April 21, 2021

Poxel Provides Corporate Update and Reports Cash and Revenue for the First Quarter 2021

- **Imeglimin Japanese New Drug Application (J-NDA) under review by the Pharmaceuticals and Medical Devices Agency (PMDA) following submission by Poxel's partner, Sumitomo Dainippon Pharma in July 2020, with product launch anticipated in 2021[1]**
- **Poxel regained Imeglimin rights from Metavant for US, Europe and other countries not covered by its agreement with Sumitomo Dainippon Pharma and is pursuing next steps to advance its development including partnering activities**
- **Poxel continues to prepare for initiation of Phase 2b trial with PXL770 in patients with biopsy-proven NASH and pre-diabetes or type 2 diabetes, expected to commence in H2 2021**
- **PXL065 Phase 2 study ongoing with completion of recruitment expected in mid-2021 and topline data readout in mid-2022**
- **Imeglimin and PXL065 preclinical and clinical data published in peer reviewed journals; PXL770 data accepted for oral and poster presentations at an upcoming scientific conference**
- **As of March 31, 2021, cash and cash equivalents were EUR 32.8 million (USD 38.4 million)**

LYON, France--(BUSINESS WIRE)-- POXEL SA (Euronext: POXEL - FR0012432516), a biopharmaceutical company focused on the development of innovative treatments for metabolic disorders, including type 2 diabetes and non-alcoholic steatohepatitis (NASH), today provided a corporate update and announced its cash position and revenue for the first quarter ended March 31, 2021.

"Closing the first quarter of 2021, we remain on track with our corporate and clinical timelines and objectives. We look forward to the completion of the J-NDA review of Imeglimin, and based on a typical 12-month review by the PMDA, we believe Imeglimin could be approved in mid-2021 with an anticipated product launch by our partner Sumitomo Dainippon Pharma in Fiscal Year 2021[1]. Further, having regained Imeglimin rights from Metavant in the US, Europe and other countries not covered by our agreement with Sumitomo, we are pursuing various opportunities to advance its development including partnering activities," commented Thomas Kuhn, CEO of Poxel.

"Our NASH candidates, PXL770 and PXL065 continue to move forward. For PXL770, we are actively preparing for a Phase 2b trial in biopsy-proven NASH patients with a focus on

patients with pre-diabetes or type 2 diabetes, and anticipate initiating this clinical trial in H2 2021. For PXL065, the enrollment of our DESTINY-1 trial in biopsy-proven NASH patients is moving along well and we anticipate completion of recruitment in mid-2021 as planned, with topline data expected in mid-2022. Moving forward, we remain focused on developing our clinical candidates and showcasing their value in the metabolic disease space. In parallel, we continue evaluating our AMP-kinase (AMPK) and deuterium-modified thiazolidinedione (d-TZD) platforms in preclinical studies targeting a range of metabolic disorders including specialty and rare diseases," concluded Mr. Kuhn.

Clinical Development Updates

Imeglimin (Type 2 Diabetes)

- Poxel continues to work closely with its partner, Sumitomo Dainippon Pharma, regarding the J-NDA, with the approval anticipated in Fiscal Year 2021[2]. The approval would trigger a JPY 1.75 billion (approximately EUR 13.8 million, USD 16.9 million)[3] milestone payment as well as the ability for Poxel to draw down EUR 13.5 million from the Company's debt facility with IPF. The target product launch date is anticipated in 2021[2] which would trigger the potential for sales-based payments and escalating double-digit royalties on sales.
- In February, Poxel announced it had regained the rights to Imeglimin from Metavant for US, Europe, and other countries not covered by the Company's agreement with Sumitomo Dainippon Pharma. Metavant has returned all data, materials and information, including FDA regulatory filings, related to the program and is not entitled to any payments from Poxel as part of the return. Poxel is pursuing next steps for the development of Imeglimin in these geographic areas including partnering activities.
- Throughout the first quarter, the Company published several papers describing Imeglimin's innovative MoA and Phase 2b/3 results from Japan in peer reviewed journals.

PXL770 (NASH)

- Poxel is preparing a 52-week Phase 2b trial evaluating up to two doses of PXL770 in approximately 100 patients per study arm with biopsy-proven NASH and pre-diabetes or type 2 diabetes expected to commence in H2 2021.
- The PXL770 program was presented and discussed at the 2021 NASH-TAG conference in March.
- Clinical results for PXL770 were also selected for presentations at the upcoming EASL (European Association for the Study of the Liver) in June 2021.

PXL065 (NASH)

- The recruitment for DESTINY-1, a Phase 2 study in biopsy proven NASH patients remains on track and is expected to be completed in mid-2021, with topline data available in mid-2022. The results of this trial will be used to help identify the dose or doses for a Phase 3 registration trial.
- In March, recent PXL065 Phase 1 clinical results, drug metabolism data and PK-PD modeling were presented at the 2021 NASH-TAG conference.
- A publication in Hepatology Communications journal entitled *Deuterium-Stabilized (R)-*

Pioglitazone (PXL065) Is Responsible for Pioglitazone Efficacy in NASH yet Exhibits Little to No PPARγ Activity was released in April 2021. The study highlights the potential of PXL065, the deuterium-stabilized R-stereoisomer of pioglitazone, to provide a safer and more effective treatment for NASH than pioglitazone in its racemic mixture form.

