Press Release

Poxel Reports Financial Results for Full Year 2023 and Provides Corporate Update

- **Agreement with OrbiMed to monetize a portion of TWYMEEG® Royalties for USD 50 million in the form of bonds issuance**
- **In return OrbiMed to obtain the royalties received by Poxel from sales by Sumitomo Pharma of TWYMEEG® in Japan for a total amount of USD 100 million**
- **Proceeds from the OrbiMed's bonds issuance will be used to reduce the Company's debt towards IPF Partners and the PGE[1] banks and to support its strategic plan in rare diseases, while pursuing partnership discussions for its products**
- **Following the non-dilutive financing agreement with OrbiMed, cash runway extension until end of 2025, including** the full residual drawdown of the equity-linked financing facility put in place with IRIS

The management team will host webinars **today; October 3, 2024**, at:
- **6:00 pm CEST, Paris time** (12:00 pm ET) in **French** and
- **1:15 pm ET, New York time** (7:15 pm CEST) in **English**.

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

To register for the webinar in **French**:
https://app.livestorm.co/newcap-1/poxel-presentation-des-resultats-financiers-pour-lannee-2023?type=detailed

To register for the webinar in **English:**
https://app.livestorm.co/newcap-1/poxel-presentation-of-financial-results-for-full-year-2023?type=detailed

LYON, France, October 3, 2024 – POXEL SA (Euronext: POXEL - FR0012432516), a clinical stage biopharmaceutical company developing innovative treatments for serious chronic diseases with metabolic pathophysiology, including non-alcoholic steatohepatitis (MASH[2]) and rare metabolic disorders, today announced its results for the year ended December 31, 2023, and provided a corporate update.

"With the royalty monetization agreement concluded with OrbiMed, we are now focused on the plans for each of our products. First, as we recovered the rights for countries, other than Japan, covered under the agreement with Sumitomo Pharma,

[1] *State-guaranteed loan in response to the health crisis in 2020*
[2] *Metabolic dysfunction-associated steatohepatitis also called NASH.*

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we have already engaged in partnering discussions to develop and market Imeglimin in China, the world's second-largest type 2 diabetes market, and other regions where Imeglimin can potentially be quickly developed and approved. We are also looking forward to the results of the discussions by Sumitomo Pharma with the regulatory authorities in Japan on revising TWYMEEG® package insert for type 2 diabetic patients with renal impairment, anticipated in FY 2024[3]. For PXL770 and PXL065, we aim to finalize discussions with several potential partners before deciding on our investment decisions and development strategies," stated ***Thomas Kuhn, Chief Executive Officer of Poxel.***

TWYMEEG® (Imeglimin)

- For the quarter ended June 2024, TWYMEEG® gross sales in Japan increased by 62% to JPY 1.7 billion (EUR 10.1 million)[4] over the prior quarter sales of JPY 1.1 billion (EUR 6.6 million)[5] as reported by Sumitomo Pharma.
- For its FY 2024[3], Sumitomo Pharma forecasts[6] gross sales for TWYMEEG® of JPY 11.3 billion (EUR 69.1 million)[2] which would represent a 150% increase over FY 2023 TWYMEEG® gross sales.

- During Sumitomo Pharma FY 2024[3], Poxel expects TWYMEEG® net sales in Japan to reach at least JPY 5 billion (EUR 31.3 million)[4] entitling Poxel to receive 10% royalties on all TWYMEEG® net sales and a sales-based payment of JPY 500 million (EUR 3.1 million)[4]. Based on this FY 2024 forecast, TWYMEEG® net sales could also reach JPY 10 billion (EUR 62.6 million)[4] entitling Poxel to receive 12% royalties on all TWYMEEG® net sales and a second sales-based payment of JPY 1 billion (EUR 6.3 million)[4]. Based on the recent royalty monetization agreement with OrbiMed, these proceeds for FY2024 will go the reimbursement of the bonds issuance. 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 announced on August 7, 2024, topline results obtained from the post-marketing clinical study, TWINKLE (**TW**YMEEG® in d**i**abetic patients with re**n**al impairment: A post-mar**k**eting **l**ong-t**e**rm study) conducted by Sumitomo Pharma in Japanese type 2 diabetic patients with renal impairment confirmed TWYMEEG®'s safety and tolerability profile, which is consistent with prior clinical studies in the general type 2 diabetes population. Based on these results, Sumitomo Pharma is planning to conduct discussions with the regulatory authorities in Japan during its FY 2024[3], on revising TWYMEEG® package insert for patients with renal impairment with eGFR (estimated glomerular filtration rate) less than 45 ml/min/1.73m².

