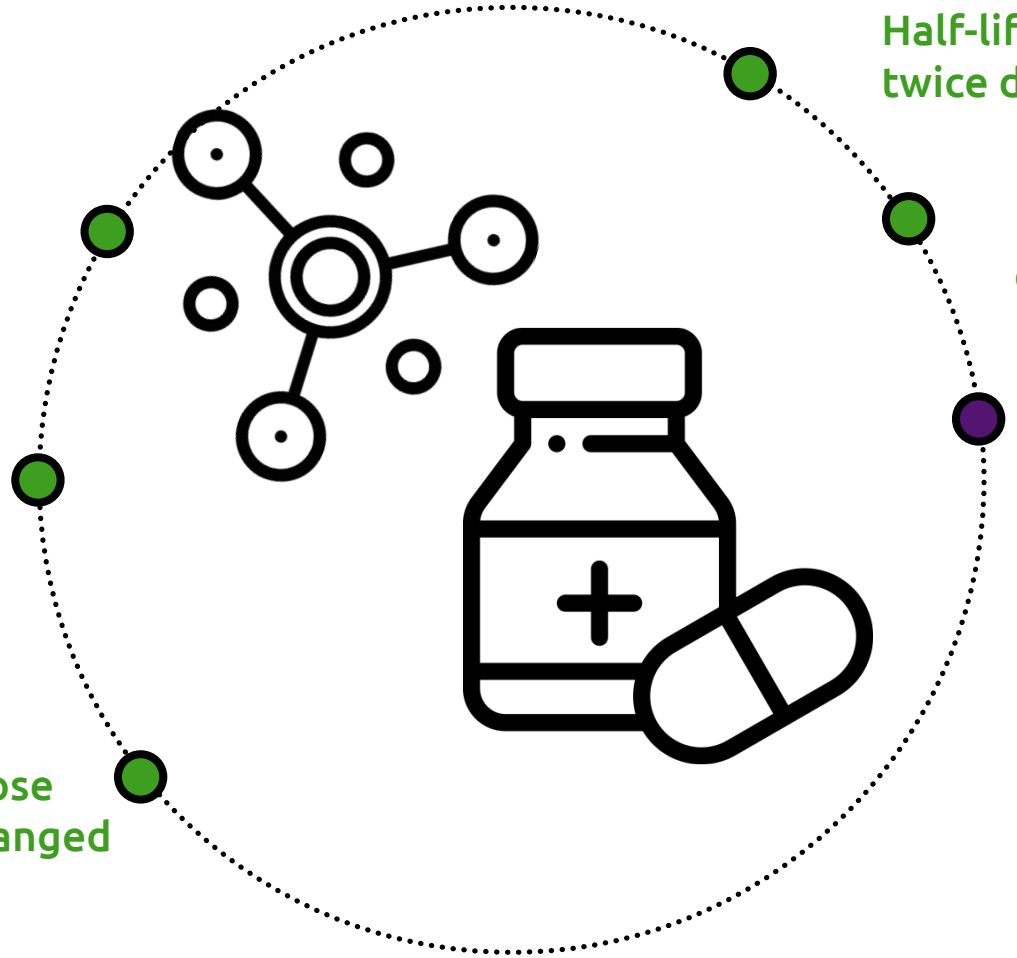
Lucerastat clinical pharmacology



Half-life: approximately 6 hours – twice daily dosing

Dose-proportional exposure

Dose adjustment required in subjects with renal function impairment

Negligible food effect

Low potential for drug-drug interaction

>85% of the dose excreted unchanged in urine

eGFR (mL/min/1.73 m^2)	Dosing regimen (mg b.i.d.)
≥ 60	1000
≥ 45 and < 60	750
≥ 30 and < 45	500
≥ 15 and < 30	250