Additional Development Opportunities

- In addition to the clinical studies for PXL770 and PXL065, the Company is also conducting preclinical combination studies with its NASH drug candidates to explore the potential to show additive or synergistic benefits to treat the root causes of NASH with other agents in development.
- The Company is actively planning further pipeline growth and conducting additional preclinical studies to evaluate its next generation direct AMPK activators and d-TZDs, as well as considering external opportunities, with a focus on metabolic disorders, including rare diseases.

Corporate Updates

- In March, Poxel released its Universal Registration Document (URD).
- In February, Poxel announced the resolution of the arbitration procedure with Merck Serono.

First Quarter 2021 Financial Update

As of March 31, 2021, cash and cash equivalents were EUR 32.8 million (USD 38.4 million), as compared to EUR 40.2 million (USD 49.4 million) as of December 31, 2020. Cash and cash equivalents net of financial liabilities were EUR 9.8 million as of March 31, 2021, as compared to EUR 17.2 million as of December 31, 2020.

EUR (in millions)	**Q1 2021**	**Q4 2020**
Cash	18.5	15.6
Cash equivalents	14.3	24.6
Total cash and cash equivalents*	**32.8**	**40.2**

Unaudited data
**Cash and cash equivalents net of financial liabilities were EUR 9.8 million at the end of Q1 2021 and EUR 17.2 million at the end of Q4 2020.*

First Quarter 2021 revenue

Poxel reported no revenue for the quarter ended March 31, 2021, as compared to EUR 1.5 million during the corresponding period in 2020.

The revenues for the first quarter of 2020 included an allocated portion of the EUR 36.0 million upfront payment received from Sumitomo Dainippon Pharma relating to the strategic corporate partnership announced on October 30, 2017, as well as the residual Imeglimin Phase 3 program costs in Japan incurred in 2020 that were re-invoiced to Sumitomo Dainippon Pharma. Both the allocated portion of the upfront payment and the re-invoiced

costs of the Phase 3 **T**rials of **IM**eglimin for **E**fficacy and **S**afety (TIMES) program were recognized based on the percentage of the completion of this program. This program has been fully completed in 2020, and led to no revenue for the first quarter in 2021.

EUR (in millions)	**Q1 2021 3 months**	**Q1 2020 3 months**
Roivant Agreement	-	-
Sumitomo Agreement	-	1.5
Other	-	
Total revenues	-	**1.5**

Unaudited data

Planned Presentations and Participation at the Following Upcoming Virtual Events

- Mitochondria-Targeted Drug Development Summit, April 27-29
- Kempen Life Sciences Conference, May 5
- The 64th Annual Meeting of the Japanese Diabetes Society, May 20-22
- Jefferies Healthcare Conference, June 1-4
- JMP Securities Conference, June 16-18
- Raymond James Human Health Innovations Conference, June 21-23
- EASL ILC, June 23-26

Next Financial Press Release: Second Quarter 2021 Financial Update, July 21, 2021

About Poxel SA

Poxel is a dynamic biopharmaceutical company that uses its extensive expertise in developing innovative drugs for metabolic diseases, with a focus on type 2 diabetes and non-alcoholic steatohepatitis (NASH). In its mid-to-late-stage pipeline, the Company is currently advancing three drug candidates as well as earlier-stage opportunities. Imeglimin, Poxel's first-in-class lead product, targets mitochondrial dysfunction. Poxel has a strategic partnership with Sumitomo Dainippon Pharma for Imeglimin in Japan, China, South Korea, Taiwan and nine other Southeast Asian countries. A Japanese new drug application (J-NDA) is under review by the Pharmaceuticals and Medical Devices Agency (PMDA) to request approval for the manufacturing and marketing of Imeglimin for the treatment of type 2 diabetes. After successfully completing a Phase 2a proof-of-concept trial for the treatment of NASH, which met its primary endpoint and study objectives, for PXL770, a first-in-class direct adenosine monophosphate-activated protein kinase (AMPK) activator, Poxel plans to initiate a Phase 2b program in the second half of 2021. PXL770 could also have the potential to treat additional metabolic diseases. PXL065 (deuterium-stabilized R-pioglitazone), a MPC inhibitor, is in a streamlined Phase 2 trial for the treatment of NASH. Poxel also has additional earlier-stage programs from its AMPK activator and deuterated TZD platforms targeting chronic and rare metabolic diseases. The Company intends to generate further growth through strategic partnerships and pipeline development. 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

In the context of the COVID-19 outbreak, which was declared a pandemic by the World

Health Organization (WHO) on March 12, 2020, the Company is regularly reviewing the impact of the outbreak on its business.

As of the date of this press release, and based on publicly available information, the Company has not identified the occurrence of any material negative effect on its business due to the COVID-19 pandemic that remains unresolved. However, the Company anticipates that the COVID-19 pandemic could have further material negative impact on its business operations. The worldwide impact of COVID-19 may notably affect the Company's internal organization and efficiency, particularly in countries where it operates and where confinement measures are implemented by the authorities. In addition, COVID-19 may impact market conditions and the Company's ability to seek additional funding or enter into partnerships. Particularly, delays in the supply of drug substance or drug products, in the initiation or the timing of results of preclinical and/or clinical trials, as well as delays linked to the responsiveness of regulatory authorities could occur, which could potentially have an impact on the Company's development programs and partnered programs. The Company will continue to actively monitor the situation.

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.

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[1] Year noted is Fiscal Year from April 2021 to March 2022, which is Sumitomo Dainippon Pharma's Fiscal Year.
[2] Year noted is Fiscal Year from April 2021 to March 2022, which is Sumitomo Dainippon Pharma's Fiscal Year.
[3] Based on the JPY/EUR exchange rate on July 28, 2020.

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