Press Release

The management team will host a conference call today, Thursday, March 26th in English ***at 2:30 pm EDT (New York time) / 7:30 pm CET (Paris time).*** *A presentation will be available in the Investors section of the Poxel website.*

To access the call, please use the dial-in numbers below according to your location. ***US****: +1 (646) 722 4916* ***UK****: +44 (0) 20 7194 3759* ***FR****: +33 (0) 1 72 72 7403. Access code:* ***53593329#.*** *A replay will be available for 90 days. To access the replay, please use one of the following numbers:* ***US:*** *+1 (646) 722 4969* ***UK:*** *+44 (0) 20 3364 5147* ***FR:*** *+33 (0) 1 70 71 01 60 Access code:* ***418906110#***

Poxel Reports Financial Results for Full Year 2019 and Provides Corporate Update

- **Successful completion of Imeglimin Phase 3 TIMES program in Japan for the treatment of type 2 diabetes in over 1,100 patients; Japanese New Drug Application (JNDA) submission on track and expected in Q3 2020[1] with target launch anticipated in 2021**
- **Successful completion of Imeglimin Metavant trial in type 2 diabetes patients with chronic kidney disease (CKD) stages 3b/4; ongoing discussions with the U.S. Food and Drug Administration (FDA) for the Phase 3 program continue**
- **Advanced PXL770 in a Phase 2a study and separate pharmacokinetic (PK)/pharmacodynamic (PD) trial for the treatment of NASH; patient enrollment for both trials completed in Q1 2020**
- **Successful completion of PXL065 Phase 1a/1b trials with a single, comprehensive Phase 2 study for the treatment of NASH expected to initiate in Q2 2020; PXL065 program to utilize the 505(b)(2) regulatory pathway**
- **Initiated preclinical NASH model combination studies for PXL770 and PXL065 with other agents**
- **Secured bond loan financing for up to EUR 30 million with IPF Partners; contingent on achieving Imeglimin-related milestones and including debt covenants**
- **Company is proactively monitoring and managing potential impacts caused by the coronavirus (COVID-19) pandemic**

[1]Quarter noted is Poxel's fiscal year from January to December.

LYON, France, March 26, 2020 – 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 announced its results for the year ended December 31, 2019 and provided a corporate update.

"Last year we achieved many important clinical development milestones for Imeglimin, PXL770 and PXL065. Together with our partner, Sumitomo Dainippon Pharma, we 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, which included three pivotal trials in over 1,100 patients. The Phase 3 trials were observed to demonstrate a consistent HbA1c reduction in several patient populations. Leading a large Phase 3 clinical development program in Japan as a European-based company is a strong validation of our internal drug development skills," said Thomas Kuhn, CEO of Poxel. "In parallel, we advanced PXL770 for the treatment of NASH into a Phase 2a study designed to assess efficacy and safety plus an additional PK/PD trial in the target population. Following the successful completion of the PXL065 Phase 1 program late last year for our second clinical candidate for the treatment of NASH, we began preparing for a single, comprehensive Phase 2 study. Following a positive meeting with the FDA in Q4 2019, we are utilizing the 505(b)(2) regulatory pathway, which has the opportunity to provide a streamlined and efficient development approach."

"Looking forward in 2020, we expect to achieve several important and transformational milestones. We have been working very closely with Sumitomo Dainippon Pharma on their activities related to the Imeglimin JNDA submission, targeted in Q3 2020, and 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," said Thomas Kuhn, CEO of Poxel. "While we continue to support our partners, now that the TIMES program is completed, we are shifting some of our internal resources from Imeglimin to our NASH programs as they continue to advance in development. For PXL770, the PK/PD and Phase 2a results are currently expected in Q2 and Q3 2020, respectively; they should provide key data to confirm PXL770's potential for the treatment of NASH and also to validate our hypothesis that AMPK activation will favorably impact other metabolic disease parameters more broadly. For PXL065, a 36-week Phase 2 study in at least 120 biopsy-proven NASH patients is expected to begin in Q2 2020; the goal is to identify the optimal dose or doses for the Phase 3 registration trial."

"Additionally, we are planning for future pipeline growth and evaluating additional research and development opportunities from our internal pipeline as well as external opportunities focused on metabolic disorders. We are also conducting preclinical combination studies with our 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," continued Thomas Kuhn, CEO of Poxel.