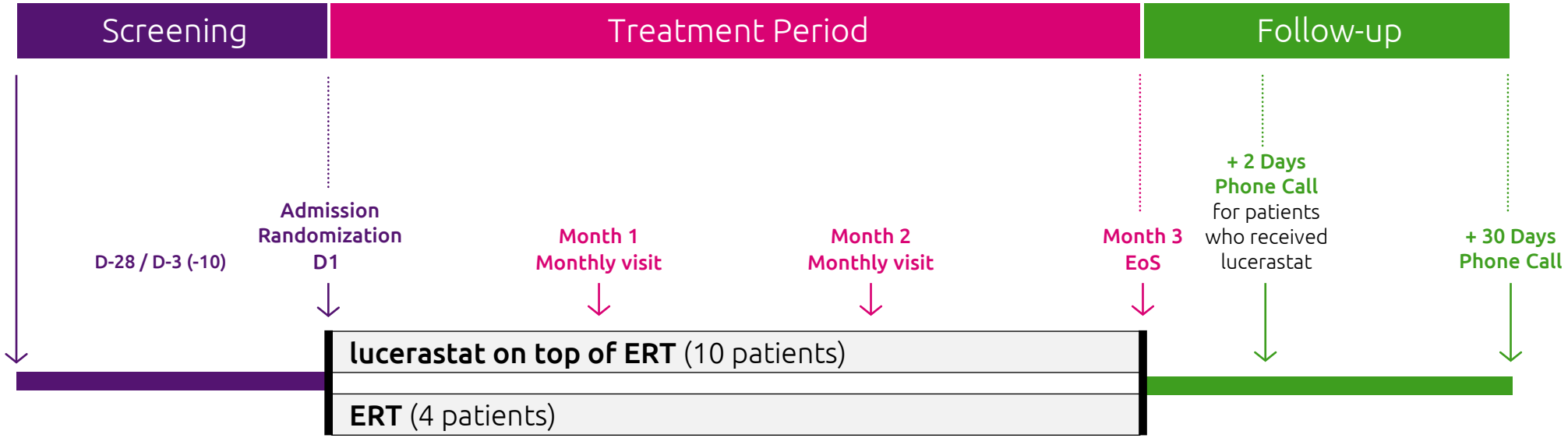
Guérard et al. (2017) Orphanet J Rare Dis
Guérard et al. (2017) J Clin Pharmacol
Guérard et al. (2018) Clin Pharmacol Ther

Lucerastat is investigational, in development and not approved or marketed in any country.

Lucerastat exploratory study design

Phase 1b study

Prospective, single-center, open-label, randomized,
study in 14 male/female adult patients with Fabry disease receiving enzyme replacement therapy (ERT)



Lucerastat is investigational, in development and not approved or marketed in any country.

Lucerastat exploratory study

Primary objective

- **To assess the safety and tolerability**
  of lucerastat 1000 mg b.i.d. for 12 weeks

Secondary objectives

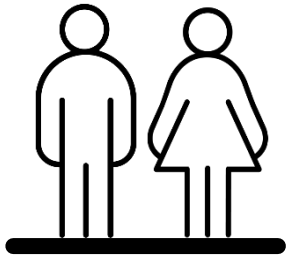
- To investigate the effect of lucerastat on
  plasma biomarker levels following a 12-week treatment
- To assess the effect of lucerastat on renal and cardiac function
- To determine the 12-hour pharmacokinetic profile
  of lucerastat at steady state
- To identify metabolites in plasma

Lucerastat is investigational, in development and not approved or marketed in any country.

Lucerastat exploratory study

Patient demographics

Phase 1b study

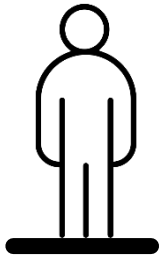


Lucerastat group

- 6 females, 4 males
- Mean age (SD): 47.7 (15.0), range from 18 to 67
- Mean ERT duration in years (SD): 4.5 (2.6)

Medical history:

- All patients had comorbidities, most of them manifestations of Fabry disease
- None of these affected eligibility for the study
- Overall balanced between groups



Control group

- 4 males
- Mean age (SD): 39.8 (19.1), range from 21 to 62
- Mean ERT duration in years (SD): 6.3 (4.2)

Lucerastat is investigational, in development and not approved or marketed in any country.

Lucerastat exploratory study

Safety results

Lucerastat was safe and well tolerated in patients with Fabry disease over 12 weeks on top of ERT

One Serious Adverse Event, unrelated to lucerastat:
Re-occurrence of atrial fibrillation in a patient
with underlying hypertrophic cardiomyopathy

No specific pattern in the nature and distribution
of Treatment-Emergent Adverse Events

No trends for changes from baseline in:
Vital signs, body weight, ECG recordings, clinical laboratory parameters

Lucerastat is investigational, in development and not approved or marketed in any country.

