November 8, 2022

Poxel Provides Corporate Update and Reports Cash and Revenue for the Third Quarter and Nine Months 2022

- **TWYMEEG® (Imeglimin) net sales in Japan for the quarter (July-September) grew four-fold over the prior quarter, in part due to the lifting of the prescription days limitation in September 2022, as recently reported by Sumitomo Pharma**
- **Phase 2 NASH Trial (DESTINY-1) for PXL065 met its primary efficacy endpoint for liver fat content reduction at 36 weeks for all doses; PXL065 prioritized for further development in NASH based on positive results from the DESTINY-1 trial**
- **PXL770 development to focus exclusively on rare diseases, driven by promising data which showed strong potential in multiple rare metabolic indications**
- **Extension of the cash runway through at least February 2023 with debt restructuring agreement with IPF Partners (IPF) and equity-linked financing facility with Iris Capital Investment (IRIS)**
- **As of September 30, 2022, cash and cash equivalents were EUR 17.1 million (USD 16.6 million)**

LYON, France--(BUSINESS WIRE)-- 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 third quarter and the nine months ended September 30, 2022.

"*This quarter's royalty revenues from TWYMEEG, marketed in Japan by Sumitomo Pharma for Type 2 diabetes, increased four-fold over the prior quarter, in part due to the removal of prescribing restrictions after the initial year on the market. The royalty stream from TWYMEEG's growth is poised to deliver significant value to Poxel*," noted Thomas Kuhn, Chief Executive Officer of Poxel. "*From our clinical programs, our DESTINY-1 Phase 2 Trial for PXL065 in NASH recently reported positive results, especially with respect to fibrosis which represents the highest unmet need in non-cirrhotic NASH. This is an important milestone for Poxel, but also more broadly for NASH, for which there is still no approved treatment. Based on these results, we are prioritizing PXL065 in NASH and are actively looking for a partner to advance its development. By leveraging the 505(b)(2) regulatory pathway, the extensive safety database of the parent molecule, and our recent Phase 2 results, we are well-positioned amongst other drugs in development for future development. In addition, PXL770 is a Phase 2 ready asset that is focused exclusively on rare diseases, starting with adrenoleukodystrophy and autosomal-dominant polycystic kidney disease*."

Clinical Updates

- 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 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 PPARg-mediated side effects vs. published results of pioglitazone.
- 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 continues to be planned in order to assess the potential of the deuterium-modified TZD platform with PXL065 in ALD. ALD studies are expected to initiate as soon as possible, subject to additional financing.
- PXL770 was granted Orphan Drug Designation (ODD) by the U.S. Food and Drug Administration (FDA) for the treatment of patients with autosomal-dominant polycystic kidney disease (ADPKD).

TWYMEEG® (Imeglimin)

- TWYMEEG net sales in Japan for the quarter (July-September) grew significantly to JPY 0.4 billion (EUR 2.5 million)[1], over the prior quarter (April-June) of JPY 0.1 billion (EUR 0.6 million)1 as recently reported by Sumitomo Pharma. As of September 1st, initial launch year restrictions for TWYMEEG which limited new products to two weeks prescriptions have been lifted. Sumitomo Pharma's forecast for net sales of TWYMEEG in Japan is JPY 1.5 billion (EUR 10.6 million)1 for fiscal year 2022 (April 2022 to March 2023). Based on the current forecast, Poxel expects to receive 8% royalties on TWYMEEG net sales in Japan through the Sumitomo Pharma fiscal year 2022. 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. Since TWYMEEG's launch in September 2021, Sumitomo Pharma's commercial efforts have leveraged TWYMEEG's potential to 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.

Financing

- In August, the Company announced that it restructured its debt with IPF, resulting in the postponement of the Q3 2022 and Q4 2022 amortization payments under the

existing debt facility, and lowering certain financial covenants until the end of January 2023. As part of the restructuring, the Company agreed to certain additional commitments which include the increase of the amounts due to IPF and potential partial early repayments of the debt.
- Concurrently, the Company entered into an equity-linked financing arrangement with IRIS for an initial gross amount of EUR 4 million, with the option, at the latest on December 31, 2022, and, at the Company's sole discretion, to draw a second and third tranche of up to EUR 1 million each.
- As a result of these two agreements, the Company expects that its resources will be sufficient to fund its operations and capital expenditure requirements through at least February 2023.

Event after the Period

- On November 7, Stephen Harrison, MD, President of the Summit Clinical Research, presented DESTINY-1 Phase 2 Results for PXL065 in NASH at The Liver Meeting® 2022, hosted by the American Association for the Study of Liver Diseases (AASLD).

Third Quarter and Nine Months Ended September 30, 2022 Cash and Revenue

Cash

As of September 30, 2022, total cash and cash equivalents were EUR 17.1 million (USD 16.6 million), as compared to EUR 16.1 million at June 30, 2022.

EUR (in thousands)	**Q3 2022**	**Q2 2022**	**Q1 2022**	**Q4 2021**
Cash	15,062	16,143	24,043	28,753
Cash equivalents	2,000	-	-	3,534
Total cash and cash equivalents*	**17,062**	**16,143**	**24,043**	**32,287**

Unaudited data

** Net financial debt (excluding IFRS 16 impacts and derivative debts) was EUR 16.8 million at the end of Q3 2022 as compared to EUR 17.3 million at the end of Q2 2022.*

Based on:

i. its cash position at September 30, 2022,
ii. the current development plan of the Company, excluding the initiation of Phase 2a clinical proof-of-concept (POC) biomarker studies for PXL065 and PXL770 in adrenomyeloneuropathy (AMN),
iii. the cash forecast approved by the Board of Directors of the Company, that does not include, as a conservative approach, any net royalties from Imeglimin in Japan,
iv. a strict control of its operating expenses, and
v. the amendment to the IPF debt facility with the postponement of the Q3 2022 and Q4 2022 amortization payments until end of February 2023, as well as a full drawdown of all tranches of the equity-linked financing arrangement with IRIS for a total amount of EUR 6 million, before December 31, 2022,

the Company expects that its resources will be sufficient to fund its operations and capital expenditure requirements through at least February 2023.

The Company is actively pursuing additional financing options, including ongoing active partnership discussions related to its programs.

Nine Months 2022 Revenue

Poxel reported revenues of EUR 286 thousand for the nine months ended September 30, 2022, as compared to EUR 13.3 million during the corresponding period in 2021, which mostly reflected the EUR 13.2 million milestone payment for the approval of TWYMEEG in Japan on June 23, 2021.

Revenue for the first nine months of 2022 mostly reflects the JPY 40 million (EUR 286 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 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)*	**Sept. 2022 9 months**	**Q3 2022 3 months**	**H1 2022 6 months**	**Sept. 2021 9 months**	**Q3 2021 3 months**	**H1 2021 6 months**
Sumitomo Pharma Agreement	286	203	83	13,274	-	13,274
Other	-	-	-	-	-	-
Total revenues	**286**	**203**	**83**	**13,274**	**-**	**13,274**

Unaudited data

Planned Presentations and Participation at the Following Upcoming Events

- ALD Connect 2022 Annual Meeting & Patient Learning Academy, November 11, 2022
- Jefferies Healthcare Conference, London, UK, November 15-17, 2022
- ODDO BHF Forum (virtual), January 9-10, 2023
- Degroof Petercam's Healthcare Conference, Brussels, Belgium, January 26, 2023

Next Financial Press Release: Fourth Quarter 2022 Financial Statement expected on February 15, 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 now 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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1 *Currency exchange rate at Sept 30, 2022*

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