Press Release

Poxel Reports Consolidated Revenue for the First Quarter 2025 and Provides Corporate Update

- **TWYMEEG® consolidated gross sales in Japan for Sumitomo Pharma Fiscal Year 2024[1] achieved JPY 7.6 billion (EUR 47,2 million)[2], in line with Sumitomo Pharma's latest guidance[3]**
- **Sumitomo Pharma forecast for TWYMEEG®'s FY 2025[4] of JPY 11.2 billion (EUR 69,4 million[2]), representing a 47% increase over FY 2024 sales**
- **In FY2024, Poxel started receiving 10% royalties on TWYMEEG® net sales, and from FY2025[5] anticipates receiving escalating double-digit royalties and additional sales-based payments upon achievement of contractual sales thresholds**
- **Regulatory approval on April 8, 2025, by the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan enabling Sumitomo Pharma to immediately start promoting the use of TWYMEEG® (Imeglimin) in type 2 diabetic patients with moderate to severe renal impairment**
- **Ongoing discussions with 1/ creditors to ensure continuity of the Company's operations and 2/ potential partners for the development of pipeline products**

LYON, France, May 13, 2025 – 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 reported its revenue for the quarter ended March 31, 2025 and provided corporate update.

Thomas Kuhn, Chief Executive Officer of Poxel, stated: *"TWYMEEG® has further demonstrated its strong potential in FY 2024[1] with the commercial performance in Japan representing a 65% increase over FY 2023. This robust growth is expected to continue in FY 2025 and beyond, and should be further strengthened driven by a number of key recent milestones, including the recent regulatory approval in Japan allowing TWYMEEG® to be prescribed to type 2 diabetic patients with moderate to severe renal impairment, a key patient population, particularly elderly individuals with renal impairment, who are faced with limited treatment options. In parallel of these achievements, our top priority remains to secure a path forward for the Company. We continue to be actively engaged in discussions with our creditors with the aim of*

[1] *Sumitomo Pharma fiscal year 2024 ends March 31, 2025*

[2] *Converted at the exchange rate on March 31, 2025*

[3] *As per Sumitomo Pharma FY2024 forecast of JPY 7.9 billion published on January 31, 2025*

[4] *As per Sumitomo Pharma FY2024 forecast published on May 13, 2025*

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reaching a structuring solution that would ensure the continuity of the Company's operations, and with potential partners to develop strategic opportunities to unlock the value of our pipeline of products."

Commercial and Clinical Update

TWYMEEG® (Imeglimin)

- For the quarter ended March 2025, TWYMEEG® gross sales in Japan totalled JPY 1.9 billion (EUR 12 million)[2]. As a result, for Sumitomo Pharma's FY 2024[1], TWYMEEG® gross sales reached JPY 7.6 billion (EUR 47.1 million)[2], in line with Sumitomo Pharma's most recent FY 2024 guidance (JPY 7.9 billion) and representing an increase by 65% over FY 2023.

- For its FY 2025[5], Sumitomo Pharma forecasts gross sales for TWYMEEG® of JPY 11.2 billion[4] (EUR 69.4 million)[2] which would represent a 47% increase over FY 2024 TWYMEEG® gross sales. This forecast includes an incremental uptake among type 2 diabetic patients with renal impairment following the recent approval by the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan to revise TWYMEEG® package insert for patients with renal impairment with eGFR (estimated glomerular filtration rate) less than 45 mL/min/1.73m^2.

- Based on this FY 2025 forecast, TWYMEEG® could reach JPY 10 billion net sales (EUR 62 million)[2] entitling Poxel to receive 12% royalties on all TWYMEEG® net sales and a second sales-based payment of JPY 1 billion (EUR 6.3 million)[2]. Following the recent royalty monetization agreement with OrbiMed, these proceeds will go exclusively towards the reimbursement of the bonds issuance. Beyond 2025, Poxel expects to receive escalating double-digit royalties as well as additional sales-based payments upon achievement of contractually based sales thresholds.

- In August 2024, topline results 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. Based on these results, Sumitomo Pharma led discussions with the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan leading to the revision of TWYMEEG® package insert for patients with renal impairment with eGFR (estimated glomerular filtration rate) less than 45 mL/min/1.73m^2 on April 8, 2025. This approval has enabled Sumitomo Pharma to immediately start promoting the use of TWYMEEG® in this population.