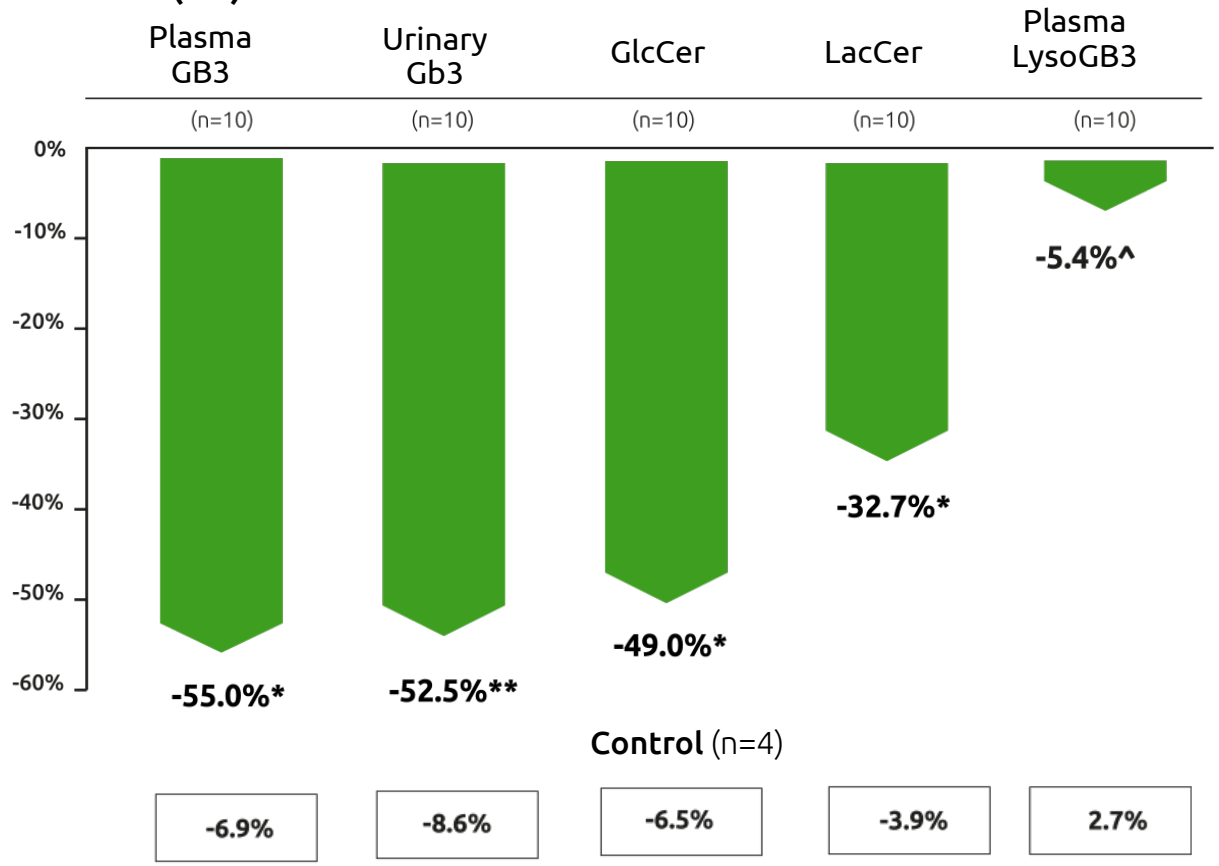
Lucerastat exploratory study

Results: rapid and additional reduction in Gb3 when added to enzyme replacement therapy

Phase 1b study

- **Lucerastat was safe and well tolerated** in patients with Fabry disease over 12 weeks on top of ERT
- **Pharmacokinetic findings consistent** with previous studies in healthy subjects
- **Proof of mechanism achieved with lucerastat:**
  Lucerastat significantly reduced Fabry disease-elevated Gb3
  and other relevant biomarkers

Mean % (SD) biomarker reduction from baseline at week 12



*P<0.0001,**statistical significance not calculated, ^non-significant

Lucerastat is investigational, in development and not approved or marketed in any country.

Fabry patients survey

Goals

Better understand patients' disease and needs from the patient perspective

1

Investigate key aspects of Phase 3 study MODIFY with respect to symptoms: neuropathic pain and gastrointestinal symptoms

2

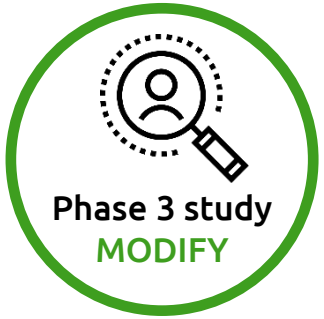
Complement existing information/data from the literature

3

In addition, collect information on:

- Use of enzyme replacement therapy (ERT)
- Impact on daily life
- Participation in clinical trials

Designing the confirmatory study: MODIFY



- **Informed design** based on patients survey
- **Development of endpoint measurement** – neuropathic pain, based on Brief Pain Inventory instrument, modified for Fabry's neuropathic pain according to FDA guidelines for PRO
- **Development and validation of electronic tool** to collect pain and gastro-intestinal daily data
- **Input from patient organization and from specialists**
- **Input from regulatory agencies including FDA**, and in Europe through scientific advice and the VHP procedure

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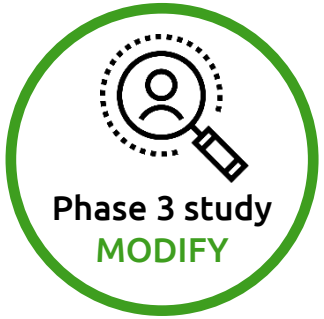
MODIFY: Objectives



Primary objective

- **To determine the effect of lucerastat on neuropathic pain** in patients with Fabry disease

Secondary objectives

- **To determine the effect of lucerastat on gastro-intestinal symptoms** (abdominal pain and diarrhea) in patients with Fabry disease and GI symptom(s) at baseline
- **To confirm the effect of lucerastat on biomarkers** of Fabry disease
- **To determine the safety and tolerability** of lucerastat in patients with Fabry disease

