



Press Release

Poxel Provides Corporate Update and Reports Cash and Revenue for the Third Quarter and Nine Months 2023

- **TWYMEEG sales in Japan for the last quarter (July-September) grew by 28% over the prior quarter. Current trajectory, if maintained, would lead to higher TWYMEEG annual sales than Sumitomo Pharma's FY 2023 forecast¹, which would already represent a 90% increase over the prior year sales**
- **Company in active discussions with various investors and potential partners with the objective to receive additional financing and pursue the execution of its rare diseases strategy**
- **As of September 30, 2023, cash and cash equivalents were EUR 5.3 million (USD 5.6 million)²; assuming full drawdown of the existing equity-linked financing facility with IRIS, cash runway through Q2 2025**

LYON, France, November 8, 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 provided a corporate update and announced its cash position and revenue for the third quarter and the nine months ended September 30, 2023.

"We are extremely satisfied with TWYMEEG strong growth trajectory over this past quarter, with an almost 30% growth reported by our partner, Sumitomo Pharma. It is a sustained confirmation of the value of TWYMEEG to treat patients with type-2-diabetes. Also, if the current trend is maintained, we could expect to exceed Sumitomo Pharma's FY 2023 forecast, which would entitle us to higher royalties on all TWYMEEG net sales and a sales-based payment of EUR 3.4 million² sooner than expected," stated Thomas Kuhn, Chief Executive Officer of Poxel. *"We are still in active discussions with investors and potential partners as we are focused on securing additional fundings to move forward our rare diseases strategy and launch Phase 2 Proof-of-Concept (POC) studies in ALD."*

Third Quarter and Nine Months Ended September 30, 2023, Cash and Revenue

Cash

As of September 30, 2023, total cash and cash equivalents were EUR 5.3 million (USD 5.6 million), as compared to EUR 7.6 million as of June 30, 2023.

¹ As per Sumitomo Pharma FY23 forecast of JPY 4.2 billion published on May 15, 2023.

² Converted at the exchange rate as of September 30, 2023.





EUR (in thousands)	Q3 2023	Q2 2023	Q1 2023	Q4 2022
Cash	5,265	7,597	10,629	13,058
Cash equivalents	-	-	-	-
Total cash and cash equivalents*	5,265	7,597	10,629	13,058

Unaudited data

* Net financial debt (excluding IFRS 16 impacts and derivative debts) was EUR 41.4 million at the end of Q3 2023 as compared to EUR 37.7 million at the end of Q2 2023.

Based on:

- (i) this cash position on September 30, 2023,
- (ii) the full drawdown of the tranches available under the equity-linked financing with IRIS,
- (iii) the current research and development plan, excluding the initiation of Phase 2 clinical POC biomarker studies for PXL065 and PXL770 in AMN, and
- (iv) a strict control of its operating expenses,

Poxel expects that its resources will be sufficient to fund its operations and capital expenditure requirements through Q2 2025.

The full drawdown of the IRIS equity linked facility can be made subject to certain conditions described in the Company's Universal Registration Document. At the date of this press release and only based on the tranches already drawn³ or fully available⁴, the Company expects that its resources will be sufficient to fund its operations and capital expenditure requirements until January 2024.

Nine Months 2023 Revenue

Poxel reported revenues of EUR 1,619 thousand for the nine months ended September 30, 2023, as compared to EUR 286 thousand during the corresponding period in 2022.

Revenue for the first nine months of 2023 mostly reflects the JPY 253 million (EUR 1,619 thousand) of royalty revenue from Sumitomo Pharma which represents 8% of TWYMEEG net sales in Japan. Based on the current forecast, Poxel expects to receive 8% royalties on TWYMEEG net sales in Japan through the Sumitomo Pharma fiscal year 2023 (April 2023 to March 2024). 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.

³ Since March 31, 2023, 4 additional tranches have been drawn for a total amount of EUR 2,3 million.

⁴ At the date of this press release, the amount of redeemable bonds owned by IRIS is EUR 6,917,500, and the Group has the ability to drawdown EUR 82,500 under the additional tranches.



