Press Release

Poxel Reports Financial Results for First Half 2023 and Provides a 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**

The management team will host webcast conference calls on Tuesday, September 26 at:

- **1:00 pm CEST, Paris time** (7:00 am ET) in **French** and
- **8:30 am ET, New York time** (2:30 pm CEST) in **English**.

A presentation will be available after the event on Poxel's website in the Investor section.

To register for the webcast in **French**: click here

To register for the webcast in **English:** click here

LYON, France, September 26, 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 announced its financial results for the period ended June 30, 2023 and provided a corporate update.

Thomas Kuhn, Chief Executive Officer of Poxel, stated: *"During the first semester of 2023, TWYMEEG strong sales momentum has been confirmed, with a total growth sales amount for the year 2022 that exceeded Sumitomo Pharma's forecast by 20%, and a 23% increase for the first quarter of Sumitomo Pharma fiscal year. This trend has been key to the success of our recent debt restructuring with our lenders. Our debt restructuring, along with the potential full drawdown of a new equity-linked financing with IRIS, extended our cash runway through Q2 2025. We are now concentrating our*

[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.

resources to actively work on other financing options to allow us to pursue our strategy in rare diseases, which includes the launch of Phase 2 proof-of-concept studies in this area, starting with adrenoleukodystrophy."

First Half 2023 Key Events

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.
- 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 is working 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 billion[1] (EUR 28.9 million)[3] 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)[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 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,

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

at the latest). After this time, subsequent net royalties and sales-based payments will revert back to Poxel.

- As part of the Sumitomo Pharma'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 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 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 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 15 employees at Poxel compared to 37 at the end of December 2022.

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.

First Half 2023 Financial Results (IFRS standards)

Revenue

EUR (in thousands)	**H1 2023** **6 months**	**H1 2022** **6 months**
Sumitomo Pharma Agreement	955	83
Other	-	-
Total revenues	**955**	**83**

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.

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

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 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.

Income Statement

EUR (in thousands)	**2023 6 months**	**2022 6 months**
Revenue	955	83
Cost of sales	(955)	(83)
Gross margin	-	-
Research and development expenses*	(2,772)	(7,882)
Depreciation and amortization of intangible assets	(16,572)	-
General and administrative expenses	(4,278)	(4,295)
Operating gain (loss)	(23,274)	(12,178)
Financial income (loss)	(2,968)	(1,223)
Income tax	-	-
Net income (loss)	**(26,243)**	**(13,401)**

**Net of R&D tax credit.*

In the first half of 2023, the amount of amortization and depreciation of intangible assets includes exclusively the impairment of PXL065 for EUR 16.6 million. This impairment aims to best reflect the current value of PXL065, taking into account the Company's need to obtain additional financing to pursue its development plan in NASH or ALD, its current market capitalization and the macroeconomic context in which it operates. However, the Company considers that the potential of PXL065 in its targeted indications remains unchanged and very promising. Depending on the evolution of ongoing discussions for a partnership for PXL065, the Company will reassess the value of the PXL065 asset at the end of the second half of 2023.

R&D expenses totaled EUR 2.8 million for the first half of 2023, as compared to EUR 7.9 million for the corresponding period in 2022. The 2023 decrease primarily reflects the end, in 2022, of the Phase 2 DESTINY study evaluating PXL065 in NASH.

R&D expenses are net of the R&D Tax Credit (CIR) that resulted in an income of EUR 0.3 million for the first half of 2023 as compared to EUR 0.9 million for the corresponding period in 2022.

General and administrative expenses totaled EUR 4.3 million for the first half of 2023, unchanged compared to the corresponding period in 2022.

The financial loss amounted to EUR 3.0 million for the first half of 2023, compared to EUR 1.2 million during the first half of 2022. It primarily reflected the interests attached to the Company indebtedness.

The net result for the financial period ending June 30, 2023, was a net loss of EUR 26.2 million, as compared to a net loss of EUR 13.4 million in the corresponding period in 2022.

First Half 2023 Cash and Cash equivalent

EUR (in thousands)	**H1 2023**	**Q4 2022**
Cash	7,597	13,058
Cash equivalents	-	-
Total cash and cash equivalents	**7,597**	**13,058**

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.

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.

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.

Planned Presentations and Participations at the Following Upcoming Events

- 12th International Meeting on AMPK, October 5 (virtual)
- 7th Annual H.C. Wainwright NASH Investor Conference, October 24 (virtual)
- Healthtech Innovation Days (HTID), HealthTech For Care, October 24-25 (in Paris and virtual)

Next Financial Press Release: Third Quarter 2023 Results and Corporate Update, on November 8, 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

[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 5,545,000, and the Group has the ability to drawdown EUR 1,155,000 under the additional tranches.

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 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.