



Press Release

Poxel Reports Cash and Revenue for the Full Year 2023 and Provides Corporate Update

- **TWYMEEG[®] sales continue to perform well in Japan with JPY 3.5 billion (EUR 22.4 million¹) total sales over the first 3 quarters of 2023², up +170% vs. the corresponding period in 2022. This growth trajectory is in line to meet or potentially surpass Sumitomo Pharma's FY 2023 forecast³**
- **The Company remains focused on securing additional financing to execute its strategic plan in rare diseases:**
 - **Exclusive advanced discussions with a leading investor to monetize royalties from TWYMEEG[®] (Imeglimin) sales in Japan**
 - **Advanced discussions with several potential partners for its three proprietary products: Imeglimin, PXL065 and PXL770**
- **Cost-saving plan completed end of 2023, with significant reduction in headcount to adapt resources to the Company's current needs**
- **Cash runway until March 2024, including tranches already drawn on the equity-linked financing facility with IRIS**
- **As of December 31, 2023, cash and cash equivalents were EUR 2.3 million (USD 2.6 million); Poxel generated revenue of EUR 2.0 million for FY 2023**

LYON, France, February 15, 2024 – **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 its cash position and revenue and provided a corporate update for the twelve months ended December 31, 2023.

Thomas Kuhn, Chief Executive Officer of Poxel, stated: *"We remain focused and continue to concentrate all our efforts at securing financing options, prioritizing non-dilutive solution, and partnerships. In particular, our relentless work as well as TWYMEEG[®]'s robust performance in Japan had led to the ongoing exclusive advanced discussions with a leading investor for monetizing royalties on TWYMEEG[®] sales in Japan. We've also progressed our advanced discussions – in some cases on an exclusive basis – with several potential partners for each of our three proprietary products. Our goal is still to finalize one or more of these financing options and/or partnerships by the end of the first quarter of 2024 to start as soon as possible the next chapter of Poxel in rare metabolic diseases."*

¹ Converted at the exchange rate as of December 31, 2023.

² Sumitomo Pharma fiscal year 2023 ends March 31, 2024.

³ As per Sumitomo Pharma FY2023 forecast of JPY 4.2 billion published on May 15, 2023.



Commercial Update

TWYMEEG® (Imeglimin)

- For the quarter ended December 2023, TWYMEEG® sales in Japan were of JPY 851 million (EUR 5.5 million)¹ as reported by Sumitomo Pharma.
- For its FY 2023, Sumitomo Pharma announced a forecast for TWYMEEG® of JPY 4.2 billion³ (EUR 26.9 million)¹, which would represent a 90% increase over FY 2022 TWYMEEG® gross sales. Based on this conservative assumption, 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's FY 2024 (ending March 31, 2025), Poxel expects TWYMEEG® net sales in Japan to reach JPY 5 billion (EUR 35.6 million)¹ entitling Poxel to receive 10% royalties on all TWYMEEG® net sales and a sales-based payment of JPY 500 million (EUR 3.6 million)¹. Beyond Sumitomo Pharma's FY 2024, Poxel expects to receive escalating double-digit royalties as well as additional sales-based payments upon achievement of contractually based sales thresholds.
- For territories not covered by its agreement with Sumitomo Pharma, Poxel is still in advanced ongoing discussions with various potential partners for Imeglimin.

Clinical, Manufacturing and Patent Update

TWYMEEG® (Imeglimin)

- Following the much higher increase in demand for TWYMEEG® than expected, and temporarily tight inventories, Sumitomo Pharma continues to work diligently to increase production to ensure sustained inventory capacity.
- The Long-Term, 52-week, Open-label, Phase 4 Study conducted by Sumitomo Pharma of Imeglimin in Japanese Type 2 Diabetic Patients with Renal Impairment is currently ongoing in Japan to strengthen TWYMEEG® profile in this key subpopulation. Top line results are expected in 2024.

Rare metabolic diseases

- In February 2024, the European Patent Office (EPO) granted Poxel a new patent for PXL770, a novel, proprietary direct adenosine monophosphate kinase activator, which describes the use of PXL770 in the treatment of Autosomal-dominant polycystic kidney disease (ADPKD). This issued patent provides additional protection for PXL770 through 2041, with the potential for an additional 5 years through patent term extension. End of 2023, Poxel had been granted the same patent for PXL770 from the Japan Patent Office and the obtention is currently under review in other territories, including in the US.



- 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 studies will evaluate pharmacokinetics, safety and potential for efficacy, following 12-week treatment, based on relevant disease biomarkers, such as the effect on very long chain fatty acids (VLCFA), the characteristic plasma marker of the disease.

Full-Year Cash and Revenue, ended December 31, 2023

Cash

As of December 31, 2023, total cash and cash equivalents were EUR 2.3 million (USD 2.6 million)¹, as compared to EUR 13.1 million (USD 14.0 million) as of December 31, 2022.

EUR (in thousands)	Q4 2023	Q4 2022
Cash	2,341	13,058
Cash equivalents	-	-
Total cash and cash equivalents*	2,341	13,058

Unaudited data.

¹Net financial debt (excluding IFRS 16 impacts and derivative debts) was 45.1 million euros at the end of Q4 2023 as compared to EUR 29.5 million at the end of Q4 2022.

With the priority objective of relaunching its R&D activities and executing its strategic plan in rare diseases, the Company has focused in recent months on securing additional financing, in particular non-dilutive solutions. In this context, the Company entered into exclusive negotiations with a leading investor to monetize royalties from TWYMEEG® (Imeglimin) sales in Japan. In addition, the Company is in advanced discussions – in some cases on an exclusive basis – with several potential partners for each of its three products: Imeglimin, for several countries not covered by its agreement with Sumitomo Pharma, PXL065 and PXL770.

Poxel's goal is to finalize one or more of these financing options and/or partnerships by the end of the first quarter of 2024.

Pending finalization of one or more of these agreements, and in a cautious approach given its limited financial visibility, the Company has completed a cost-saving plan in December, which includes a significant reduction in headcount, in order to adapt the Company's cost structure to its current operating needs. Key functions that enable the Company to finalize current transaction opportunities and continue its day-to-day operations have been retained, managing clinical, financial and business development activities.



Based on:

- i. its cash position on December 31, 2023,
- ii. the tranches already drawn⁴ as of the date of this press release under the equity-linked financing facility with IRIS,
- iii. no research and development expenses, and
- iv. a strict control of operating expenses,

Poxel expects that its resources, including funds available to it, will be sufficient to finance its operations and capital expenditure requirements until March 2024, by which time the Company expects to have completed one or more of its ongoing operations.

Full-Year 2023 Revenue

Poxel reported revenues of EUR 2.0 million for the year ended December 31, 2023, as compared to EUR 0.674 thousand during the corresponding period in 2022.

Revenues for 2023 mostly reflects the JPY 313 million (EUR 2.0 million) of royalty revenue from Sumitomo Pharma, which represents 8% of TWYMEEG[®] net sales in Japan. Based on its 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.

EUR (in thousands)	2023 Q1 3 months	2023 Q2 3 months	2023 Q3 3 months	2023 Q4 3 months	FY 2023 12 months	FY 2022 12 months
Sumitomo Pharma Agreement	449	506	664	362	1,981	673
Other	-	-	-	-	-	1
Total revenues	449	506	664	362	1,981	674

Unaudited data

Next Financial Press Release: 2023 Annual Results, on April 09, 2024

⁴ Since March 31, 2023, 6 additional tranches have been drawn for a total amount of EUR 3.3 million.



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 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.