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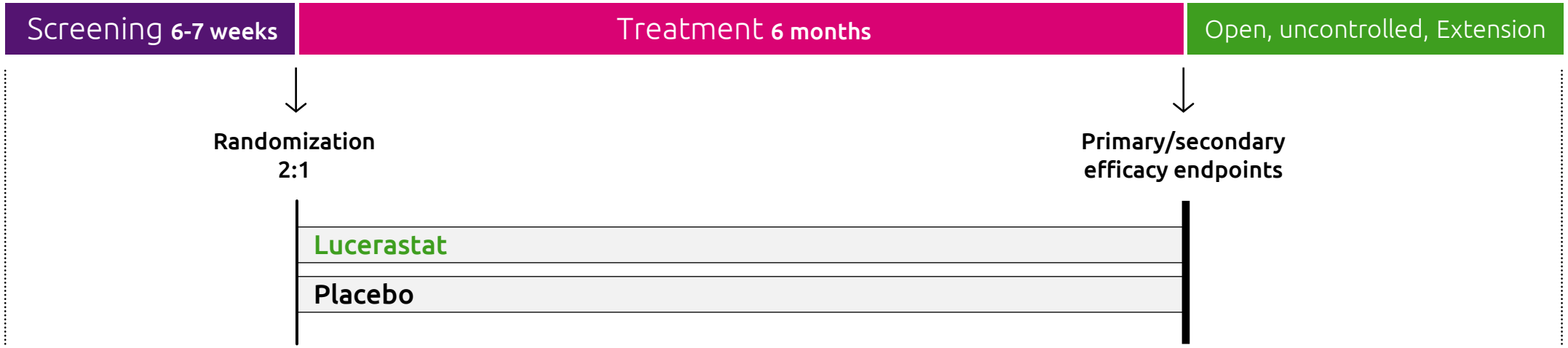
MODIFY: Study design

Phase 3 study
MODIFY



Site visits
Screening, Randomization,
Months 1, 2 (phone), 3, 4 (phone), 5, 6
+ 2 FU visits (phone)

Stratification by
- Sex
- ERT use (on ERT at screening vs never treated/previously treated)

Lucerastat dose
- 1000 mg b.i.d.
- Adjusted in subjects with moderate renal failure

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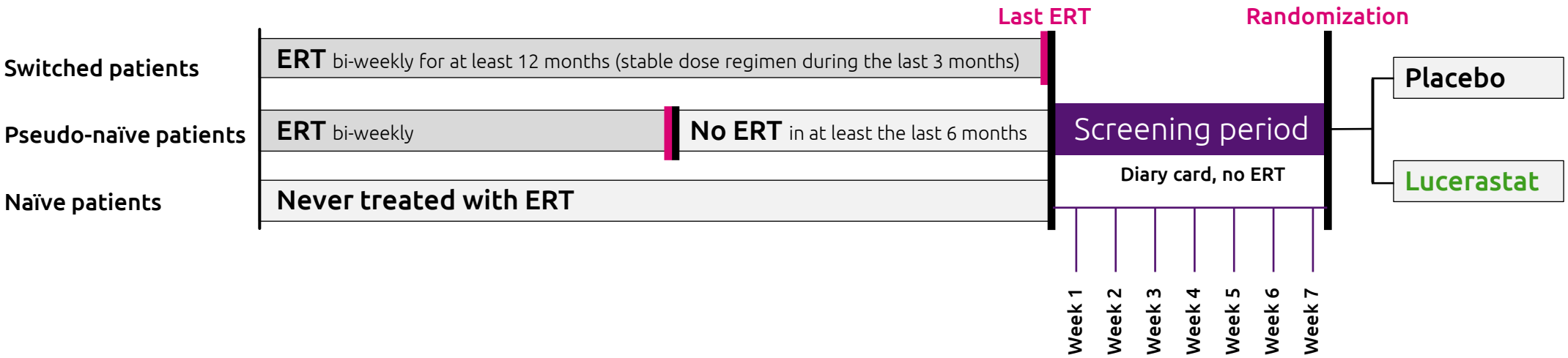
MODIFY: Patient population

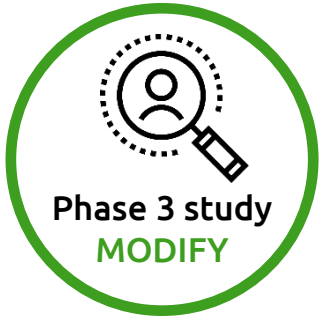
Phase 3 study
MODIFY



- Confirmed Fabry disease – presence of at least 1 mutation in GLA (the gene coding for α-galactosidase A) as measured with genetic test
- Neuropathic pain in the last 3 months preceding the screening period
- Three options for ERT status at baseline

Lucerastat is investigational, in development and not approved or marketed in any country.

