January 31, 2025

# Poxel's partner Sumitomo Pharma reports TWYMEEG® gross sales in Japan for Q4 2024 and FY 2024 sales forecast

- **TWYMEEG® sales continued to increase in Japan for the last quarter 2024 (October-December) by 17% over the prior quarter and by 154% over Q4 2023**
- **TWYMEEG®'s FY 2024[1] revised forecast[2] of JPY 7.9 billion (EUR 48.4 million[3]), vs. JPY 11.3 billion[4] (EUR 69.2 million[3]), which would represent a 72% increase over FY 2023 sales**
- **Poxel eligible for royalties equaling 10% of all TWYMEEG® net sales for 2024 and a one-time sales-based payment of JPY 500 million (EUR 3.1 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**

LYON, France--(BUSINESS WIRE)-- Regulatory News:

POXEL SA (Euronext : POXEL - FR0012432516), a clinical stage biopharmaceutical company developing innovative treatments for chronic serious diseases with metabolic pathophysiology, including metabolic dysfunction-associated steatohepatitis (MASH) and rare metabolic disorders, today reports TWYMEEG® gross sales in Japan for Q4 2024 and sales forecast shared by its partner Sumitomo Pharma as part of its Q3 FY2024 financial results[1].

"*We believe TWYMEEG® is an important asset in our existing diabetes franchise and are committed to support its sales trajectory. Based on the safety and tolerability profile observed from TWINKLE study, we are conducting discussions with the regulatory authorities in Japan, on revising TWYMEEG® package insert for patients with renal impairment,*" stated **Koichi Kozuki, Executive Officer, Corporate Regulatory Compliance & Quality Assurance Division, Senior Vice President, Head of Corporate Regulatory Compliance & Quality Assurance Division of Sumitomo Pharma**.

For the quarter ending December 2024, TWYMEEG® gross sales in Japan increased by 17% to JPY 2.1 billion (EUR 13 million)[3] over the prior quarter sales of JPY 1.8 billion (EUR 11.2 million)3 as reported by Sumitomo Pharma. As announced on January 20, 2025, TWYMEEG® achieved JPY 5 billion net sales in Japan in Sumitomo Pharma's fiscal year 2024[1], making Poxel eligible for royalties equaling 10% of all TWYMEEG® net sales for 2024

and a one-time sales-based payment of JPY 500 million (EUR 3.1 million[3]). Based on the royalty monetization agreement with OrbiMed, these proceeds for FY2024, net of Poxel's obligation to Merck Serono, will be directed to the reimbursement of the bond issue.

During FY 2024[1], Sumitomo Pharma now expects TWYMEEG® net sales in Japan to reach JPY 7.9 billion (EUR 48.4 million[3]), compared to the previous forecast of JPY 11.3 billion (EUR 69.2 million[3]) published on May 14, 2024, which would represent an increase by 72% over FY 2023 sales (JPY 4.6 billion). This revision is driven by Sumitomo Pharma's internal restructuring initiative as well as an evolving competitive landscape in Japan. To support TWYMEEG® sales trajectory going forward, Sumitomo Pharma has implemented measures to minimize potential impact from this internal restructuring initiative and continues to work on expanding the TWYMEEG® package insert.

As announced on August 7, 2024, topline results obtained from the post-marketing clinical study, TWINKLE (**TW**YMEEG® in d**i**abetic patients with re**n**al impairment: A post-mar**k**eting **l**ong-t**e**rm study) conducted by Sumitomo Pharma in Japanese type 2 diabetic patients with renal impairment confirmed TWYMEEG®'s safety and tolerability profile, which is consistent with prior clinical studies in the general type 2 diabetes population. Based on these results, Sumitomo Pharma is conducting discussions with the regulatory authorities in Japan for revising TWYMEEG® package insert for patients with renal impairment with eGFR (estimated glomerular filtration rate) less than 45 mL/min/1.73m$^2$ and expects outcome in the first half of 2025.

**Next Financial Press Release:**

- Fourth Quarter 2024 Cash and Revenue update, on February 19, 2025

**About Poxel SA**

Poxel is a **clinical stage biopharmaceutical company** developing **innovative treatments for chronic serious diseases with metabolic pathophysiology**, including **metabolic dysfunction-associated steatohepatitis (MASH)** and rare disorders. For the treatment of MASH, **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 now 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. 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.

## 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 of bringing clarification and transparency:

- **Sumitomo Pharma fiscal year** runs April to March. As an example, Fiscal Year 2024 is April 1, 2024, through March 31, 2025.
- **TWYMEEG royalties:** As per the Sumitomo Pharma’s agreement, Poxel is entitled to receive royalties from the sales of TWYMEEG (Imeglimin) in Japan
    - Sumitomo Pharma communicates gross sales of TWYMEEG, while TWYMEEG royalties are calculated on net sales.
    - Net sales represent the amount of gross sales to which are deducted potential rebates, allowances, and costs such as prepaid freight, postage, shipping, customs duties and insurance charges.
    - Poxel is entitled to receive escalating royalties of 8-18% on TWYMEEG net sales from Sumitomo Pharma.

**Positive net royalties**: 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. All royalties that Poxel receives from TWYMEEG net sales above that 8% level are considered as positive net royalties. Net royalties will therefore be positive for Poxel when TWYMEEG net sales exceed JPY 5 billion in a fiscal year and royalties reach 10% and above.

*[1] Sumitomo Pharma fiscal year 2024 ends March 31, 2025*
*[2] As per Sumitomo Pharma FY2024 forecast published on January 31, 2025*
*[3] Converted at the exchange rate as of December 31, 2025.*
*[4] As per Sumitomo Pharma FY2024 forecast published on May 14, 2024*

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