Press Release

Poxel Reports Cash and Revenue for the Full Year 2022 and Provides Corporate Update

- **TWYMEEG® (Imeglimin) recent growth trajectory confirmed with a 90% increase in sales in Japan over the prior quarter, leading to a 20% increase of the fiscal year 2022[1] forecast[2]**
- **Phase 2 NASH Trial (DESTINY-1) for PXL065 met its primary efficacy endpoint for liver fat content reduction at 36 weeks for all doses**
- **The Company is in advanced discussions with its lenders to restructure its debt and further extend its cash runway by aligning debt repayments with future net positive TWYMEEG royalty flows. The Company has obtained a standstill of its current debt obligations from IPF Partners until March 31, 2023**
- **As of December 31, 2022, cash and cash equivalents were EUR 13.1 million (USD 14 million)[3]; Revenue of EUR 0.674 million for FY2022**

LYON, France, February 15, 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 cash position and revenue and provided a corporate update for the twelve months ended December 31, 2022.

Thomas Kuhn, Chief Executive Officer of Poxel, stated: *"We are very pleased with the most recent figures of TWYMEEG sales in Japan. These strong sales results support the trend we have observed since the end of the first year of commercialization restrictions, and above all, we believe that TWYMEEG's benefit to type 2 diabetes patients is recognized more and more among prescribing doctors. We expect this royalty stream from TWYMEEG sales to continue to grow and generate significant revenue for Poxel and we have reached a preliminary agreement with IPF to align the debt repayments with future net positive TWYMEEG royalty flows. We are actively working to finalize our debt restructuring in the coming weeks. We are concurrently working to secure additional financing to launch our POC studies for PXL770 and PXL065 in ALD to start the next chapter of Poxel's strategic focus in rare metabolic diseases."*

[1] Sumitomo Pharma fiscal year 2022 ends March 31, 2023.
[2] As per Sumitomo Pharma forecast published on January 31, 2023.
[3] Currency exchange rate at December 31, 2022.

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Commercial Update

TWYMEEG® (Imeglimin)

- For the quarter ended December 2022, TWYMEEG sales[4] in Japan increased 90% to JPY 0.8 billion (EUR 5.5 million)[3] over the prior quarter sales of JPY 0.4 billion (EUR 2.9 million)[3] as reported by Sumitomo Pharma (Sumitomo).
- The recent acceleration in sales reflects both 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 in combination with other treatments, such as DPP4i's, which are the most prescribed treatments for Japanese Type-2-Diabetes patients, and as monotherapy.
- Based on sales trends and cumulative TWYMEEG sales of JPY 1.3 billion for the first nine months, Sumitomo has increased its fiscal year 2022[1] forecast by 20% to JPY 1.8 billion[2] (EUR 12.8 million)[3].
- For the Sumitomo fiscal year 2023 (ending March 31, 2024), as a conservative assumption 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.
- Before the end of Sumitomo fiscal year 2024 (ending March 31, 2025), Poxel expects TWYMEEG net sales in Japan to reach JPY 5 billion (EUR 35.6 million)[4] entitling Poxel to receive 10% royalties on all TWYMEEG net sales and a sales-based payment of JPY 500 million (EUR 3.6 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.
- 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.

Clinical Updates

NASH

- Positive topline results were announced for the Phase 2 trial for the treatment of NASH (DESTINY-1) for PXL065 stating that the primary efficacy endpoint was met. PXL065-treated patients achieved statistically significant improvements in the relative decrease in liver fat content measured by magnetic resonance

[4] Sumitomo Pharma reports gross sales

imaging estimated proton density fat fraction (MRI-PDFF) at 36-weeks for all doses. Histology findings from paired liver biopsies showed strong improvement in fibrosis without worsening of NASH, consistent with dose-dependent reduction of all biomarkers related to fibrinogenesis and fibrosis risk scores. Additional dose-dependent benefits on glucose control and indices of insulin sensitivity were also observed. PXL065 was observed to be safe and well tolerated with no dose-dependent increase in body weight and no increased lower extremity edema vs. placebo. The safety profile is consistent with reduced PPARγ-mediated side effects vs. published results of pioglitazone.

