April 21, 2020

Poxel Announces First Quarter 2020 Financial and Corporate Update

- **Expanded management team with the appointment of David E. Moller, MD, as Chief Scientific Officer (CSO) in January 2020**
- **Presented new preclinical results for PXL770 at the 3rd Annual Global NASH Congress in February 2020 demonstrating PXL770 was observed to reduce liver inflammatory cells**
- **Metavant met with the U.S. Food and Drug Administration (FDA) in Q1 2020; discussions continue about Phase 3 clinical development plan in type 2 diabetes patients with chronic kidney disease (CKD) stages 3b/4**
- **Strengthened cash position in March 2020; drew down EUR 10 million from IPF Partners bond loan**
- **Imeglimin manuscript recently published in scientific journal *Clinical Pharmacokinetics*; results demonstrate repeated co-administration with two commonly prescribed anti-diabetic drugs, metformin and sitagliptin (Januvia®; Merck & Co.) did not result in clinically relevant changes in drug exposure and Imeglimin was observed to be safe and well tolerated**
- **Proactively monitoring and managing potential impacts caused by the coronavirus (COVID-19) pandemic**

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, 2020.

“During the first quarter, we completed a number of important accomplishments within the Company and for our clinical programs. We strengthened our executive management team with the appointment of David E. Moller, MD, as CSO. As an industry leader in drug development with expertise in type 2 diabetes and metabolic diseases, David is leading activities related to scientific innovation, specifically with adenosine monophosphate-activated protein kinase (AMPK) and mitochondrial pyruvate carrier (MPC). In addition, he is expanding our scientific communications activities through the publication of new data,” said Thomas Kuhn, CEO of Poxel. “We recently showcased new results demonstrating that PXL770 was observed to reduce liver inflammation, a hallmark of NASH, and published a manuscript demonstrating Imeglimin’s safety and tolerability profile as well as the absence of clinically relevant pharmacokinetic interactions after being co-administered with two widely prescribed medications for type 2 diabetes. We look forward to publishing and presenting additional results from our pipeline programs throughout the year.”

“Also, during the first quarter, we continued to work closely with Sumitomo Dainippon Pharma on activities related to the Imeglimin Japanese New Drug Application (JNDA) submission for type 2 diabetes targeted in Q3 2020. In parallel, we worked with Metavant, who is in discussions with the FDA for the Imeglimin Phase 3 program in type 2 diabetes patients with CKD stages 3b/4, an underserved patient population,” added Thomas Kuhn. “For our two clinical stage NASH programs, we look forward to several upcoming milestones. For PXL770, during the first quarter of 2020, we fully enrolled the pharmacokinetic (PK)/pharmacodynamic (PD) and Phase 2a trials with results currently expected in Q2 and Q3 2020, respectively. For PXL065, we are preparing for the 36-week Phase 2 study in at least 120 biopsy-proven NASH patients with the goal of identifying the optimal dose or doses for the Phase 3 registration trial.”

Clinical Development Updates

Imeglimin (Type 2 Diabetes)

- Recently, Imeglimin results were published in *Clinical Pharmacokinetics* showing that repeated co-administration of Imeglimin with metformin or sitagliptin did not result in clinically relevant changes in drug exposure and Imeglimin was observed to be safe and well tolerated. These results are consistent with prior preclinical and longer-term clinical studies.
- Poxel continues to work closely with Sumitomo Dainippon Pharma on activities related to the JNDA submission for the treatment of type 2 diabetes, which is anticipated in the third quarter of 2020, with a target launch in 2021.
- The Company is working with Metavant, who is in discussions with the FDA for the Imeglimin Phase 3 program in the US in type 2 diabetes patients with CKD stages 3b/4.

PXL770 (NASH)

- During Q1 2020, patient enrollment was completed for the Phase 2a and PK/PD trials.
- In February 2020, important new preclinical results for PXL770 were presented at the 3rd Annual Global NASH Congress. PXL770 was observed to reduce liver inflammatory cells, which may contribute to an improvement of fibrogenesis, in a preclinical NASH model.
- Results from the PK/ PD trial are currently expected late second quarter of 2020.
- Results from the Phase 2a trial are currently expected late third quarter of 2020.

PXL065 (NASH)

- Poxel is preparing for the Phase 2 study in at least 120 biopsy-proven NASH patients with the aim to identify the optimal dose or doses to be evaluated in a Phase 3 registration trial. The Company planned to initiate study enrollment during the second quarter of 2020 and is now anticipating a delay due to the current COVID-19 situation. The Company is working with the lead clinical investigator and clinical trial sites and is currently reviewing the timing and plans to initiate this study, contingent on a safe and stable environment for patient recruitment and the availability of clinical trial sites during the COVID-19 outbreak.