Clinical Development Updates

Imeglimin (Type 2 Diabetes)

- In April 2019, positive topline results for the Imeglimin Phase 3 TIMES 1 monotherapy trial were reported; the trial met its primary and secondary endpoints.
- In June 2019, positive topline results were reported for the Imeglimin Phase 3 TIMES 3 16-week portion of the trial; Imeglimin in combination with insulin met its primary endpoints with a favorable safety and tolerability profile.
- In July 2019, Poxel and Metavant announced positive topline safety and PK/PD results from an Imeglimin trial in patients with type 2 diabetes and chronic kidney disease stages 3b/4.
- In September 2019, the TIMES 1 results were presented in a symposium at the 55th Annual Meeting of the European Association for the Study of Diabetes (EASD).
- In November 2019, positive topline results were reported for the Imeglimin Phase 3 TIMES 3 36-week portion of the trial. Imeglimin in combination with insulin was observed to demonstrate consistent and sustained efficacy with a favorable safety profile in the open-label extension period.
- In December 2019, positive topline Phase 3 results were reported for the Imeglimin Phase 3 TIMES 2 trial, marking successful completion of the program. The trial met its key efficacy endpoint of HbA1c reduction, demonstrating how Imeglimin's unique dual mechanism of action was observed to show added efficacy benefits in combination with existing hypoglycemic agents.
- The JNDA submission is on track for Q3 2020 with a target launch anticipated in 2021.
- During Q1 2020, Metavant met with the FDA to discuss the Imeglimin Phase 3 program in type 2 diabetes patients with CKD stages 3b/4, an underserved patient population. Ongoing discussions with the FDA continue on the development plan for the Imeglimin Phase 3 program in the US.

PXL770 (NASH)

- A Phase 2a study for PXL770 is ongoing and evaluating efficacy and safety in patients who likely have NASH; results are currently expected in Q3 2020.
- A separate PK/PD trial for PXL770 is ongoing; results are currently expected in Q2 2020.
- 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.
- During Q1 2020, patient enrollment was completed for the Phase 2a and PK/PD trials.

PXL065 (NASH)

- In April 2019, positive results for the PXL065 Phase 1a trial were reported; PXL065 was observed to have a favorable safety, tolerability and PK profile.
- In November 2019, Poxel announced a positive update for PXL065 following an

FDA meeting; based on feedback, PXL065 is utilizing the 505(b)(2) regulatory pathway.

- In November 2019, positive results from the PXL065 1a trial were presented during a poster presentation session at the Liver Meeting® hosted by the American Association for the Study of Liver Diseases (AASLD). PXL065 was observed to have a favorable safety, tolerability and PK profile.
- In December 2019, positive results from the Phase 1b multiple ascending dose trial were reported. PXL065 was observed to demonstrate a dose-proportional PK profile and consistent stabilization of R-pioglitazone at all doses tested.
- In Q2 2020, Poxel plans to initiate a single, comprehensive Phase 2 36-week study in at least 120 biopsy-proven NASH patients. The study is designed to identify the optimal dose or doses for a Phase 3 registration trial.

Early Stage Development

- Preclinical studies are underway to assess the combination potential of PXL770 and PXL065 with other agents in development. Furthermore, preclinical studies are ongoing to evaluate direct adenosine monophosphate-activated protein kinase (AMPK) activation and mitochondrial pyruvate carrier (MPC) inhibition in additional metabolic, specialty and 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.

Recent Events

- In January 2020, Poxel appointed David E. Moller, MD, as Chief Scientific Officer (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.

Financial Statements for Full Year 2019 (IFRS Standards)

Revenue

Poxel reported revenue of EUR 26.6 million in 2019, as compared to revenue of EUR 62.4 million in 2018 (adjusted). The revenue primarily 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 Imeglimin Phase 3 program costs in Japan incurred during the year of 2019 that were re-invoiced to Sumitomo Dainippon Pharma. Both the portion of the upfront

payment and the re-invoiced costs of the Phase 3 Trials of IMeglimin for Efficacy and Safety (TIMES) program are allocated to the development service performance obligation and are recognized based on the percentage of completion of this program.

EUR (in millions)	**FY 2019 12 months**	**FY 2018 12 months (adjusted)**	**FY 2018 12 months (historical)**
Roivant Agreement	0.3	8.2	8.2
Sumitomo Agreement	26.2	54.2	66.4
Other	0.1	-	-
Total revenues	**26.6**	**62.4**	**74.6**

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

Note: There was a change in accounting policy resulting in an adjustment to the Sumitomo Dainippon Pharma partnership revenue recognition, which was reported on February 12, 2020.

The revenue derived from our strategic corporate partnership announced on October 30, 2017 with Sumitomo Dainippon Pharma is recorded in accordance with IFRS 15, which was adopted by the Company in 2017. For accounting purposes, the agreement is comprised of two separate performance obligations: (1) a license granted to Sumitomo Dainippon Pharma to develop, manufacture and sell the product and, (2) a development service. Originally, the transaction price was allocated to both performance obligations using the residual method, whereby the amount allocated to the service was based on an estimation of its standalone selling price and the amount allocated to the license was the difference between the transaction price and the estimated standalone value of the service.

