

## Poxel Reports Revenue for the Full Year 2024 and Provides an Update on its Financial Position and Outlook

- Following the non-adoption of key financial delegations at the Combined General Meeting held on February 11, 2025, the Company is facing an uncertain and adverse situation regarding the continuation of its activities
  - Event of default under the IRIS and IPF Partners financing agreements allowing each of them to request immediate redemption of the outstanding bonds they hold (EUR 4.3 million and EUR 17.1 million respectively)
  - With a cash position of EUR 3.7 million as of December 31, 2024, the Company will be unable to repay IRIS and IPF Partners if they redeem their outstanding bonds, which significantly compromises its ability to continue as a going concern
  - The Board of Directors and the Management are actively engaged in working on potential solutions with Poxel's creditors
- On the commercial aspects of TWYMEEG<sup>®</sup>, outlook remains promising despite Poxel's financial challenges
  - TWYMEEG<sup>®</sup> sales in Japan continued to increase by 17% in Q4 2024 (October-December) over the prior quarter and by 154% over Q4 2023
  - Poxel is entitled to 10% royalties of all TWYMEEG<sup>®</sup> net sales for Sumitomo Pharma fiscal year 2024 and a one-time sales-based payment of JPY 500 million (EUR 3.1 million<sup>1</sup>) leading to a 235% increase in revenue vs FY2023
  - From 2025, Poxel expects to receive escalating double-digit royalties and additional sales-based payments upon achievement of contractual sales thresholds
  - Sumitomo Pharma is conducting discussions with the regulatory authorities in Japan for revising TWYMEEG<sup>®</sup> package insert for patients with renal impairment. Outcome is expected in the first half of 2025

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<sup>1</sup> Converted at the exchange rate as of December 31, 2024



**LYON, France, February 19, 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 reports its full-year revenue for the period ended December 31, 2024 and provides an update on its financial situation and outlook, in particular following the non-adoption of key financial resolutions by the Combined General Meeting held on February 11, 2025.

## Full-Year Revenue and Cash, ended December 31, 2024 (unaudited data)

### Consolidated Revenue

Poxel reported consolidated revenue of EUR 6.6 million for the year ended December 31, 2024, as compared to EUR 2 million during the corresponding period in 2023.

Consolidated revenue for 2024 mostly reflects the JPY 580 million (EUR 3.6 million)<sup>1</sup> of royalty revenue from Sumitomo Pharma, which represents:

- 8% of TWYMEEG<sup>®</sup> net sales in Japan for 2024 Q1 to Q3,
- 10% of TWYMEEG<sup>®</sup> net sales in Japan for 2024 Q4 and a 2% catch up of the net sales related to 2024 Q2 and Q3 following the achievement of the JPY 5 billion net sales threshold for the 2024 Sumitomo Pharma fiscal year started on April 1<sup>st</sup>, 2024.

Consolidated revenue for 2024 Q4 also includes the sales based payment of JPY 500 million (EUR 3.1 million)<sup>1</sup>. 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.

EUR (in thousands)	2024 Q1 3 months	2024 Q2 3 months	2024 Q3 3 months	2024 Q4 3 months	FY 2024 12 months	FY 2023 12 months
Royalty rate	8%	8%	8%	10%		
TWYMEEG <sup>®</sup> Royalties	449	713	854	1,554 <sup>(1)</sup>	6,636	1,981
TWYMEEG <sup>®</sup> Sales based payment	-	-	-	3,066	-	-
Other	-	-	-	-	-	-
<b>Total revenue</b>	<b>449</b>	<b>713</b>	<b>854</b>	<b>4,620</b>	<b>6,636</b>	<b>1,981</b>

<sup>(1)</sup> Including a 2% royalty rate catch up from Q2 to Q3 2024 for an amount of EUR 386 thousand.



## Consolidated cash and cash equivalents

As of December 31, 2024, total consolidated cash and cash equivalents were EUR 3.7 million (USD 3.8 million)<sup>1</sup>, as compared to EUR 13.1 million as of September 30, 2024.

EUR (in thousands)	Q4 2024	Q3 2024	Q2 2024	Q1 2024	Q4 2023
Cash	3,657 (1)	13,149	2,812	2,460	2,341
Cash equivalents	-	-	-	-	-
<b>Total cash and cash equivalents</b>	<b>3,657</b>	<b>13,149</b>	<b>2,812</b>	<b>2,460</b>	<b>2,341</b>

(1) Excluding OrbiMed deposit for an amount of EUR 4.8 million (USD 5 million) that will be allocated, in Q1 2025, to the reimbursement of the IPF Partners debt as per bonds documentation

## Cash runway following the non-adoption of key financial delegations and financial risk

The non-adoption of the financial delegations at the Combined General Meeting held on February 11, 2025, and, in particular, on the issuance of new shares in redemption for ORANE, triggers an event of default under the IRIS and IPF Partners bonds agreements allowing each of them to request mandatory redemption of the bonds they hold (EUR 4.3 million and EUR 17.1 million respectively).

In this context, despite the recent restructuring of the Company's debt made possible in particular by the royalty monetization transaction with OrbiMed and based on the cash position as of December 31, 2024, amounting to EUR 3.7 million, the Company's financial outlook is severely impacted, and the situation generates significant uncertainty regarding the Company's ability to continue as a going concern. The Board of Directors and the Management are actively engaged in working on potential solutions with Poxel's creditors.

## Business update and outlook

### TWYMEEG® (Imeglimin)

- For the quarter ending December 2024, TWYMEEG® gross sales in Japan increased by 17% to JPY 2.1 billion (EUR 13 million<sup>1</sup>) over the prior quarter sales of JPY 1.8 billion (EUR 11.2 million<sup>1</sup>) as reported by Sumitomo Pharma.
- As announced on January 20, 2025, TWYMEEG® achieved JPY 5 billion (EUR 30.6 million)<sup>1</sup> net sales in Japan in Sumitomo Pharma's fiscal year 2024, making Poxel eligible for royalties equalling 10% of all TWYMEEG® net sales for 2024 and a sales-based payment of JPY 500 million (EUR 3.1 million)<sup>1</sup>. Based on the recent royalty monetization agreement with OrbiMed, these proceeds for FY 2024, net of Poxel's obligation to Merck Serono, will be directed to the



reimbursement of the bonds issuance. From 2025, Poxel expects to receive escalating double-digit royalties as well as additional sales-based payments upon achievement of contractually based sales thresholds.

- As announced on August 7, 2024, topline results obtained from the post-marketing clinical study, TWINKLE (TWYMEEG® in diabetic patients with renal impairment: A post-marketing long-term 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 has initiated 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<sup>2</sup> and expects outcome in the first half of 2025.

#### **Next Financial Press Release:**

- **2024 Full-Year Results**, on April 22, 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](http://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

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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<sup>th</sup>, 2024.