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. Also, the Company is planning for future pipeline growth and evaluating additional research and development opportunities from its internal pipeline as well as external opportunities with a focus on metabolic disorders, including rare diseases.

Corporate Update

- In November 2019, Poxel obtained additional funding to advance its pipeline programs through a bond loan agreement of up to EUR 30 million with IPF Partners. Poxel drew down the first tranche of EUR 6.5 million in November 2019. In March 2020, the Company drew down the second tranche of EUR 10 million, which was contingent on the successful completion of the Imeglimin Phase 3 TIMES program. The third tranche of EUR 13.5 million can be drawn down by December 31, 2021, contingent on obtaining marketing authorization of Imeglimin in Japan. Specific debt covenants are attached to the bond loan agreement.
- In January 2020, Poxel appointed David E. Moller, MD, as CSO. Dr. Moller is responsible for leading scientific-related activities to support the advancement of the Company, including scientific innovation and scientific communications at Poxel. He is based in Boston and has joined the executive management team.
- During the quarter, Thibaut Roulon and Olivier Martinez resigned from their positions as Board Observers.

First Quarter 2020 Financial Update

As of March 31, 2020, cash and cash equivalents were EUR 36.9 million (USD 40.4 million), as compared to EUR 37.2 million (USD 41.8 million) as of December 31, 2019. Cash and cash equivalents net of financial liabilities were EUR 20.0 million as of March 31, 2020, as compared to EUR 27.4 million as of December 31, 2019.

EUR (in millions)	**Q1 2020**	**Q4 2019**
Cash	5.6	18.2
Cash equivalents	31.3	19.0
Total cash and cash equivalents*	**36.9**	**37.2**

Unaudited data
**Cash and cash equivalents net of financial liabilities were EUR 20.0 million at the end of Q1 2020 and EUR 27.4 million at the end of Q4 2019.*

Q1 2020 revenue

Poxel reported revenues of EUR 1.5 million for the quarter ended March 31, 2020, as compared with revenues of EUR 14.9 million during the same period in 2019 (historical).

Revenue reflects 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 during the first quarter of 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 Trials of IMeglimin for Efficacy and Safety (TIMES) program are recognized based on the accounting percentage of completion of this program, which has now been completed.

EUR (in millions)	**Q1 2020 3 months**	**Q1 2019 3 months (adjusted)***	**Q1 2019 3 months (historical)**
Roivant Agreement	-	-	-
Sumitomo Agreement	1.5	12.3	14.9
Other	-	-	-
Total revenues	**1.5**	**12.3**	**14.9**

Unaudited data
**Proforma, as if the Company applied the residual method in FY19.*

Note: A change in accounting policy was reported on February 12, 2020. This resulted in an adjustment to the Sumitomo Dainippon Pharma partnership revenue recognition for the previous years. For more information, please visit: https://www.poxelpharma.com/en_us/investors/news-events/press-releases/detail/144/poxel-reports-financial-update-for-cash-and-revenue-for-the

This change in accounting policy had no impact on Poxel's cash flows.

Planned Presentations and Participation at the Following Upcoming Events

- Jefferies Virtual Healthcare Conference, June 2-4, 2020
- BIO Digital (BIO International Convention), June 8-12, 2020

Next Financial Press Release: Second Quarter 2020 Financial Statement expected on July 21, 2020

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. Together, with its partner Sumitomo Dainippon Pharma, Poxel successfully completed the Phase 3 **T**rials of **IM**eglimin for **E**fficacy and **S**afety (TIMES) program for the treatment of type 2 diabetes in Japan. Poxel also established a partnership with Roivant Sciences for Imeglimin's development and commercialization in countries outside of the partnership with Sumitomo Dainippon Pharma, including the U.S. and Europe. **PXL770**, a first-in-class direct adenosine monophosphate-activated protein kinase (AMPK) activator, is in a Phase 2a proof-of-concept program for the treatment of NASH. PXL770 could also have the potential to treat additional metabolic diseases. **PXL065** (deuterium-stabilized R-pioglitazone), a mitochondrial pyruvate

carrier (MPC) inhibitor, is advancing into a Phase 2 clinical trial for the treatment of NASH. Poxel also has additional earlier-stage programs targeting metabolic, specialty and rare 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 has undertaken a full review of the impact of the outbreak on its business. Considering the rapidly evolving situation, the Company is updating this assessment on a regular basis.

The Company anticipates that the COVID-19 pandemic could have a material negative impact on our 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 have been implemented by the authorities. In addition, the deteriorating market conditions may impact the Company's ability to raise additional funding and/or to enter into partnerships. Particularly, delays in the supply of drug substance or drug products, in pre-clinical 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. The Company will continue to proactively 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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