EUR (in thousands)	Sept. 2023 9 months	Q3 2023 3 months	H1 2023 6 months	Sept. 2022 9 months	Q3 2022 3 months	H1 2022 6 months
Sumitomo Pharma Agreement	1,619	664	955	286	203	83
Other	-	-	-	-	-	-
Total revenues	1,619	664	955	286	203	83

Unaudited data

Commercial Update

TWYMEEG® (Imeglimin)

- For the quarter ended September 2023, TWYMEEG gross sales in Japan increased by 28% to JPY 1.48 billion (EUR 9.4 million)² over the prior quarter sales of JPY 1.16 billion (EUR 7.4 million)⁵ as reported by Sumitomo Pharma.
- 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 Pharma's commercial efforts to leverage TWYMEEG's potential. Thanks 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 are growing strongly in Japan, and contribute to the increase in sales. These factors have resulted in a much higher increase in demand for TWYMEEG than expected by Sumitomo Pharma, and thus inventories are temporarily tight. Sumitomo Pharma has worked diligently to increase the production and secure inventory capacity to meet this increasing demand.
- For its FY 2023, Sumitomo Pharma announced a forecast for TWYMEEG of JPY 4.2 billion¹ (EUR 28.9 million)⁶ which would represent a 90% increase over FY 2022 TWYMEEG gross sales.
- For the Sumitomo Pharma FY 2023, as a conservative assumption in line with Sumitomo Pharma'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 Pharma FY 2024 (ending March 31, 2025), Poxel expects TWYMEEG net sales in Japan to reach at least JPY 5 billion (EUR 34.4 million)⁶ entitling Poxel to receive 10% royalties on all TWYMEEG net sales (on which the

⁵ Converted at the exchange rate as of June 30, 2023.

⁶ Converted at the exchange rate as of March 31, 2023.



first 8% will still be paid to Merck Serono) and a sales-based payment of JPY 500 million (EUR 3.4 million)⁶. Beyond Sumitomo Pharma FY 2024, Poxel expects to receive escalating double-digit royalties as well as additional sales-based payments upon achievement of contractually based sales thresholds.

- As per the debt restructuring agreements established with its lenders in March, positive net royalties and sales-based payments will be directed to Poxel debt reimbursement until the loans are fully repaid (which Poxel expects in Q2 2029, at the latest). After this time, subsequent net royalties and sales-based payments will revert back to Poxel.
- A Phase 4, 52-week, Open-label, Long-Term Study of Imeglimin in Japanese Type 2 Diabetic Patients with Renal Impairment is currently ongoing in Japan to strengthen TWYMEEG profile in this key subpopulation, and top line results are expected in 2024.
- For territories not covered by its agreement with Sumitomo Pharma, Poxel is having active discussions with various potential partners for Imeglimin, in several countries. Those discussions also involve India, where local companies have received approval and have launched Imeglimin, in monotherapy only. At the date of this press release, no agreement has been established, and Poxel continues to be committed to asserting its rights in connection with its assets.

Rare metabolic diseases

- In July 2023, the European Patent Office (EPO) granted Poxel a new patent for PXL065, a novel, proprietary deuterium-stabilized R-stereoisomer of pioglitazone, which describes a specific form of PXL065 with unique properties. This recently issued patent provides additional protection through 2041, with the potential for an additional 5 years through patent term extension. In 2022, Poxel had been granted the same patent for PXL065 from the US Patent Office.
- In adrenoleukodystrophy (ALD), PXL770 and PXL065 are prepared to advance, subject to additional financing, into two Phase 2a biomarker proof-of-concept (POC) clinical trials in male patients with adrenomyeloneuropathy (AMN), the most common ALD subtype. The 12-week studies will evaluate pharmacokinetics, safety and potential for efficacy based on relevant disease biomarkers, such as the effect on very long chain fatty acids (VLCFA), the characteristic plasma marker of the disease.

Corporate Update

- On July 5th, Poxel was chosen as the winner of the 2023 edition of the I-nov contest for its program in ALD. Financed by the French State via the France 2030 plan, the prize of this contest includes a grant which will contribute in part in the financing of the two phase IIa proof-of-concept clinical studies for PXL770



and PXL065, which are ready to be launched, subject to additional funding, which the Company is actively working on.

Next Financial Press Release: Fourth Quarter 2023 Cash and Revenue update, on February 15, 2024

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 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, 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 2023 is April 1, 2023, through March 31, 2024.
- **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.