[5] *Sumitomo Pharma fiscal year 2025 ends March 31, 2026*

- This regulatory milestone builds on the recently granted patent (n°7635474) by the Japanese Patent Office to Poxel[6] covering the use of Imeglimin in type 2 diabetic patients with moderate to severe renal impairment until 2039, strengthening TWYMEEG®'s patent portfolio in Japan and protecting its use in this population. Poxel previously received the grant of this patent in China[7], the world's second largest type 2 diabetes market, further supporting ongoing discussions initiated by the Company to develop Imeglimin beyond Japan.

PXL065

- On March 20, 2025, positive top-line results for PXL065 were obtained from a preclinical study conducted in a mouse model of hypertrophic cardiomyopathy (HCM), the most common genetic cardiac disorder. The preclinical study was financed through a grant by DZHK[8] and conducted at the TUM University Hospital German Heart Center under a research collaboration. After 10 weeks of treatment, a significant reduction in myocardial hypertrophy associated with a significant reduction in cardiac fibrosis was demonstrated, highlighting the potential of PXL065 in this pathology. These results further support the clinical development of PXL065 as a potential disease-modifying treatment for symptomatic and asymptomatic HCM and will be presented at a future scientific meeting.

First Quarter 2025 Consolidated Revenue

Poxel reported EUR 1,066 thousand[2] consolidated revenue for the quarter ended March 31, 2025, representing a 137% increase compared to the 2024 Q1 revenue.

Consolidated revenue for the first quarter of 2025 reflects JPY 172 million (EUR 1,066 thousand[2]) of royalty revenue from Sumitomo Pharma, which represents 10% of TWYMEEG® net sales in Japan. Based on the current forecast, Poxel expects to receive at least 12% royalties on TWYMEEG® net sales in Japan through the Sumitomo Pharma fiscal year 2025[5]. As part of the Merck Serono licensing agreement, Poxel will pay Merck Serono a fixed 8% royalty based on the net sales of Imeglimin, independent of the level of sales. According to the Royalty Monetization agreement with OrbiMed, the positive net Royalties will be fully dedicated to the repayment of the bonds.

[6] *"Poxel Announces Grant of New Patent in Japan for the Use of Imeglimin in Type-2 Diabetic Patients with Renal Impairment", on March 31, 2025*
[7] *"Poxel Announces the Grant of Patent in China Protecting the Use of Imeglimin for Type-2 Diabetic Patients with Renal Impairment", on January 20, 2025*
[8] *DZHK: German Center for Cardiovascular Research (Deutsches Zentrum für Herz-Kreislauf-Forschung)*

EUR (in thousands)	Q1 2025*	Q1 2024
	3 months	3 months
Sumitomo Pharma Agreement	1,066	449
Other	-	-
Total consolidated revenues	**1,066**	**449**

**Unaudited data*

Update on existing event of default under the IRIS and IPF Partners existing bond financing agreements and search of structuring financial solution to ensure the continuity of the Company

Since the announcement by the Company of the events of default under the IRIS and IPF Partners outstanding bond financing agreements triggered by the non-adoption of the financial delegations at the Combined General Meeting held on February 11, 2025, the Board of Directors and the Management of Poxel continue to actively negotiate with the Company's creditors, with the aim of reaching a structuring solution that would ensure the continuity of the Company's operations. As announced on April 16, 2025, Poxel's financial outlook remains highly constrained with a cash runway currently estimated through June 2025, depending on the outcome of current discussions with the Company's creditors.

In parallel, the Company is also progressing discussions with several potential partners for the development of its pipeline products.

As already announced on April 16, 2025, given the potential impact on the Company's financial statements of the negotiations with the Company's creditors and potential partners, Poxel has postponed the approval and publication of its 2024 Full-Year Results. A new date will be communicated once these negotiations are finalized.

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.

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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 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.

- **Poxel** refers to the Group Poxel, including its affiliates (Poxel Inc. and Poxel KK) as well as the 3 security trusts set up as part of the Royalty monetization and debt restructuring operations announced on September 30, 2024.