[3] *Sumitomo Pharma fiscal year 2024 ends March 31, 2025*
[4] *Converted at the exchange rate on October 2, 2024*
[5] *Converted at the exchange rate on March 31, 2024*
[6] *As per Sumitomo Pharma FY2024 forecast published on May 14, 2024*

- In parallel of the non-dilutive financing agreement with OrbiMed, Poxel recovered the Imeglimin rights for Asian countries other than Japan[7] from Sumitomo Pharma[8]. The Company has already initiated discussions to develop and market Imeglimin in China, the world's second largest type 2 diabetes market.

Royalty monetization agreement based on TWYMEEG® sales with OrbiMed, and concurrent debt restructuring with IPF Partners and PGE banks[9]

- Under the terms of the agreement, Poxel received a gross upfront payment of USD 50 million from the OrbiMed funds in exchange for an issuance of its bonds in the same aggregate amount. From such proceeds, a deposit of USD 7.5 million has been made by the Company into a deposit account, from which USD 1.25 million will be withdrawn quarterly and paid in partial repayment of the bonds issued to OrbiMed, until net sales of TWYMEEG® reach JPY 5 billion (USD 31.3 million[4]), at which point OrbiMed will begin to receive sales-based payments and royalties (anticipated in early 2025, based on the expected achievement of this sales threshold by the end of 2024[3]). The residual amount of the deposit will then be available to the Company, in addition to the USD 42.5 million deposit received upon signature of the agreement.

- For the bonds issued by Poxel, the OrbiMed funds will receive (i) royalties payable by Sumitomo Pharma on net sales of TWYMEEG® in Japan, net of Poxel's obligation to Merck Serono, (ii) sales-based payments due by Sumitomo Pharma in connection with the commercialization of TWYMEEG® in Japan, and (iii) a portion of the cash flows received by the Company, in the event of partnership for the development and commercialization of Imeglimin in Asian countries other than Japan[7].

- The agreement will expire, and the bonds deemed repaid once OrbiMed receives a capped return equivalent to 2 times its investment, i.e. USD 100 million, plus specified expenses, if any. Upon such repayment, Poxel will regain full rights to TWYMEEG® royalties in Japan and to any sales-based commercial payments and will use the majority of these proceeds to repay the outstanding amount owed to IPF Partners.

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[7] *China, South Korea, Taiwan, Indonesia, Vietnam, Thailand, Malaysia, The Philippines, Singapore, Republic of the Union of Myanmar, Kingdom of Cambodia and Lao People's Democratic Republic.*
[8] *In accordance with the Sumitomo Pharma license agreement, Poxel is entitled to receive escalating royalties of 8 - 18% on net sales of TWYMEEG®*
[9] *For more information: https://www.poxelpharma.com/en_us/investors/news-events/press-releases/detail/269/poxel-announces-agreement-with-orbimed-to-monetize-a*

- Part of the bonds issuance amount from this transaction was used to reduce significantly the Company's debt towards IPF Partners and the PGE banks:
  - (i) EUR 23.7 million for partial repayment of IPF debt, reducing it to EUR 12.3 million; and
  - (ii) EUR 2.8 million for partial repayment of the debt to the banks that granted the PGE Loan, reducing it to EUR 3 million.