Rare metabolic diseases

- In adrenoleukodystrophy (ALD), PXL770 is prepared to advance into a Phase 2a biomarker proof-of-concept (POC) clinical trial 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. Considering the DESTINY-1 results for PXL065 in NASH, which validated the deuterium-modified thiazolidinedione (TZD) platform, a second identical study is planned to assess the potential of the deuterium-modified TZD platform with PXL065 in ALD. Both ALD studies are poised to initiate, subject to additional financing.
- The European Commission granted orphan drug designation (ODD) for PXL770 and PXL065 for the treatment of adrenoleukodystrophy (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.
- PXL770 was granted ODD by the U.S. FDA for the treatment of patients with autosomal-dominant polycystic kidney disease (ADPKD).

Corporate Update & Significant Events after the Period

- The Company aims to restructure its debt and further extend its cash runway and has recently entered into a memorandum of understanding with IPF Partners and is in advanced discussions with the banks that provided the French Government Guarantee Loan (PGE Loan), obtained in 2020 in the context of the COVID-19 pandemic, for a debt restructuring. The Company expects to reschedule and align debt repayments with future net positive TWYMEEG royalty flows expected to start before the end of Sumitomo fiscal year 2024 (ending March 31, 2025). The Company anticipates finalizing its debt restructuring in the coming weeks and will provide the details of the agreements upon closing.
- The Company has obtained a standstill of its current debt obligations from IPF until the earlier of the finalization of its debt restructuring with IPF or March 31, 2023.
- In Q4 2022, Poxel initiated a corporate savings plan which includes a significant workforce reduction. This saving plan aims to adapt the Company's resources

to the current clinical development plan while preserving critical resources and competencies.

- In December, the Company announced the drawdown of the remaining two tranches, representing a total of EUR 2 million, of the convertible bonds as part of the equity-linked financing facility with Iris Capital Investment (IRIS).
- After 6 years as Chief Financial Officer of Poxel where she has been instrumental in the Company's development, Anne Renevot has recently left Poxel to pursue another opportunity. The Company plans to launch the search for a new CFO and, in the interim, can rely on its experienced finance team.

Full-Year Cash and Revenue ended December 31, 2022

Cash

As of December 31, 2022, total cash and cash equivalents were EUR 13,1 million (USD 14 million)[3], as compared to EUR 32,3 million at December 31, 2021 and EUR 17.1 million at September 30, 2022.

EUR (in thousands)	**Q4 2022**	**Q4 2021**
Cash	13,058	28,753
Cash equivalents	-	3,534
Total cash and cash equivalents*	**13,058**	**32,287**

Unaudited data.

**Net financial debt (excluding IFRS 16 impacts and derivative debts) was 29.5 million euros at the end of Q4 2022 (including debt obligations with IPF and the banks parts of the French PGE loan, as well as the equity-linked financing with IRIS) and EUR 2.6 million at the end of Q4 2021.*

The Company has obtained a standstill of its current debt obligations from IPF Partners until the earlier of the finalization of its debt restructuring or March 31, 2023. The Company anticipates finalizing its debt restructuring in the coming weeks. However, in the absence of debt restructuring and based on the Company's cash position at December 31, 2022, certain financial covenants related to the Company's debt with IPF Partners could be breached after March 31, 2023.

The Company is actively pursuing additional financing options which together with its debt restructuring would significantly extend its cash runway.

Full-Year 2022 Revenue

Poxel reported revenues of EUR 0.674 million for the year ended December 31, 2022, as compared to EUR 13.4 million during the corresponding period in 2021, which mainly reflected the EUR 13.2 million milestone payment for the approval of

TWYMEEG in Japan on June 23, 2021.

Revenue for 2022 mainly consists of JPY 93 million (EUR 0.673 million) of royalty revenue from Sumitomo Pharma which represents 8% of TWYMEEG net sales in Japan. Based on its current forecast, Poxel expects to receive 8% royalties on TWYMEEG net sales in Japan through the Sumitomo Pharma fiscal year 2022 (April 2022 to March 2023). 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)*	**2022 Q1 3 months**	**2022 Q2 3 months**	**2022 Q3 3 months**	**2022 Q4 3 months**	**FY 2022 12 months**	**FY 2021 12 months**
Sumitomo Pharma Agreement	32	51	203	388	673	13,377
Other	-	-	-	1	1	20
Total revenues	**32**	**51**	**203**	**389**	**674**	**13,397**

Unaudited data

Planned Presentations and Participation at the Following Upcoming Events

- JMP Securities Life Sciences Conference, New York, NY, May 15-16

Next Financial Press Release: 2022 Annual Results, on March 22, 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

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