Press Release

Poxel Reports Cash and Revenue for the Second Quarter and First Half 2023 and Provides Corporate Update

- **TWYMEEG sales in Japan for the last quarter (April-June) grew 23% over the prior quarter, in line with Sumitomo Pharma's FY 2023 forecast[1], which would represent a 90% increase over the prior year sales**
- **Company actively pursuing additional financing to initiate ALD Phase 2 Proof-of-Concept (POC) studies and execute its rare diseases strategy**
- **As of June 30, 2023, cash and cash equivalents were EUR 7.6 million (USD 8.2 million)[2]; cash runway through Q2 2025, assuming full drawdown of the existing equity-linked financing facility with IRIS**

LYON, France, August 30, 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 second quarter and first half of 2023.

Thomas Kuhn, Chief Executive Officer of Poxel, stated: *"During this past semester, we have diligently worked to improve our financial flexibility, and this has been a success through the combination of the restructuring of our existing debt obligations and the setup of a new equity-linked financing with IRIS. Now that our financial visibility extends through Q2 2025, we can concentrate on our strategy, which includes the launch of Phase 2 proof-of-concept studies in rare diseases, starting with adrenoleukodystrophy, subject to additional financing. The recent trajectory of TWYMEEG sales has also been key in the restructuring of our debt. Sumitomo Pharma, our partner commercializing TWYMEEG in Japan, recently reported gross sales for its Q1 2023, which shows a 23% increase over the prior quarter, and gives us confidence in the ability to meet Sumitomo Pharma's FY 2023 forecast."*

[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 June 30, 2023.

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Commercial Update

TWYMEEG® (Imeglimin)

- For the quarter ended June 2023, TWYMEEG gross sales in Japan increased 23% to JPY 1.16 billion (EUR 7.4 million)[2] over the prior quarter sales of JPY 0.9 billion (EUR 6.2 million)[2] as reported by Sumitomo Pharma (Sumitomo).
- 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'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 contributes to the increase in sales. These factors have resulted in a much higher increase in demand for TWYMEEG than expected by Sumitomo, and thus inventories are temporarily tight. Sumitomo is working diligently to increase the production and secure inventory capacity to meet this increasing demand.
- For its FY 2023, Sumitomo announced a forecast for TWYMEEG of JPY 4.2 billion[1] (EUR 28.9 million)[3] which would represent a 90% increase over FY 2022 TWYMEEG gross sales.
- For the Sumitomo FY 2023, as a conservative assumption in line with Sumitomo'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 FY 2024 (ending March 31, 2025), Poxel expects TWYMEEG net sales in Japan to reach at least JPY 5 billion (EUR 34.4 million)[3] entitling Poxel to receive 10% royalties on all TWYMEEG net sales (on which the first 8% will still be paid to Merck Serono) and a sales-based payment of JPY 500 million (EUR 3.4 million)[3]. Beyond Sumitomo 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.
- As part of the Sumitomo's ongoing efforts to communicate TWYMEEG's unique mechanism of action and safety profile, 9 abstracts based on Imeglimin Phase 2b and Phase 3 clinical trials were accepted for oral presentations at the 66th

[3] Converted at the exchange rate as of March 31, 2023.

Annual Meeting of the Japanese Diabetes Society (JDS), held in Kagoshima, Japan, May 11-13, 2023.

- 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, Poxel is in ongoing discussions with various potential partners for Imeglimin, including in India, where local companies have recently received approval and have launched 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.

Rare metabolic diseases

- In adrenoleukodystrophy (ALD), PXL770 and PXL065 are prepared to advance, subject to additional financing, into two Phase 2 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.
- In line with its mission, Poxel aims to bring therapeutic options to treat ALD, and supported the Alex Leukodystrophy Charity during their Community Weekend, which took place from April 28th to May 1st in Birmingham, England. This event brings together leukodystrophy sufferers and their families, alongside doctors, researchers and scientists from around the world to discuss leukodystrophies.
- On June 23rd and 24th, Poxel participated virtually at the ULF (United Leukodystrophy Foundation) Scientific Symposium and Family Conference in Itasca, Illinois, USA. Sophie Bozec, Poxel Senior Vice President, R&D Pharmacology and Scientific Communication presented Poxel's status and plans for PXL770 and for the deuterium-modified TZD platform, using PXL065, based on robust scientific rationale and a complete preclinical package.