MODIFY: Study endpoints



Primary efficacy endpoint

- The primary efficacy endpoint is a response to study treatment on neuropathic pain, defined as a reduction from baseline to Month 6 of at least 30% in the "modified" BPI-SF3 score of "neuropathic pain at its worst in the last 24 hours".

Secondary efficacy endpoints

- Change from baseline to Month 6 in the average daily 11-point Numerical Rating Scale (NRS-11) score of "abdominal pain at its worst in the last 24 hours" in subjects with GI symptoms at baseline.
- Change from baseline to Month 6 in the number of days with at least one stool of a Bristol Stool Scale (BSS) consistency Type 6 or 7 in subjects with GI symptoms at baseline;
- Change from baseline to Month 6 in plasma globotriaosylceramide (Gb3).

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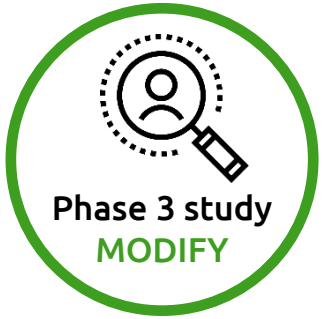
MODIFY: Results



- October 2021 MODIFY did not meet the primary endpoint of reducing neuropathic pain during 6 months of treatment versus placebo
- Substantial and consistent reduction of plasma Gb3 – confirming the pharmacological activity of lucerastat
- Based on historical patient data, mean estimated glomerular filtration rate (eGFR) – a measure of kidney function – was decreasing prior to the study. During the 6 months of the MODIFY study, eGFR increased in both arms of the study (as measured by the eGFR slope), with a slightly higher increase observed in the lucerastat group than in the placebo group.
- Lucerastat was well tolerated
- Lucerastat will therefore be further characterized in the Open label extension (OLE) study

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MODIFY: Open label extension study

- To determine the long-term safety and tolerability of lucerastat oral therapy and to further evaluate its clinical effects on renal and cardiac function in adult patients with Fabry disease over an additional period of up to 72 months
- October 2022: Interim analysis of the OLE study – all patients continuing in the study have now been treated with lucerastat for at least 12 months
- The analysis corroborated the long-term effect on the reduction of plasma Gb3 and showed that the signal seen on kidney function after 6 months of treatment is still observed after the longer treatment duration, supporting a potential positive long-term effect on kidney function
- The analysis also showed a safety and tolerability profile consistent with that observed during the 6-month randomized treatment period

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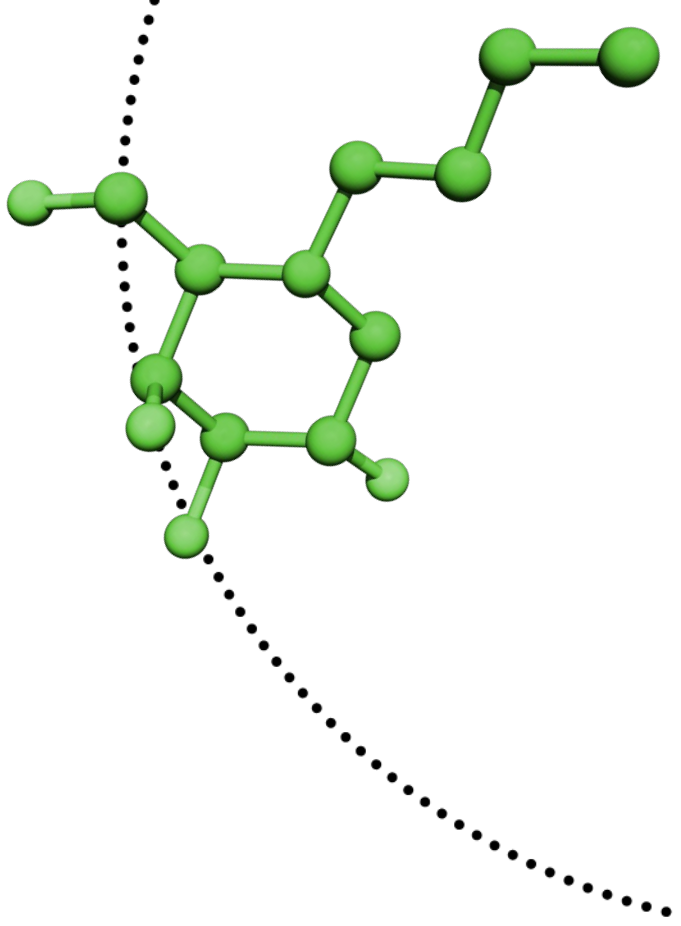
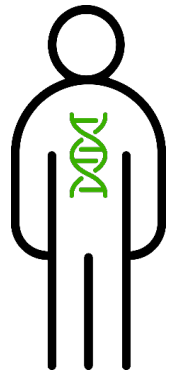
Lucerastat for Fabry disease

Glucosylceramide synthase inhibitor

An oral substrate reduction therapy investigated for the treatment of adult patients with Fabry disease.

