



# Media Release

## January 9, 2023

Ad hoc announcement pursuant to Art. 53 LR

### Idorsia presents at the 41st J.P. Morgan Healthcare Conference – Achievements in 2022 provide the foundation for our success in 2023

#### **Allschwil, Switzerland – January 9, 2023**

Idorsia Ltd (SIX: IDIA) today announced that Jean-Paul Clozel, Chief Executive Officer of Idorsia, will present at the 41<sup>st</sup> J.P. Morgan Healthcare Conference on January 9, 2023, at 17:15 Pacific Standard Time / 02:15 Central European Time. The conference will take place at the Westin St. Francis hotel in San Francisco, USA.

Jean-Paul will describe how Idorsia is building momentum to become a leading mid-sized biopharmaceutical company. The presentation will cover the launch of the company's first products, PIVLAZ™ (clazosentan) in Japan and QUVIVIQ™ (daridorexant) in the US and Europe. He will also present opportunities for future growth coming from the clinical development pipeline, including the recent filing of a new drug application for apocritentan with the US Food and Drug Administration (FDA), the eagerly anticipated Phase 3 REACT clinical results expected in the near-term, and the progress made with other late-stage assets. Follow this [link](#) to access the audio stream and find the presentation available [here](#).

#### **Jean-Paul Clozel MD and Chief Executive Officer of Idorsia commented:**

“Our achievements in 2022 provide the foundation for our success in 2023. QUVIVIQ is on track to become the leading global brand in insomnia. The feedback from physicians has been overwhelmingly positive. In the US, the team has done a great job in creating awareness and demand with patients and physicians alike. We now need to conclude the access discussions in 2023 to translate the strong and growing demand into revenue. Meanwhile, Germany and Italy are off to a great start, and we expect to see additional European countries launching QUVIVIQ during 2023, as well as the regulatory decision in Canada. Following the excellent Phase 3 results in Japan, I also expect the filing of the daridorexant Japanese NDA.”

#### **Jean-Paul continued:**

“PIVLAZ has had a great start in Japan with around 95% of the target accounts now ordering and around 25% of patients suffering from an aSAH in November receiving PIVLAZ. I am very eager to see the results for clazosentan in the global REACT study which are expected in the coming weeks.”

### **Expected highlights in 2023**

- Secure additional funding through non-equity dilutive instruments to narrow the funding gap
- Secure broader payer coverage for QUVIVIQ (daridorexant) in the US – removing an important barrier to prescribing<sup>†</sup>
- Commercial launch of QUVIVIQ (daridorexant) in additional European countries, regulatory decision in Canada, and new drug application for daridorexant in Japan
- Results of REACT, the Phase 3 study with clazosentan for the prevention of cerebral vasospasm associated with aneurysmal subarachnoid hemorrhage outside of Japan
- Marketing authorization application (MAA) for aprocitentan for difficult-to-treat hypertension
- FDA decision for the NDA for aprocitentan for difficult-to-treat hypertension

<sup>†</sup>Effective January 15, 2023, QUVIVIQ will be covered at parity to the other branded dual orexin receptor antagonist (DORA) products for the Express Scripts National Preferred Formulary (NPF).

### **Jean-Paul commented on the pipeline:**

“The pipeline has also progressed in 2022. The positive results with aprocitentan were rapidly analyzed and documented to achieve the US NDA before the end of 2022. This puts us in a good position for other regulatory filings in the coming months and the decision from the FDA before the end of 2023. Our Phase 3 SOS-AMI study investigating selatogrel for the treatment of heart attack has now exceeded 2,800 patients and recruitment will ramp up in 2023, we are encouraged that the patient education material and device is performing well. Having opened recruitment into the Phase 3 OPUS program investigating cenerimod for lupus in December 2022, I expect great interest from patients to participate and it should take off in 2023.”

### **Jean-Paul concluded:**

“For me, a very important aspect to our long-term success is that our drug discovery engine continues to deliver innovative products to the clinical development pipeline. I’m pleased to have a new compound entering the clinic this year and am very excited by what I see coming through from the drug discovery team. These highlights are perfect examples of how we have created a solid foundation in 2022 to succeed in 2023 and for our team to see the fruits of all our labors.”

