Press Release

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

- **TWYMEEG sales in Japan for Sumitomo Pharma Fiscal Year 2022[1] exceeded guidance[2] by more than 20%, and TWYMEEG's FY 2023 forecast[3] from Sumitomo Pharma would represent a 90% increase over the prior year sales**
- **Cash runway extended through Q2 2025 through debt restructuring and assuming full drawdown of the equity-linked financing facility with IRIS**
- **Company actively pursuing additional financing to initiate adrenoleukodystrophy (ALD) Phase 2 Proof-of-Concept (POC) studies**
- **As of March 31, 2023, cash and cash equivalents were EUR 10.6 million (USD 11.6 million)[4]**

LYON, France, May 17, 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 first quarter ended March 31, 2023.

Thomas Kuhn, Chief Executive Officer of Poxel, stated: "*This quarter we successfully restructured our debt obligations and increased our financial flexibility with a new equity-linked financing with IRIS. Together these actions significantly extend our financial visibility through Q2 2025. Our lenders agreed to postpone initiation of repayments until Q1 2025, based on future potential royalties from increasing TWYMEEG net sales which will be directed towards debt repayments. Sumitomo Pharma, our partner commercializing TWYMEEG in Japan, recently reported the total sales for their fiscal year 2022, which significantly exceeded the forecast they had just increased by more than 20% a few months before. We are of course extremely pleased with this trajectory that confirms the value of TWYMEEG and gives us confidence in the timing of future expected positive royalties and sales-based payments. This also allows us to fully dedicate ourselves to our strategy, including the launch of Phase 2 proof-of-concept studies in adrenoleukodystrophy, pending additional financing. We continue to believe that our strategy in rare diseases has great potential for value creation.*"

[1] Sumitomo Pharma fiscal year 2022 ends March 31, 2023.
[2] Sumitomo increased its FY2022 forecast to JPY 1.8 billion from JPY 1.5 billion on January 31, 2023.
[3] As per Sumitomo Pharma FY23 forecast of JPY 4.2 billion published on May 15, 2023.
[4] Converted at the exchange rate as of March 31, 2023.

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Corporate Update

- On March 23rd, the Company announced that it had restructured its existing debt with its lenders, IPF and the banks that are part of the French Government Guarantee Loan (PGE Loan). In both agreements, amortization payments under the existing debt facility have been postponed and will reinitiate when the Company starts receiving positive net royalty flows from TWYMEEG® (Imeglimin) sales in Japan. Based on the conservative forecast agreed upon by the Company and its lenders, amortization payments would be postponed until Q1 2025. During Sumitomo Pharma's (Sumitomo) fiscal year (FY) 2024 (ending March 31, 2025), Poxel expects TWYMEEG net sales in Japan to reach at least JPY 5 billion (EUR 34.4 million)[4], entitling Poxel to receive 10% royalties on all TWYMEEG net sales and a sales-based payment of JPY 500 million (EUR 3.4 million)[4]. Positive net royalties and sales-based payments will be directed to the debt reimbursement until the loans are fully repaid, which the Company expects in Q2 2029, at the latest. After this time, subsequent net royalties and sales-based payments will revert back to the Company. In addition to the postponement of debt repayments mentioned above, the Company and IPF have agreed to new financial covenants[5].

- Concurrent with this debt restructuring, the Company entered into a new equity-linked financing arrangement with IRIS in the form of bonds redeemable for new or existing shares, in order to provide additional liquidity and flexibility intended to support its ongoing regulatory and development activities, as well as general corporate purposes. An initial amount of EUR 3.5 million was drawn down, and the Company has the option, at its sole discretion subject to certain condition precedent, to draw additional tranches up to the remaining EUR 11.5 million (for a total of EUR 15 million) over 2 years[6]. Upon conversion of the equity-linked instruments, IRIS will be issued Poxel shares to be created from the Company's authorized capital and/or will receive existing ordinary shares of the Company and is expected to sell these shares on the market or in block trades.

- As part of refocusing its activities, the Company reviewed the organization of its Board of Directors and decided to reduce the size of the Board. Since March 31st, Poxel's Board of Directors is comprised of 4 members: Khoso Baluch as Chairman of the Board, Thomas Kuhn as CEO of Poxel, Pascale Boissel and Richard Kender as independent members. IPF remains an observer on the Board.

