July 21, 2020

Poxel Provides Corporate Update and Reports Cash and Revenue for the Second Quarter and First Half 2020

- **Poxel completed a capital raise of EUR 17.7 million (USD 19.4 million) to accelerate development of PXL770 and PXL065 in NASH and to pursue early-stage opportunities for pipeline growth from its adenosine monophosphate-activated protein kinase (AMPK) activator and deuterated thiazolidinedione (TZD) platforms in chronic and rare metabolic diseases**
- **PXL770, a first-in-class direct AMPK activator produced positive results in a pharmacokinetic (PK) / pharmacodynamic (PD) trial in likely-NASH patients**
- **PXL770 preclinical results produced additive benefits in a NASH model when combined with other late-stage agents in development**
- **PXL770 was observed to improve cardio-renal disease and adrenoleukodystrophy (ALD) / adrenomyeloneuropathy (AMN) in animal models**
- **PXL770 Phase 2a study results in approximately 100 likely-NASH patients are expected in late third quarter 2020**
- **Imeglimin Japanese new drug application (J-NDA) submission for the treatment of type 2 diabetes is anticipated in the third quarter of 2020 with a target launch in 2021**

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 second quarter and first half of 2020.

“During the second quarter, we accomplished a number of important corporate and clinical objectives, including strengthening our cash position to help accelerate our NASH programs and earlier stage opportunities from our AMPK activator and deuterated TZD platforms. In addition, we reported positive results from preclinical and clinical studies for PXL770 demonstrating its potential in NASH and that AMPK activation may lead to broader utility for the treatment of other chronic and rare metabolic diseases,” said Thomas Kuhn, CEO of Poxel. “We are enthusiastic to evaluate earlier stage opportunities from our platforms and are committed to pursuing all options to continue to build value in our pipeline.”

“Also, during the second quarter, we continued to work closely with Sumitomo Dainippon Pharma on activities related to the Imeglimin J-NDA submission for type 2 diabetes, anticipated in Q3 2020. In parallel, we continued to support Metavant, who is making

adjustments to the initial Imeglimin Phase 3 plan based on feedback from the U.S. Food and Drug Administration (FDA) and new draft guidance released in March 2020. Further FDA interactions are expected during the second half of 2020 and we plan to provide an update when the Phase 3 plan is finalized," added Thomas Kuhn, CEO of Poxel. "For our two first-in-class NASH programs, we are looking forward to the PXL770 Phase 2a efficacy results in approximately 100 likely-NASH patients expected in late Q3 2020. Furthermore, in the second half of 2020, contingent on the COVID-19 environment, we plan to initiate enrollment of the PXL065 Phase 2 36-week 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)

- The Company continues to work closely with Sumitomo Dainippon Pharma on activities related to the J-NDA 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 regarding the Imeglimin Phase 3 program in type 2 diabetes patients with chronic kidney disease (CKD) stages 3b/4. Further FDA interactions are expected during the second half of 2020.
- 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 that Imeglimin was observed to be safe and well-tolerated. These results are consistent with prior preclinical and longer-term clinical studies.

PXL770 (NASH)

- The PXL770 PK/PD trial in 16 likely-NASH patients met its primary endpoint and objectives. PXL770 was observed to demonstrate a consistent PK profile, was safe and well-tolerated and showed target engagement and efficacy signals in NASH and for the AMPK platform in other chronic and rare metabolic diseases.
- Results from a PXL770 preclinical trial demonstrated additive benefits in a NASH model when combined with other late-stage agents in development, including an FXR agonist (obeticholic acid), a GLP-1 receptor agonist (semaglutide) and a thyroid receptor β agonist (MGL-3196).
- Results from a PXL770 preclinical trial demonstrated in animal models improvements in cardio-renal disease and ALD / AMN, a deadly inherited rare metabolic disease characterized by neurodegeneration.
- Results from the Phase 2a trial in approximately 100 likely-NASH patients are currently expected late third quarter of 2020.
- Poxel anticipates presenting new data for PXL770 in a peer-reviewed format at scientific meetings and in published results in scientific journals during the second half of 2020.