## Idorsia's portfolio

Compound	Mechanism of action	Target indication	Status
<b>PIVLAZ™ (clazosentan)</b>	Endothelin receptor antagonist	Cerebral vasospasm assoc. aSAH	Commercially available in Japan; Global Phase 3 complete – results expected Q1 2023
<b>QUVIVIQ™ (daridorexant)</b>	Dual orexin receptor antagonist	Insomnia	Commercially available in the US, and the first countries in Europe; Approved in the UK and Switzerland; Under review in Canada; Phase 3 in Japan successful – filing expected in H2 2023; Phase 2 in pediatric insomnia – recruiting
<b>Aprocitentan*</b>	Dual endothelin receptor antagonist	Difficult-to-control hypertension	NDA under review in US, other country filings in preparation
<b>Lucerastat</b>	Glucosylceramide synthase inhibitor	Fabry disease	Phase 3 primary endpoint not met; Open Label Extension ongoing
<b>Selatogrel</b>	P2Y <sub>12</sub> inhibitor	Suspected acute myocardial infarction	Phase 3 recruiting
<b>Cenerimod</b>	S1P <sub>1</sub> receptor modulator	Systemic lupus erythematosus	Phase 3 recruiting
<b>ACT-1004-1239</b>	ACKR3 / CXCR7 antagonist	Multiple sclerosis	Phase 2 in preparation
<b>Sinbaglustat</b>	GBA2/GCS inhibitor	Rare lysosomal storage disorders	Phase 1 complete
<b>ACT-1014-6470</b>	C5aR1 antagonist	Immune-mediated disorders	Phase 1
<b>ACT-777991</b>	CXCR3 antagonist	Recent-onset Type 1 diabetes	Phase 1
<b>IDOR-1117-2520</b>	Undisclosed	Immune-mediated disorders	Phase 1

\*In collaboration with Janssen Biotech to jointly develop aprocitentan, Janssen Biotech has sole commercialization rights worldwide

Neurocrine Biosciences has a global license to develop and commercialize ACT-709478 (NBI-827104), Idorsia's novel T-type calcium channel blocker. ACT-709478 was investigated in a Phase 2 study for the treatment of a rare form of pediatric epilepsy. The study did not meet the primary endpoint. ACT-709478 was generally well tolerated. Neurocrine continues to analyze the data generated in the study to determine next steps.

Further details including the current status of each project in our portfolio can be found in our [innovation fact sheet](#).

### Creation of Treasury Shares

The Company today reports that it has created 10,000,000 treasury shares with a nominal value of CHF 0.05 each, thereby increasing its registered share capital from CHF 8,848,349.75 to CHF 9,348,349.75. The new shares, created on January 6, 2023, out of the Company's authorized share capital, were subscribed at nominal value by Idorsia Pharmaceuticals Ltd, a wholly owned subsidiary, and are expected to be listed on the SIX Swiss Exchange on or around January 9, 2023. With this increase, the Company now holds treasury shares that can be used in a cash preservative manner for potential share-based compensation, effective fund raising, or business development purposes.

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## Notes to the editor

### About Idorsia

Idorsia Ltd is reaching out for more – We have more ideas, we see more opportunities, and we want to help more patients. In order to achieve this, we will develop Idorsia into a leading biopharmaceutical company, with a strong scientific core.

Headquartered near Basel, Switzerland – a European biotech-hub – Idorsia is specialized in the discovery, development and commercialization of small molecules to transform the horizon of therapeutic options. Idorsia has a broad portfolio of innovative drugs in the pipeline, an experienced team of professionals covering all disciplines from bench to bedside, state-of-the-art facilities, and a strong balance sheet – the ideal constellation to translate R&D efforts into business success.

Idorsia was listed on the SIX Swiss Exchange (ticker symbol: IDIA) in June 2017 and has over 1'200 highly qualified specialists dedicated to realizing our ambitious targets.

### For further information, please contact

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