- Lucerastat for Fabry disease has received orphan drug designation in the US and the EU
- MODIFY did not meet the primary endpoint
- Observations on renal function which, if confirmed with longer-term data, would indicate a treatment effect on the main organs affected by the disease
- Interim analysis showed that the signal seen on kidney function after 6 months of treatment is still observed after the longer treatment duration
- The company is conducting a kidney biopsy sub-study within a subset of patients currently participating in the OLE study – results are expected in Q2 2025
- Regulatory pathway to then be discussed with the US FDA





Lucerastat is investigational, in development and not approved or marketed in any country.

Idorsia-led early stage clinical development assets

Leveraging our innovative pipeline – Early-stage

Idorsia exploring potential collaboration or option deals until the next inflection point

ACKR3 antagonist

Progressive multiple sclerosis

Proof-of-concept in preparation

Unique combination of re-myelination and anti-inflammatory effect with decreased inflammatory cell infiltration.

CXCR3 antagonist

Vitiligo

Proof-of-concept in preparation

First-in-class inhibition of CXCR3+ CD8+ T-cells for effective and safer treatment of immuno-dermatology and autoimmune disorders.

CCR6 antagonist

Psoriasis

Proof-of-concept in preparation

Unique potential as a **first-in-class**, oral, targeted systemic therapy for effective treatment of Th17-driven immuno-dermatology and autoimmune disorders.

Leveraging our innovative pipeline – Preclinical

Idorsia exploring potential collaboration or option deals until the next inflection point

LPA 1 receptor antagonist

Immune-mediated and fibrosis related disorders

Entry-in-human package complete

Potential **best-in-class** due to insurmountable binding mode – proven inhibitory activity in preclinical models of inflammation and fibrosis

Undisclosed mechanism

Organ injury / fibrosis

Entry-in-human package in progress

Broad potential of undisclosed mechanism for inhibiting organ injury and fibrosis – proven effectiveness (i.v. & oral) in several preclinical models of organ injury

Orexin 2 receptor agonist

Narcolepsy, Hypersomnia

Entry-in-human package ready to begin

Potential **best-in-class** – sustained chronic efficacy in a preclinical model of narcolepsy

CFTR type-IV corrector

Cystic Fibrosis

Entry-in-human package in progress

A unique corrector targeting an Idorsia-identified binding site on the Cystic Fibrosis Transmembrane regulator (CFTR) protein. Potential synergy with other molecules

Leveraging our innovative pipeline – Vaccines

Idorsia exploring potential collaboration

Synthetic glycan vaccine platform

Transforming vaccines from biologics to medicinal chemistry:
fast approach to find new optimized vaccines for bacterial, fungal, oncological threats, substantially reducing costs in development

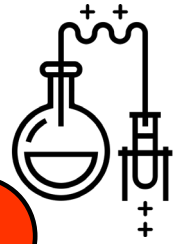
***Clostridium difficile* infection vaccine**

Idorsia is conducting a Phase 1 clinical pharmacology study which will test the immune response of the vaccine and evaluate its safety and tolerability.
Results expected in Q2 2025.

Pentavalent *Klebsiella pneumonia* infection vaccine

Entry-in-human package in progress

More knowledge – Powered by science



Focus on small molecules

- Based on organic chemistry
- Suitable for acute and chronic diseases
  - Suitable for oral use
    - Clear patent protection

Vaccine platform

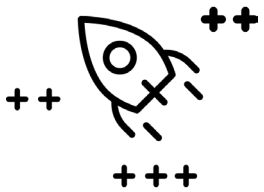
- Discovering and developing glycoconjugate vaccines
- Containing synthetic antigenic glycan molecules
- +/- carrier protein to prevent infection

