September 15, 2020

Poxel Reports Financial Results for First Half 2020 and Provides a Corporate Update

- **Strengthened financial position during H1 2020 with drawdown of IPF loan of EUR 10 million and a capital raise of EUR 17.7 million**
- **Imeglimin New Drug Application in Japan (J-NDA) was submitted for the treatment of type 2 diabetes in Q3 2020 and a target launch is expected in 2021[1]; a milestone payment of EUR 4 million was received in Q3 2020 from Sumitomo Dainippon Pharma**
- **Initiated PXL065 Phase 2 trial in biopsy-proven NASH patients in Q3 2020; streamlined development with a single Phase 2 trial given knowledge of pioglitazone, including data in NASH, and 505(b)(2) regulatory pathway, which offers the opportunity for an efficient and lower risk development program**
- **PXL770, a first-in-class direct AMPK activator produced positive results in a pharmacokinetic (PK) / pharmacodynamic (PD) trial in likely-NASH patients; PXL770 Phase 2a efficacy and safety results expected around the end of September 2020**
- **PXL770 produced additive benefits in a preclinical NASH model when combined with other late-stage agents in development and was observed to improve cardio-renal disease and adrenoleukodystrophy (ALD) / adrenomyeloneuropathy (AMN) in animals**

*Poxel will host an **investor conference call today** to discuss the **Half Year 2020 results** at **1:30 pm EDT (New York time) / 7:30 pm CEST (Paris time).** To participate in the call, please use the dial-in numbers: **US: +1 646-722-4916 UK: +44 20 71 94 37 59 France: +33 1 72 72 74 03 Access Code: 97417835#**.*
*A **slide presentation** to accompany the conference call will be available in the Investors / Company Info / Corporate Presentations section of the Poxel website: https://www.poxelpharma.com/en_us/investors/company-information/corporate-presentations*
*For a **replay** of the call, please use: US: +1 646-722-4969 UK: +44 20 3364 5147 FR: +33 1 70 71 01 60 Access Code: 418947860#.*

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 reported its financial results for the period ended June 30, 2020 and provided a corporate update.

“Through September, we accomplished several important corporate and clinical objectives,

including strengthening our financial position through multiple financial sources including the drawdown of the IPF loan of EUR 10 million in March, a capital raise of EUR 17.7 million in May and a subsequent milestone payment of EUR 4 million during the third quarter from our partner Sumitomo Dainippon Pharma for the Imeglimin J-NDA submission," said Thomas Kuhn, CEO of Poxel. "We also continued to make solid progress with our development programs. We reported positive results from preclinical and clinical studies for PXL770 and are continuing to evaluate broader metabolic diseases, including chronic and rare diseases, for our AMPK activation and D-TZD platforms."

"From an execution standpoint in the context of the COVID-19 pandemic, I am very pleased to report that we recently initiated the Phase 2 trial for PXL065 in biopsy-proven NASH patients across multiple clinical sites in the U.S.," continued Thomas Kuhn, CEO of Poxel. "This is a streamlined development program with a single Phase 2 trial given the knowledge of pioglitazone, including data in NASH, and the 505(b)(2) regulatory pathway. Based on pioglitazone's known efficacy and safety results in NASH, its cardiovascular benefits combined with the exciting PXL065 results to-date, we believe that PXL065 has the potential to produce compelling results and become a leading oral drug candidate in development for this important unmet medical need."

"For the remainder of 2020, we expect several important upcoming milestones and events, including the PXL770 Phase 2a efficacy and safety results in approximately 100 likely-NASH patients around the end of September 2020, finalization of the Imeglimin Phase 3 plan in the U.S. by Metavant, additional preclinical data related to our AMPK and D-TZD platforms and presentations for Imeglimin, PXL770 and PXL065 at several scientific meetings and published results in peer-reviewed scientific journals," added Thomas Kuhn.

Clinical Development Updates

Imeglimin (Type 2 Diabetes)

- The J-NDA for Imeglimin was submitted by Sumitomo Dainippon Pharma to the Pharmaceuticals and Medical Devices Agency (PMDA) to request approval for the manufacturing and marketing for the treatment of type 2 diabetes. Poxel received a milestone payment of EUR 4.0 million related to the J-NDA submission. J-NDA approval and a target launch is expected in 2021.[2] A J-NDA approval would trigger a milestone payment of EUR 14.2 million ($16.6 million).[3]
- 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.
- Poxel anticipates presenting Imeglimin results at the European Association for the Study of Diabetes (EASD) meeting and the Japanese Diabetes Society meeting as well as publishing data in scientific journals during the second half of 2020.

PXL770 (NASH)

- A PXL770 PK/PD trial in 16 likely-NASH patients met its primary endpoint and objectives. PXL770 was observed to demonstrate a consistent PK profile and to be safe and well-tolerated. In addition, it showed target engagement and efficacy signals in NASH that support the potential for PXL770 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.
- Efficacy and safety results from the Phase 2a trial in approximately 100 likely-NASH patients are currently expected around the end of September 2020.
- Poxel anticipates presenting results for PXL770 at the EASD meeting, American Association for the Study of Liver Diseases (AASLD) meeting and NASH Summit as well as publishing data in scientific journals during the second half of 2020.

PXL065 (NASH)

- The single Phase 2 study in approximately 120 biopsy-proven NASH patients was initiated in September 2020. The single Phase 2 study will evaluate efficacy and safety and aims to identify the optimal dose or doses to be evaluated in a Phase 3 registration trial. Results from this study are expected during the first half of 2022.
- Poxel is developing PXL065 using the 505(b)(2) regulatory pathway, which offers the opportunity for a streamlined and lower risk development program.
- Poxel anticipates presenting results for PXL065 at the AASLD meeting and publishing data in scientific journals during the second half of 2020.