[5] New covenants require that the Company maintain: i) a minimum cash position between EUR 1 million and EUR 9 million, ii) a gearing ratio, as measured by total net debt to the market capitalization value of the Company, at a level lower than 150% (vs 50% initially), The complete details and conditions of the debt restructuring agreement are presented on the dedicated press release issued on March 23, 2023 and in the Company's 2022 Universal registration Document.
[6] The drawdown of additional tranches will be subject only to a maximum cumulative outstanding amount of redeemable bonds owned by IRIS at any time not to exceed EUR 7.0 million.

Commercial Update

TWYMEEG® (Imeglimin)

- For the quarter ended March 2023, TWYMEEG gross sales in Japan increased 23% to JPY 0.9 billion (EUR 6.2 million)[4] over the prior quarter sales of JPY 0.8 billion (EUR 5.5 million)[4] as reported by Sumitomo. As a result, for Sumitomo's FY 2022, TWYMEEG gross sales reached JPY 2.2 billion (EUR 15.0 million)[4], exceeding Sumitomo's most recent FY 2022 forecast[2] by 22%.
- 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. Due 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 is growing strongly in Japan. 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 capacity over the summer.
- For its FY 2023, Sumitomo announced a forecast for TWYMEEG of JPY 4.2 billion[3] (EUR 28.9 million)[4] 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)[4] entitling Poxel to receive 10% royalties on all TWYMEEG net sales and a sales-based payment of JPY 500 million (EUR 3.4 million)[4]. 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 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 Annual Meeting of the Japanese Diabetes Society (JDS), held in Kagoshima, Japan, May 11-13, 2023.
- 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 a Phase 2 biomarker proof-of-concept (POC) clinical trials in male patients with adrenomyeloneuropathy (AMN), the most common ALD subtype. The 12-week study 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.
- The European Commission granted orphan drug designation (ODD) for PXL770 and PXL065 for the treatment of ALD. The U.S. Food and Drug Administration (FDA) has previously granted ODD and Fast Track Designation to both PXL770 and PXL065 for the treatment of ALD.
- Preclinical study results in autosomal dominant polycystic kidney disease (ADPKD) for PXL770 that support Phase 2 development in this indication were published in the life sciences journal, *Kidney International*. To access the online publication, please use the following link: A novel direct adenosine monophosphate kinase activator ameliorates disease progression in preclinical models of Autosomal Dominant Polycystic Kidney Disease. (kidney-international.org)

NASH

- Positive results for DESTINY-1 (Deuterium-stabilized R-pioglitazone [PXL065] Efficacy and Safety Trial In NASH), a 36-week dose-ranging Phase 2 trial, were published in the *Journal of Hepatology*. The online publication can be accessed with the following link: Evaluation of PXL065 – Deuterium-Stabilized (R)-Pioglitazone in NASH Patients: a Phase 2 randomized placebo-controlled trial (DESTINY-1) - Journal of Hepatology (journal-of-hepatology.eu)

Significant Event after the Period

- At the end of April, Noah Beerman, Executive Vice President, Business Development and President of U.S. Operations, and David Moller, Chief Scientific Officer, left the Company to pursue other endeavours.

First Quarter 2023 Financial Update

As of March 31, 2023, cash and cash equivalents were EUR 10.6 million (USD 11.6 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 34.8 million as of March 31, 2023, as compared to EUR 29.5 million as of December 31, 2022.

EUR (in thousands)	Q1 2023	Q4 2022
Cash	10,629	13,058
Cash equivalents	-	-
Total cash and cash equivalents	**10,629**	**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.

Based on (i) this cash position on March 31, 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.

First Quarter 2023 Revenue

Poxel reported EUR 449 thousand revenue for the quarter ended March 31, 2023, as compared to 32 thousand revenue during the corresponding period in 2022.

Revenue for the first quarter of 2023 reflects JPY 67.0 million (EUR 449 thousand) of royalty revenue from Sumitomo, 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[2]. 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	Q1 2022
	3 months	3 months
Sumitomo Pharma Agreement	449	32
Other	-	-
Total revenues	**449**	**32**

Unaudited data

Planned Presentation and Participation at the Following Upcoming Event

- 2023 ULF Family Conference, Itasca, Illinois, USA, June 23-24, 2023

Next Financial Press Release: 2023 Second Quarter Financial Update, on August 30, 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.