Target selection

- High medical need – patient focused
- Therapeutic novelty

State-of-the-art technologies

- Artificial intelligence
- Computer modelling
- High throughput screening

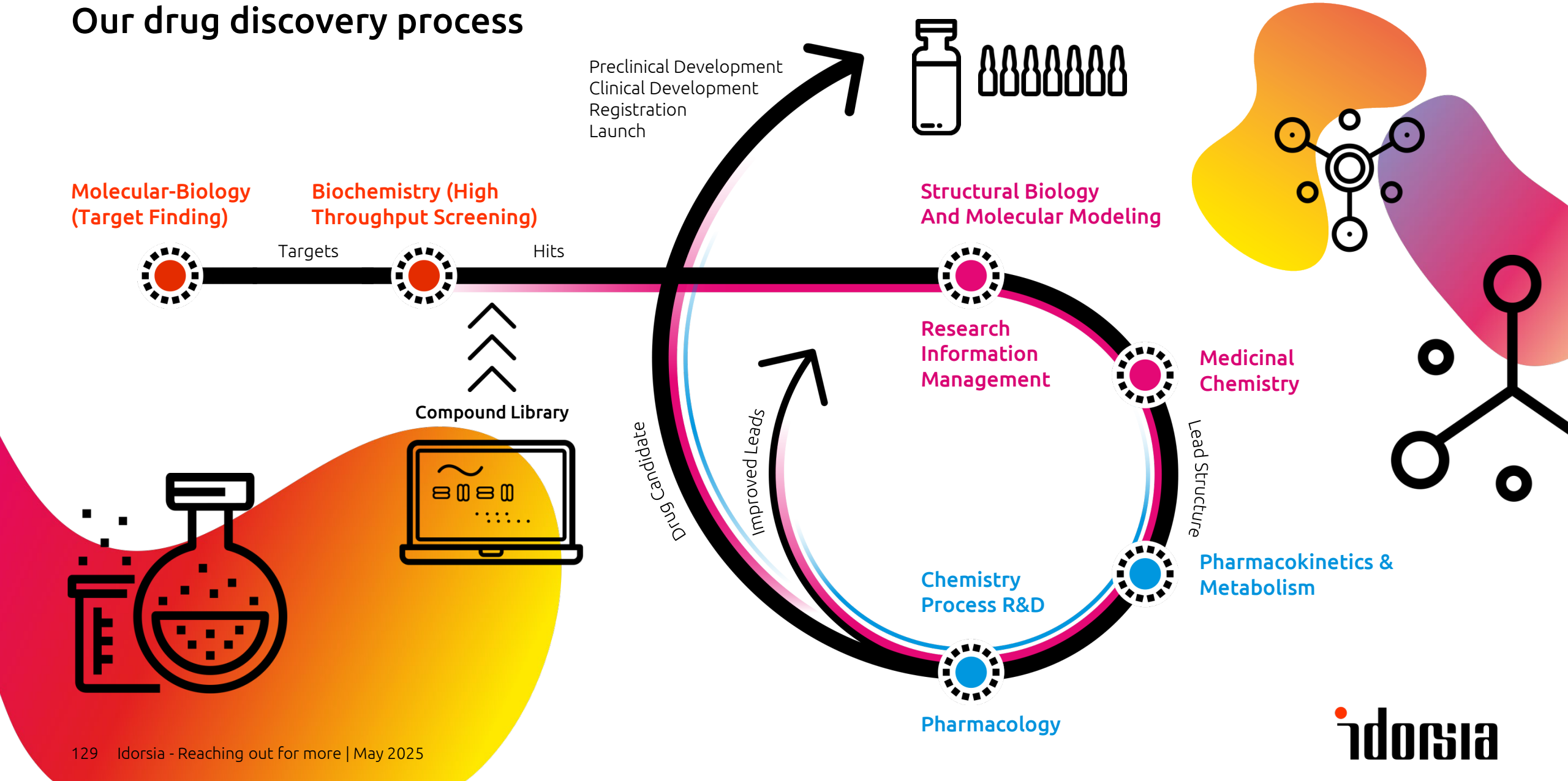


Industry leading talent

- Highly experienced and motivated team
- Medical expertise in multiple therapeutic areas