  Consequently, the Company amended its agreements respectively with IPF Partners and the banks that granted a PGE loan for the repayment of the outstanding principal of each of these debts.

Financial Statements for Full Year 2023 (IFRS Standards)

Income statement

EUR (in thousands)	**FY 2023 12 months**	**FY 2022 12 months**
Revenue	1,981	674
Cost of sales	(1,980)	(672)
Gross margin	1	2
Net research and development expenses*	(3,823)	(12,449)
Depreciation and amortization of intangible assets	(16,572)	
General and administrative expenses	(8,370)	(9,443)
Operating income (loss)	(28,764)	(21,890)
Financial income (expenses)	(6,325)	(9,509)
Income tax	(2)	(2)
Net income (loss)	**(35,090)**	**(31,398)**

**Net of R&D tax credit.*
The audit procedures are ongoing.

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.

Cost of sales amounted to EUR 1.980 million, corresponding to the 8% royalties on net sales of Imeglimin in Japan due to Merck Serono, as part of the Merck Serono license agreement.

R&D expenses totaled EUR 3.8 million in 2023, as compared to EUR 12.4 million in 2022. The 2023 decrease primarily reflects the end, in 2022, of the positive Phase 2 DESTINY study evaluating PXL065 in MASH.

R&D costs are net of the R&D Tax Credit (CIR) and other subsidies that resulted in income of EUR 0.6 million in 2023, as compared to EUR 1.5 million in 2022.

As presented in the Company's half-yearly financial results 2023, the amount of amortization and depreciation of intangible assets includes exclusively the impairment of PXL065 for EUR 16.6 million. This impairment translates the Company's need to obtain additional financing to pursue its development plan in MASH 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.

General and administrative expenses totaled EUR 8.4 million in 2023, as compared to EUR 9.4 million in 2022.

The financial loss amounted to EUR 6.3 million in 2023, as compared to a loss of EUR 9.5 million in 2022. It primarily reflects the interests attached to the Company indebtedness.

The net result for the financial period ending December 31, 2023, was a net loss of EUR 35.1 million, as compared to a net loss of EUR 31.4 million in 2022.

Cash

Following the non-dilutive financing agreement with OrbiMed, and according to Poxel's current forecasts, including in particular:

(i) The Company's cash position estimated, as of August 31st, 2024, at EUR 2,9 million
(ii) the net upfront of USD 42.5 million (EUR 38,1 million[4]) from the monetization of royalties from TWYMEEG® sales;
(iii) the partial redemption of the IPF Partners bond loan and the PGE loans for a total amount of EUR 26,5 million
(iv) the advisory fees linked to the transaction
(v) the full residual drawdown of the equity-linked financing facility put in place with IRIS[10];and
(vi) the anticipated business plan including strict control of its operating expenses;

[10] *Since March 31, 2023, 14 additional tranches have been drawn down for a total of EUR 7.3 million. 6 tranches are currently secured for a total of EUR 3 million. and an additional amount of 1.2 million euros could be drawn down by the Company depending on the liquidity and exposure conditions under the contract..*

the Company expects that its resources will be sufficient to finance its operations and capital expenditures until the end of 2025.

2023 Universal Registration Document

The Company will make its 2023 Universal Registration Document in French available to the public and file it with the Autorité des marchés financiers no later than October 11, 2024. A translation in English will be available later on the Company's website.

Planned Presentations and Participation at the Following Upcoming Events:
H.C. Wainwright 8th Annual MASH Virtual Conference, October 7, 2024 (virtual)

- Thomas Kuhn, CEO, will be available for one-on-one meetings.

Bio Europe, November 4 – 6th 24 (in-person)

- Tejdeep Bawa, Head of Business Development, will be available for one-on-one in-person meetings.

Next Financial Press Releases:
- 2024 Third Quarter Financial Update, on November 6, 2024
- 2024 First Half Results, on December 9, 2024

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. 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 from 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
    - 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.