Additional Development Opportunities

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

Corporate Highlights

- During the first quarter, Poxel appointed David E. Moller, MD, as Chief Scientific Officer. Dr. Moller is responsible for leading scientific-related activities to support the advancement of the Company, including scientific innovation and scientific communications at Poxel.
- During the first quarter, the Company drew down the second tranche of EUR 10 million of the IPF loan, which was contingent on the successful completion of the Imeglimin Phase 3 **T**rials of **IM**eglimin for **E**fficacy and **S**afety(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 loan agreement.
- During the second quarter, Poxel completed a capital raise of EUR 17.7 million with

U.S. and European investors, including long-term shareholder, Bpifrance Participations, through its Large Venture Fund.

- 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.

First Half 2020 Financial Results (IFRS standards)

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 trials of the 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)[4] milestone payment that Poxel is entitled to receive from Sumitomo Dainippon Pharma upon submission of the Imeglimin J-NDA, which was anticipated to occur in Q3 2020 and was recognized in Q2 2020 according to the IFRS15 accounting standard.

EUR (in thousands)	**H1 2020 6 months**	**H1 2019 6 months**	
		(adjusted)	(historic)
Roivant Agreement	13	155	155
Sumitomo Agreement	6,359	18,909	22,914
Other	-	100	100
Total revenues	**6,372**	**19,164**	**23,169**

The review procedures have been performed and the issuance of the report is in process.

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.

Income Statement

Poxel devotes the bulk of its resources to research and development (R&D) activities. R&D expenses totaled EUR 12.6 million for the first half of 2020, as compared to EUR 24.2 million for the corresponding period in 2019. R&D expenses for the first half of 2020 primarily reflect the clinical study costs incurred for PXL770 and PXL065, Poxel's two Phase 2 clinical-stage programs for the treatment of NASH. To a lesser extent, they also reflect the remainder of the R&D costs for the Phase 3 TIMES program and the regulatory costs incurred over the period for the preparation of the Imeglimin J-NDA submission that occurred in July 2020.

R&D expenses are net of the R&D Tax Credit (CIR) that resulted in an income of EUR 1.5 million for the first half of 2020 as compared to EUR 1.6 million for the corresponding period of 2019.

General and administrative expenses totaled EUR 5.9 million for the first half of 2020, as compared to EUR 4.9 million for the first half of 2019.

The financial income amounted to EUR 0.2 million for the first half of 2020, as compared to EUR 0.1 million for the first half of 2019, which primarily reflected the change in fair value of the IPF warrants and the interests attached to this debt.

The net result for the financial period ending June 30, 2020 was a net loss of EUR 12.1 million, as compared to a net loss of EUR 9.8 million in the corresponding period in 2019.

Condensed Income Statement

EUR (in thousands)	**HY 2020 6 months**	**HY 2019 6 months (adjusted)**	**HY 2019 6 months (historic)**
Revenue	6,372	19,164	23,169
Research and development expenses*	(12,580)	(24,164)	(24,164)
General and administrative expenses	(5,983)	(4,868)	(4,868)
Operating gain (loss)	(12,191)	(9,869)	(5,864)
Financial income (loss)	249	71	71
Income tax	(118)	-	-
Net income (loss)	**(12,060)**	**(9,798)**	**(5,792)**

**Net of R&D tax credit*
The review procedures have been performed and the issuance of the report is in process.

Cash

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. In September 2020, Poxel received a EUR 4.0 million milestone payment from its partner Sumitomo Dainippon Pharma for the Imeglimin J-NDA submission, which is not reflected in the June 30, 2020 cash update.

EUR (in thousands)	**Q2 2020**	**Q4 2019**
Cash	26,122	18,161
Cash equivalents	19,846	19,026
Total cash and cash equivalents*	**45,968**	**37,187**

** 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.*

The review procedures have been performed and the issuance of the report is in process.

Planned Presentations and Participation at the Following Upcoming Events

- 56th European Association for the Study of Diabetes (EASD) Annual Meeting, September 21-25, 2020, Virtual Meeting
- The 63rd Annual Meeting of the Japan Diabetes Society, October 5-16, 2020, Virtual Meeting
- The American Association for the Study of Liver Diseases (AASLD), the Liver Meeting®, November 13-16, 2020, Digital Meeting
- The 4th Annual NASH Summit, December 15-18, 2020, Digital Meeting

Next Financial Press Release: Third Quarter 2020 Financial and Corporate Update is expected on October 20, 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. 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. 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 MPC inhibitor, is in a single 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.

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.

---

[1] Year noted is Fiscal Year from April 2021 to March 2022, which is Sumitomo Dainippon Pharma's Fiscal Year.

[2] Converted at the exchange rates as of July 28, 2020.

[3] Converted at the exchange rates as of June 30, 2020.

View source version on businesswire.com:
https://www.businesswire.com/news/home/20200915006034/en/

Poxel SA
Jonae R. Barnes
Senior Vice President, Investor Relations, Corporate Communication and Public Relations
jonae.barnes@poxelpharma.com
+1 617 818 2985

Aurélie Bozza
Investor Relations and Communication Director
aurelie.bozza@poxelpharma.com
+33 6 99 81 08 36

Investor relations / Media - EU/US

Trophic Communications
Joanne Tudorica or Valeria Fisher
tudorica@trophic.eu or fisher@trophic.eu
+49 171 351 2733 or +49 175 804 1816

Investor relations / Media - France
NewCap
Emmanuel Huynh / Arthur Rouillé
poxel@newcap.eu
+33 1 44 71 94 94

Source: Poxel SA