More joy – Transforming the horizon

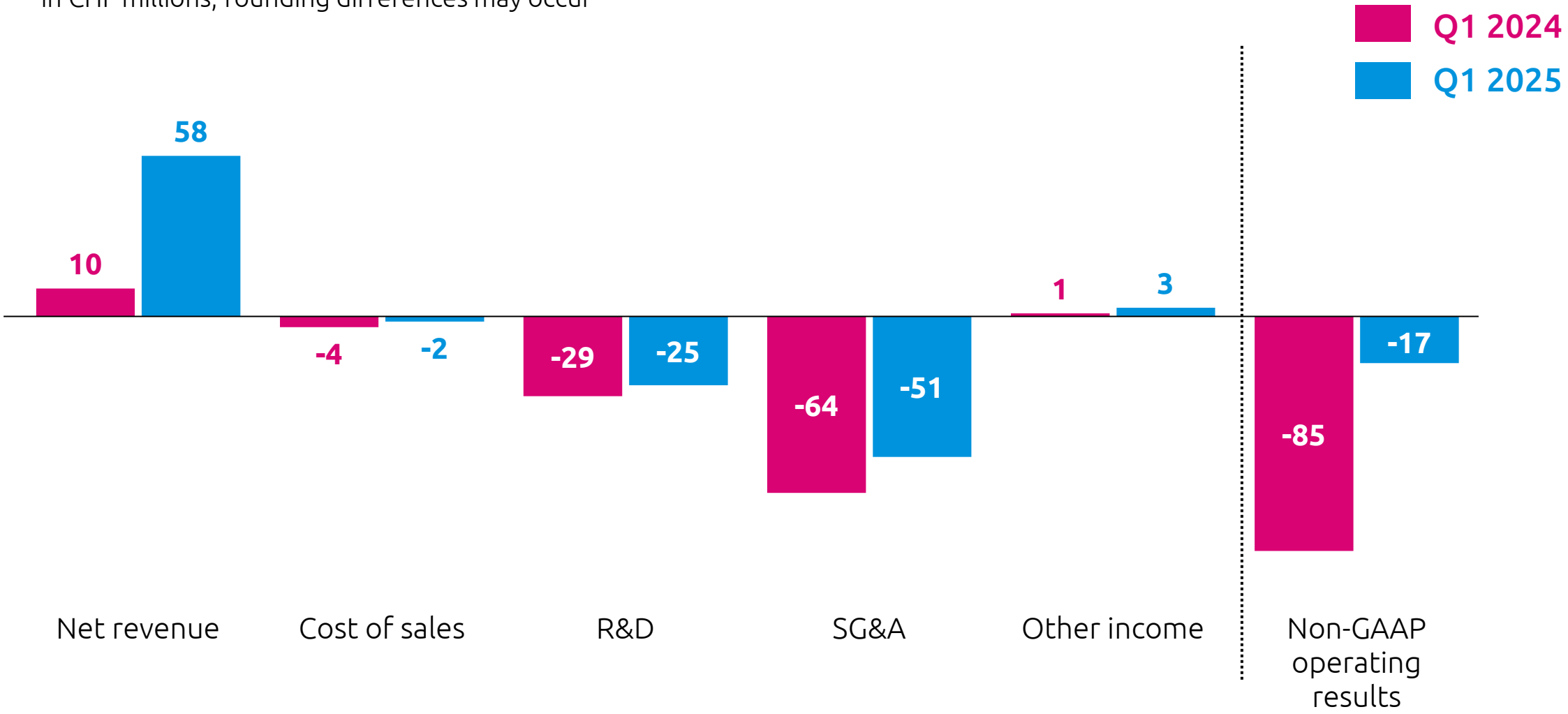
Our drug discovery process



Financial information Q1 2025

Non-GAAP operating results

in CHF millions, rounding differences may occur



Financial results as of March 31, 2025

Q1 2024 vs Q1 2025 operating performance

in CHF millions, rounding differences may occur	Q1 2024 Idorsia business	Q1 2024 Partnered business	Q1 2024 Global Business	Q1 2025 Idorsia business	Q1 2025 Partnered business	Q1 2025 Global Business
REVENUE	10	-	10	25	33	58
COGS	-4	-	-4	-2	-0	-2
SG&A OPEX	-64	-	-64	-51		-51
R&D OPEX	-29	-	-29	-25		-25
Other	0	-	0	3		3
Non-GAAP EBIT	**-85**	**-**	**-85**	**-50**	**33**	**-17**
D&A	-4	-	-4	-4		-4
SBC	-5	-	-5	-2		-2
Other	-1	125	124	-1	91	90
US-GAAP EBIT	**-95**	**125**	**31**	**-57**	**124**	**67**

Q1 2025 cash development

in CHF millions, rounding differences may occur

Financial outlook

Financial outlook

Status: May 2025

CHF million	Idorsia-led business		
	2023 proforma*	2024 as reported	2025 guidance**
REVENUE	32	61	130
COGS	-4	-6	-15
SG&A OPEX	-358	-263	-200
R&D OPEX	-262	-128	-90
Other	-	6	-
Non-GAAP EBIT	**-591**	**-330**	**-175**

* Excluding the business sold as part of the Nxera deal

** Excluding unforeseen events

- Accelerate sales
- Reduce cost-base

Financial outlook

Status: May 2025

CHF million	Guidance for 2025		
	Idorsia-led business	Partner-led business	Global Business
REVENUE	130	45	175
COGS	-15	-	-15
SG&A OPEX	-200	-	-200
R&D OPEX	-90	-	-90
Non-GAAP EBIT	**-175**	**45**	**-130**
D&A	-20	-	-20
SBC	-15	-	-15
Other	-10	90	80
US-GAAP EBIT	**-220**	**135**	**-85**

Idorsia has a **strong and visionary leadership team** with the power and drive to create more remarkable innovations and more new medicines

Idorsia Executive Committee

Alberto Gimona
Head of Global Clinical Development & Medical Affairs

Julien Gander
Group General Counsel

André C. Muller
Chief Executive Officer

Martine Clozel
Chief Scientific Officer

Arno Groenewoud
Chief Financial Officer

Idorsia Leadership Team

Olivier Lambert
Head of Technical Operations

Kerstin Niggemann
Head Pharmacological Sciences

Gaby Scherer
Head of Global Human Resources

Eva Caroff
Head Chemical Sciences

Andrew Jones
Head of Corporate Communications & Investor Relations

Be prepared for more