Press Release

Poxel Provides a Financial Update for the First Quarter 2024 and Announces the Postponement of its 2023 Full-Year Results Release

- **TWYMEEG gross sales in Japan should exceed its FY 2023[1] guidance[2] of JPY 4.2 billion (EUR 25.7 million)[3] driven by a favourable sales trend in Japan. Sumitomo Pharma to report full year results on May 14th, 2024**
- **Company expects TWYMEEG's FY 2024[4] forecast to increase by more than 150% over the prior year sales, which would represent over JPY 10 billion (EUR 61.2 million[3]) gross sales**
- **Exclusive advanced discussions with a leading investor to monetize royalties from TWYMEEG® (Imeglimin) sales in Japan**
- **As of March 31, 2024, cash and cash equivalents were EUR 2.5 million (USD 2.7 million)[3]**
- **Cash runway until transaction closing, including tranches already drawn or fully available on the equity-linked financing facility with IRIS**

LYON, France, April 29, 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 reported its cash position, provided a financial and business update for the first quarter ended March 31, 2024, and announced the postponement of its 2023 full-year results release, in view of the expected closing of a transaction.

Thomas Kuhn, Chief Executive Officer of Poxel, stated: *"The increase in TWYMEEG gross sales recorded by our partner Sumitomo Pharma in its fiscal year 2023, has further confirmed the unique value of our asset, paving the way to a strong increase for FY 2024, which could lead to two sales-based payment and double-digit royalties in this next fiscal year. This strong momentum fully supports our efforts to secure a non-dilutive financing option, based on the monetization of royalties from TWYMEEG sales in Japan. We are particularly confident that this agreement will enable us to open the next chapter in Poxel's history, focused on the development of innovative treatments for rare metabolic diseases."*

[1] *Sumitomo Pharma fiscal year 2023 ends March 31, 2024.*
[2] As per Sumitomo Pharma FY2023 forecast of JPY 4.2 billion published on May 15, 2023.
[3] *Converted at the exchange rate on March 31, 2024.*
[4] *Sumitomo Pharma fiscal year 2023 ends March 31, 2025.*

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TWYMEEG® (Imeglimin)

Commercial Update

- For the quarter ended March 2024, TWYMEEG gross sales in Japan increased significantly over the prior quarter sales. As a result, TWYMEEG gross sales should exceed its FY 2023 guidance of JPY 4.2 billion (EUR 25.7 million)[3] driven by a favourable sales trend in Japan. Sumitomo Pharma will report full year results on May 14th, 2024.
- Poxel expects TWYMEEG's FY 2024 forecast to increase by more than 150% over the prior year sales, which would lead to annual gross sales over JPY 10 billion (EUR 61.2 million)[3]. Sumitomo Pharma will report FY2024 guidance for TWYMEEG in Japan on May 14th, 2024.
- During Sumitomo Pharma FY 2024 (ending March 31, 2025), Poxel expects TWYMEEG net sales in Japan to reach at least JPY 5 billion (EUR 30.6 million)[3] entitling Poxel to receive 10% royalties on all TWYMEEG net sales and a sales-based payment of JPY 500 million (EUR 3.1 million)[3]. Based on this FY 2024 forecast, Poxel expects that TWYMEEG net sales can also reach JPY 10 billion (EUR 61.2 million)[3] which would lead Poxel to receive 12% royalties on all TWYMEEG net sales and a second sales-based payment of JPY 1 billion (EUR 6.1 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.
- 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.
- For territories not covered by its agreement with Sumitomo Pharma, Poxel is in ongoing discussions with potential partners for Imeglimin. 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.

Clinical and Manufacturing Update

- Following the much higher increase in demand for TWYMEEG® than expected, and temporarily tight inventories, Sumitomo Pharma's diligent work has enabled to significantly increase production to ensure sustained inventory capacity and support the strong sales momentum expected in Japan.
- A Phase 4, 52-week, Open-label, Long-Term Study of Imeglimin in Japanese Type 2 Diabetic Patients with Renal Impairment conducted by Sumitomo Pharma is currently ongoing in Japan to strengthen TWYMEEG® profile in this key subpopulation. Topline results are expected in mid-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.

First Quarter 2024 Financial Update

As of March 31, 2024, cash and cash equivalents were EUR 2.5 million (USD 2.7 million)[3], as compared to EUR 2,3 million (USD 2.6 million[5]) as of December 31, 2023. Net financial debt (excluding IFRS16 impacts and derivative debts) was EUR 47.4 million as of March 31, 2024, as compared to EUR 45.6 million as of December 31, 2023.

EUR (in thousands)	**Q1 2024**	**Q4 2023**
Cash	2,460	2,341
Cash equivalents	-	-
Total cash and cash equivalents	**2,460**	**2,341**

Unaudited data

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.

[5] Converted at the exchange rate on December 31, 2023

Based on:

i. its cash position on March 31, 2024,
ii. the tranches already drawn[6] or fully available 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 maintain its operations and capital expenditure requirements until the completion of the transaction to monetize royalties from TWYMEEG® (Imeglimin) sales in Japan.

The Company therefore announces that it will postpone the publication of its 2023 Full-Year Results and will communicate its new financial calendar for 2024 as soon as this transaction will be finalized.

[6] Since March 31, 2023, 9 additional tranches have been drawn for a total amount of EUR 4.8 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.