PXL065 (NASH)

- The Company 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 plans to initiate study enrollment during the second half of 2020, 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

- The Company is currently evaluating additional research and development opportunities from its AMPK activation and deuterated TZD platforms as well as external opportunities with a focus on chronic and rare metabolic diseases.

Corporate Update

- During the second quarter, Poxel completed a capital raise of EUR 17.7 million (USD 19.4 million) with U.S. and European investors, including long-term shareholder Bpifrance Participations through its Large Venture Fund. The use of proceeds will help to accelerate advancement of PXL770 and PXL065 in NASH and pursue development activities with its AMPK activator and deuterated TZD platforms in chronic and rare metabolic diseases for pipeline growth.
- During the second quarter, Poxel conducted the Annual and Extraordinary General Meeting. The shareholders approved all the resolutions that were recommended by the Board of Directors. For further information, please visit: https://www.poxelpharma.com/en_us/investors/shareholder-information/annual-general-meeting-documents.

Second Quarter and First Half 2020 Cash and Revenue

As of June 30, 2020, cash and cash equivalents were EUR 46.0 million (USD 51.5 million), as compared to EUR 37.2 million (USD 41.8 million) at December 31, 2019. Cash and cash equivalents net of financial liabilities (excluding IFRS16 impacts and derivative debts) were EUR 29.0 million as of June 30, 2020, as compared to EUR 27.4 million at December 31, 2019.

EUR (in millions)	**Q2 2020***	**Q4 2019**
Cash	26.1	18.2
Cash equivalents	19.9	19.0
Total cash and cash equivalents**	**46.0**	**37.2**

**Unaudited data*
***Cash and cash equivalents net of financial liabilities (excluding IFRS 16 impacts and derivative debts) were EUR 29.0 million at the end of Q2 2020 and EUR 27.4 million at the end of Q4 2019.*

Q2 2020 Revenue

Poxel reported revenues of EUR 6.4 million for the six months ended June 30, 2020, as compared to EUR 23.2 million during the corresponding period in 2019 (historical).

Revenue in the first half of 2020 includes 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 half 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 **T**rials of **IM**eglimin for **E**fficacy and **S**afety (TIMES) program are recognized based on the accounting percentage of completion of this program, which has been completed. Revenue also includes a JPY 500 million (EUR 4.1 million, USD 4.5 million) milestone payment that Poxel is entitled to receive from Sumitomo Dainippon Pharma upon submission of the Imeglimin J-NDA, which is anticipated to occur in Q3 2020 and was recognized in Q2 2020 according to the IFRS15 accounting standard.

EUR (in millions)	Q1 2020	Q2 2020	**H1 2020**	Q1 2019		Q2 2019		**H**
	3 months	3 months*	**6 months**	3 months		3 months		**6 m**
				Adjusted**	Historical	Adjusted**	Historical	Adjuste
Roivant Agreement	-	-	-	-	-	0.2	0.2	0.2
Sumitomo Agreement	1.5	4.8	6.4	12.3	14.9	6.6	8.0	18.9
Other	-	-	-	-	-	0.1	0.1	0.1
Total revenues	**1.5**	**4.8**	**6.4**	**12.3**	**14.9**	**6.9**	**8.3**	**19.2**

**Unaudited data*
***Proforma, as if the Company applied the standalone selling price method in FY19.*

Note: A change in the accounting policy of revenue recognition method was reported as part of the fiscal year 2019 financial statements reported in a press release dated 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

- William Blair Virtual Biotech Conference, August 4-6, 2020
- 56th European Association for the Study of Diabetes Annual Meeting (virtual meeting), September 21-25, 2020

Next Financial Press Release: First Half 2020 Financial Statement expected on September 15, 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 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.

Based on this review, and as of the date of this press release, the Company has identified one significant impact of the COVID-19 outbreak related to the initiation of the Phase 2 study enrollment for its drug candidate, PXL065, which the Company initially planned during the second quarter of 2020 and is now anticipated in the second half of 2020, contingent on a safe and stable environment for patient recruitment and the availability of clinical trial sites during the COVID-19 outbreak. As of the date of this press release, and based on publicly available information, the Company has not identified the occurrence of other material negative effects on its business due to the COVID-19 pandemic. 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 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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