In 2019, a review of the Company's accounting policies led to a change in the method used to allocate the transaction price of the Sumitomo Dainippon Pharma agreement to reflect a preferable method that has emerged in the biotech industry since our early adoption of IFRS 15. Under the revised allocation method, the standalone selling price of the license has also been estimated, and the total contract price has been allocated between the two performance obligations (license and service) in proportion to their respective estimated standalone selling prices (as opposed to applying the residual method). This change resulted in a higher amount allocated to the license, which is recognized at the time of its delivery in the fourth quarter of 2017, and a lower amount allocated to the service, which is recognized during the period from the fourth quarter of 2017 to-date.

Accordingly, the Company retrospectively recorded an adjustment of previously reported accounts in respect of revenue related to the partnership agreement with Sumitomo Dainippon Pharma. This change had the effect of accelerating the recognition of the revenue for the year ended December 31, 2017 and had the reverse effect for the years ended December 31, 2018 and December 31, 2019.

This change in accounting policy had no impact on our cash flows.

Income Statement

Poxel devotes the bulk of its resources to research and development (R&D) activities. R&D expenses totaled EUR 40.2 million in 2019, as compared to EUR 54.5 million in 2018. R&D expenses in 2019 primarily reflected the clinical costs incurred for the Imeglimin Phase 3 TIMES program over the period, which were mostly re-invoiced to Sumitomo Dainippon Pharma. To a lesser extent, they also included the clinical study costs incurred for the Phase 2 program of PXL770 and the Phase 1a/1b studies for PXL065, the Company's two clinical-stage programs for NASH. The decrease in R&D costs was mostly driven by the TIMES program in Japan, for which expenses of EUR 20 million were incurred in 2019, compared to EUR 46 million in 2018. The TIMES program R&D decrease during this period is related to the completion of the program.

R&D costs are net of the R&D Tax Credit (CIR) that resulted in income of EUR 4.4 million in 2019, as compared to EUR 3.6 million in 2018.

General and administrative expenses totaled EUR 11.1 million in 2019, as compared to EUR 7.5 million in 2018. The increase in G&A costs reflects the development of the Company and its affiliates. It is driven by significant personnel recruitment leading to a 33% increase in full time employees in 2019 compared to 2018. It also reflects professional fees incurred in the course of the development and the financing of the Group.

The financial income amounted to a loss of EUR 1.1 million in 2019, as compared to a gain of EUR 1.1 million in 2018. The financial loss in 2019 mostly includes a EUR 0.9 million non-cash expense reflecting the IPF warrants fair value.

The net result for the financial period ending December 31, 2019 was a net loss of EUR 25.8 million, as compared to an adjusted net income of EUR 1.3 million in 2018.

Condensed Income Statement

EUR (in thousands)	FY 2019 12 months	FY 2018 12 months (adjusted)	FY 2018 12 months (historical)
Revenue	26,557	62,381	74,605
Net research and development expenses*	(40,177)	(54,540)	(54,540)
General and administrative expenses	(11,051)	(7,527)	(7,527)
Operating gain (loss)	(24,671)	314	12,538
Financial income (expenses)	(1,071)	1,064	1,064
Income tax	(1)	(77)	(77)
Net income (loss)	**(25,743)**	**1,301**	**13,525**

**Net of R&D tax credit*

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

Cash

As of December 31, 2019, total cash and cash equivalents were EUR 37.2 million (USD 41.8 million), as compared to EUR 66.7 million (USD 76.4 million) as of December 31, 2018. Cash and cash equivalents net of financial liabilities (excluding lease and derivative debts) were EUR 27.4 million as of December 31, 2019, as compared to EUR 52.5 million as of December 31, 2018.

This figure does not include the second tranche of EUR 10 million from the bond loan agreement with IPF Partners that was drawn in March 2020.

Next Financial Press Release: First Quarter Financial Update, April 21, 2020

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.

As of the date of this press release and based on publicly available information, the Company has not identified the occurrence of a material negative effect on its business due to the COVID-19 pandemic.

However, the Company anticipates that the COVID-19 pandemic could have such a material negative impact in the near future. 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. While the Company's timelines for its manufacturing, pre-clinical and clinical operations

remain unchanged on the date hereof, the COVID-19 outbreak is likely to have an impact on the Company's operations, in the same way as for any company operating within the healthcare industry. 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.

