



Press Release

Poxel Announces TWYMEEG® (Imeglimin) Fiscal Year 2022 Sales

- TWYMEEG sales in Japan for Sumitomo Pharma Fiscal Year 2022¹ reached JPY 2.2 billion² (EUR 15.0 million)³, exceeding guidance⁴ by more than 20%
- TWYMEEG's Fiscal Year 2023⁵ forecast of JPY 4.2 billion² (EUR 28.9 million)³, which would represent a 90% growth over FY 2022 sales

LYON, France, May 15, 2023 – POXEL SA (Euronext: POXEL - FR0012432516), a clinical stage biopharmaceutical company developing innovative treatments for chronic serious diseases with metabolic pathophysiology, including non-alcoholic steatohepatitis (NASH) and rare metabolic disorders, today announced TWYMEEG® (Imeglimin) Fiscal Year (FY) and fourth quarter 2022 results, as recently published by Sumitomo Pharma (Sumitomo), its partner commercializing TWYMEEG in Japan.

Thomas Kuhn, Chief Executive Officer of Poxel, stated: *"This first full year of TWYMEEG's commercialization has demonstrated a strong increase in sales, even exceeding the recent forecast that had been increased by Sumitomo Pharma, our commercial partner in Japan. This trend confirms the strong value of our product and gives us confidence in the timing of future expected positive royalties and sales-based payments that will be directed to repay the Company's debt and fuel the future development of the Company in rare diseases."*

- For the quarter ended March 2023, TWYMEEG gross sales in Japan increased 23% to JPY 0.9 billion (EUR 6.2 million)³ over the prior quarter sales of JPY 0.8 billion (EUR 5.5 million)³ as reported by Sumitomo.
- As a result, for Sumitomo's FY 2022, TWYMEEG gross sales reached JPY 2.2 billion (EUR 15.0 million)³, exceeding Sumitomo's most recent FY 2022 forecast⁴ by 22%.
- The sales in recent quarters have accelerated due to the end of initial launch year restrictions for TWYMEEG in September 2022, which limited new products to two weeks prescriptions, and Sumitomo's commercial efforts to leverage TWYMEEG's potential. Due to its unique mechanism of action and safety profile, TWYMEEG can be used both as a monotherapy and in combination with other treatments, such as DPP4 inhibitors, the most prescribed treatment for Japanese Type-2-Diabetes patients, and SGLT2 inhibitors, which is growing

¹ Sumitomo Pharma fiscal year 2022 ends March 31, 2023.

² Published by Sumitomo Pharma on May 15, 2023.

³ Converted at the exchange rate as of March 31, 2023.

⁴ Sumitomo increased its FY2022 forecast to JPY 1.8 billion from JPY 1.5 billion on January 31, 2023.

⁵ Sumitomo Pharma fiscal year 2023 ends March 31, 2024.





strongly in Japan. These factors have resulted in a much higher increase in demand for TWYMEEG than expected by Sumitomo, and thus inventories are temporarily tight. Sumitomo is working diligently to increase capacity over the summer.

- For its FY 2023, Sumitomo announced a forecast for TWYMEEG of JPY 4.2 billion² (EUR 28.9 million)³ which would represent a 90% increase over FY 2022 TWYMEEG gross sales.
- For the Sumitomo FY 2023, as a conservative assumption in line with Sumitomo's forecast, Poxel expects to receive 8% royalties on TWYMEEG net sales. As part of the Merck Serono licensing agreement, Poxel will pay Merck Serono a fixed 8% royalty based on the net sales of TWYMEEG, independent of the level of sales.
- During Sumitomo FY 2024 (ending March 31, 2025), Poxel expects TWYMEEG net sales in Japan to reach at least JPY 5 billion (EUR 34.4 million)³ entitling Poxel to receive 10% royalties on all TWYMEEG net sales and a sales-based payment of JPY 500 million (EUR 3.4 million)³. Beyond 2024, Poxel expects to receive escalating double-digit royalties as well as additional sales-based payments upon achievement of contractually based sales thresholds.
- As part of the Sumitomo's ongoing efforts to communicate TWYMEEG's unique mechanism of action and safety profile, 9 abstracts based on Imeglimin Phase 2b and Phase 3 clinical trials were accepted for oral presentations at the 66th Annual Meeting of the Japanese Diabetes Society (JDS), held in Kagoshima, Japan, May 11-13, 2023.

About Poxel SA

Poxel is a **clinical stage biopharmaceutical company** developing **innovative treatments for chronic serious diseases with metabolic pathophysiology**, including **non-alcoholic steatohepatitis (NASH)** and rare disorders. For the treatment of NASH, **PXL065** (deuterium-stabilized *R*-pioglitazone) met its primary endpoint in a streamlined Phase 2 trial (DESTINY-1). In rare diseases, development of **PXL770**, a first-in-class direct adenosine monophosphate-activated protein kinase (AMPK) activator, is focused on the treatment of adrenoleukodystrophy (ALD) and autosomal dominant polycystic kidney disease (ADPKD). **TWYMEEG®** (Imeglimin), Poxel's first-in-class product that targets mitochondrial dysfunction, is marketed for the treatment of type 2 diabetes in Japan by Sumitomo Pharma and Poxel expects to receive royalties and sales-based payments. Poxel has a strategic partnership with Sumitomo Pharma for Imeglimin in Japan, China, and eleven other Asian countries. Listed on Euronext Paris, Poxel is headquartered in Lyon, France, and has subsidiaries in Boston, MA, and Tokyo, Japan.

For more information, please visit: www.poxelpharma.com





All statements other than statements of historical fact included in this press release about future events are subject to (i) change without notice and (ii) factors beyond the Company's control. These statements may include, without limitation, any statements preceded by, followed by or including words such as "target," "believe," "expect," "aim," "intend," "may," "anticipate," "estimate," "plan," "project," "will," "can have," "likely," "should," "would," "could" and other words and terms of similar meaning or the negative thereof. Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control that could cause the Company's actual results or performance to be materially different from the expected results or performance expressed or implied by such forward-looking statements. The Company does not endorse or is not otherwise responsible for the content of external hyperlinks referred to in this press release.

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Glossary

You will find below a list of words and/or expressions that are used in this press release or in Poxel's communication, with the aim to bring clarification and transparency:

- **Sumitomo Pharma fiscal year** runs April to March. As an example, Fiscal Year 2022 is April 1, 2022 through March 31, 2023.
- **TWYMEEG royalties:** As per the Sumitomo's agreement, Poxel is entitled to receive royalties from the net sales of TWYMEEG (Imeglimin) in Japan)
 - TWYMEEG royalties are calculated on net sales, while Sumitomo Pharma communicates only TWYMEEG gross sales.
 - Poxel entitled to receive escalating royalties of 8-18% on TWYMEEG net sales from Sumitomo Pharma.
- **Positive net royalties:** refers to royalties Poxel receives from TWYMEEG net sales after paying Merck Serono the first 8%, once Poxel starts to receive minimum 10% royalties upon TWYMEEG net sales exceeding JPY 5 billion in a fiscal year.