Corporate Update

- On June 21st, the Company held its ordinary annual and extraordinary general meeting of shareholders. The shareholders approved all the resolutions that were recommended by the Board of Directors, including the renewal of Mr. Khoso Baluch, Mr. Thomas Kuhn et Ms. Pascale Boissel as Board members.
- During the first semester, the Company pursued its corporate savings plan initiated in 2022 aiming at adapting the Company's resources to the current clinical development plan while preserving critical resources and

competencies. At the date of this press release, there are 16 employees at Poxel compared to 37 at the end of December 2022.

- At the end of June, Elizabeth Woo, Senior Vice President, Investor Relations & Communication, left the Company to pursue other endeavours.

Significant Events after the Period

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[4] 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.

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.

Second Quarter and First Half 2023 Cash and Cash equivalents

As of June 30, 2023, cash and cash equivalents were EUR 7.6 million (USD 8.2 million), as compared to EUR 13.1 million (USD 14.0 million) as of December 31, 2022.

Net financial debt (excluding IFRS16 impacts and derivative debts) was EUR 37.7 million as of June 30, 2023, as compared to EUR 29.5 million as of December 31, 2022.

EUR (in thousands)	**Q2 2023**	**Q4 2022**
Cash	7,599	13,058
Cash equivalents	-	-
Total cash and cash equivalents	**7,599**	**13,058**

Unaudited data

On March 23, 2023, the Company finalized agreements with its lenders to restructure its existing debt facility and established a new equity-linked financing with IRIS, including an initial drawdown of EUR 3.5 million.

[4] Up to 45% of the estimated eligible costs.

Based on:

(i) this cash position on June 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 drawn[5] or fully available[6], the Company expects that its resources will be sufficient to fund its operations and capital expenditure requirements until January 2024.

Second Quarter and First Half 2023 Revenue

Poxel reported revenue of EUR 955 thousand for the six months ended June 30, 2023, as compared to EUR 83 thousand revenue during the corresponding period in 2022.

Revenue for the first half of 2023 reflects JPY 148 million (EUR 955 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 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)	**Q1 2023**	**Q2 2023**	**H1 2023**	**Q1 2022**	**Q2 2022**	**H1 2022**
	3 months	**3 months**	**6 months**	**3 months**	**3 months**	**6 months**
Sumitomo Pharma Agreement	449	506	955	32	51	83
Other	-	-	-	-		
Total revenues	**449**	**506**	**955**	**32**	**51**	**83**

Unaudited data

[5] Since March 31, 2023, 2 additional tranches of EUR 600,000 each have been drawn in May and July.
[6] At the date of this press release, the amount of redeemable bonds owned by IRIS is EUR 5,980,000, and the Group has the ability to drawdown EUR 1 020 000 under the additional tranches.

Planned Presentation and Participation at the Following Upcoming Event

- 23rd edition of the European MidCap Event, Paris, September 21-22

Next Financial Press Release: 2023 First Half Results, on September 26, 2023

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 2022 is April 1, 2022 through March 31, 2023.
- **TWYMEEG royalties:** As per the Sumitomo's agreement, Poxel is entitled to receive royalties from the sales of TWYMEEG (Imeglimin) in Japan
    - TWYMEEG royalties are calculated on net sales, while Sumitomo Pharma communicates only TWYMEEG gross sales.
    - Poxel entitled to receive escalating royalties of 8-18% on TWYMEEG net sales from Sumitomo Pharma.
- **Positive net royalties**: refers to royalties Poxel receives from TWYMEEG net sales after paying Merck Serono the first 8%, once Poxel starts to receive 10% royalties upon TWYMEEG net sales exceeding JPY 5 billion in a fiscal year.