About Imeglimin

Imeglimin is a new chemical substance classified as a tetrahydrotriazine compound, and the first clinical candidate in a chemical class. Imeglimin has a unique mechanism of action (MOA) that targets mitochondrial bioenergetics. Imeglimin acts on all three key organs which play an important role in the treatment of type 2 diabetes: the pancreas, muscles, and the liver, and it has demonstrated glucose lowering benefits by increasing insulin secretion in response to glucose, improving insulin sensitivity and suppressing gluconeogenesis. This MOA has the potential to prevent endothelial and diastolic dysfunction, which can provide protective effects on micro- and macro-vascular defects induced by diabetes. It also has the potential for protective effect on beta-cell survival and function. This unique MOA offers the potential opportunity for Imeglimin to be a candidate for the treatment of type 2 diabetes in almost all stages of the current anti-diabetic treatment paradigm, including monotherapy or as an add-on to other glucose lowering therapies.

About the TIMES Program

TIMES (**T**rials of **Im**eglimin for **E**fficacy and **S**afety), the Phase 3 program for Imeglimin for the treatment of type 2 diabetes in Japan, consists of three pivotal trials involving over 1,100 patients. The TIMES program includes the following three trials performed using the dose of 1,000 mg twice daily:

TIMES 1: A Phase 3, 24-week, double-blind, placebo-controlled, randomized, monotherapy trial that assessed the efficacy, safety and tolerability of Imeglimin in Japanese patients with type 2 diabetes, using the change in HbA1c as the primary endpoint. Secondary endpoints of the trial included fasting plasma glucose, other standard glycemic and non-glycemic parameters. The TIMES 1 trial met its primary and secondary endpoints and the topline results were reported on April 9, 2019.

TIMES 2: A Phase 3, 52-week, open-label, parallel-group trial that assessed the long-term safety and efficacy of Imeglimin in Japanese patients with type 2 diabetes. In this trial, Imeglimin was administered orally as combination therapy with existing hypoglycemic agents, including a DPP-4 inhibitor, a SGLT2 inhibitor, a biguanide, a sulphonylurea, a glinide, an alpha-glucosidase inhibitor, a thiazolidine and a GLP1 receptor agonist or as monotherapy. The TIMES 2 trial met its primary objective and topline results were reported on December 20, 2019.

TIMES 3: A Phase 3, 16-week, double-blind, placebo-controlled, randomized trial with a 36-week open-label extension period that evaluated the efficacy and safety of Imeglimin in combination with insulin in Japanese patients with type 2 diabetes and

inadequate glycemic control on insulin therapy. The TIMES 3 16-week portion of the trial met its primary endpoint and the topline results were reported on June 25, 2019. The TIMES 3 36-week open-label extension period met its primary objective and the topline results were reported on November 26, 2019.

About PXL770

PXL770 is a first-in-class direct adenosine monophosphate-activated protein kinase (AMPK) activator. AMPK is a central regulator of multiple metabolic pathways leading to the control of lipid metabolism, glucose homeostasis and inflammation. Based on its central metabolic role, targeting AMPK offers the opportunity to pursue a wide range of indications to treat chronic metabolic diseases, including diseases that affect the liver, such as non-alcoholic steatohepatitis (NASH)[2].

About PXL065

PXL065 is deuterium-stabilized R-pioglitazone. Although pioglitazone is not approved by the FDA for the treatment of NASH, it is the most extensively studied drug for NASH and has demonstrated "resolution of NASH without worsening of fibrosis" in a Phase 4 trial[3]. Pioglitazone is the only drug recommended for biopsy-proven NASH patients by the Practice Guidelines published by the American Association for the Study of Liver Diseases (AASLD) and the European Association for the Study of the Liver (EASL)[4]. Pioglitazone's off-label use for NASH, however, has been limited due to the PPARγ-related side effects, which include weight gain, bone fractures and fluid retention.

Pioglitazone is a 1:1 mixture of two mirror-image compounds (R- and S-stereoisomers) that interconvert *in vivo*. Using deuterium, we stabilized each stereoisomer and characterized their different pharmacological properties. In *in vitro* studies, PXL065 has been shown to target mitochondrial pyruvate carrier (MPC) as an inhibitor. In preclinical animal models, PXL065 exhibits the anti-inflammatory and NASH activity associated with pioglitazone with little or no weight gain or fluid retention, side effects which are associated with the S-stereoisomer. Based upon preclinical and Phase 1 results to date, Poxel believes that PXL065 may have a better therapeutic profile than pioglitazone for NASH.

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

2 Smith B. K et al., (2016) Am J Physiol Endocrinol Metab 311, E730 – E740.
3 Cusi, et al., Ann Intern Med. 2016, 165(5), 305-315).
4 J Hepatol. 2016, 64(6),1388-402; Hepatology 2018, 67, 328-357.

(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.

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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