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Poxel Announces Availability of 2019 Universal Registration Document and Provides Business Update

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 announced that the Universal Registration Document (*Document d'Enregistrement Universel*) for the year ended December 31, 2019 has been filed with the stock market regulator in France, Autorité des Marchés Financiers (AMF). This document is available in English on the AMF's website and is posted on Poxel's website www.poxelpharma.com in the Investors / Shareholder Information / Regulatory Documentation section, and the French version will be available in the coming weeks on the Company's website.

"In 2019, we achieved several corporate and clinical accomplishments for our three clinical stage programs, Imeglimin, PXL770 and PXL065 and 2020 is poised to be an impactful year for the Company. We are looking forward to a number of significant milestones for our three clinical stage programs, and in parallel, we will continue to proactively manage and monitor for developments that might impact the timelines of our corporate objectives due to the COVID-19 global pandemic," said Thomas Kuhn, CEO of Poxel.

The Universal Registration Document includes:

- 2019 Annual Financial Report, including the Management Report; and
- Report on Corporate Governance

This document also includes the most recent update of the Company's activities at the date of the document, including:

- For Imeglimin, Poxel is working very closely with Sumitomo Dainippon Pharma on preparations related to the Japanese New Drug Application submission for the treatment of type 2 diabetes, which is anticipated in the third quarter of 2020. The Company is also working with Metavant, who is in discussions with the U.S. Food and Drug Administration for the Imeglimin Phase 3 program in type 2 diabetes patients with chronic kidney disease (CKD) stages 3b/4, an underserved patient population.
- For the Company's NASH programs, PXL770 and PXL065, Poxel anticipates two important clinical data readouts for PXL770 and the initiation of a Phase 2 study for PXL065. For PXL770, the pharmacokinetic (PK)/pharmacodynamic (PD) results are expected late second quarter of 2020 and the Phase 2a results are currently expected late third quarter of 2020. These results should provide key data to confirm PXL770's

potential for the treatment of NASH and also to validate the Company's hypothesis that AMPK activation will favorably impact other metabolic disease parameters more broadly. For PXL065, Poxel is preparing for the Phase 2 study in at least 120 biopsy-proven NASH patients and is currently working with the lead clinical investigator and clinical trial sites. The Company planned to initiate this study during the second quarter of 2020 and is now anticipating a delay due to the current COVID-19 environment. The Company 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. The primary objective of the trial is to identify the optimal dose or doses to be evaluated in a Phase 3 registration trial.

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 focused on metabolic disorders, including rare diseases.

From a scientific communications standpoint, the Company plans on being very active this year publishing new data in scientific journals and presenting at medical conferences.

Paper copies of the 2019 Universal Registration Document are available free of charge, upon request, at the Company's registered office located at 259/261 Avenue Jean Jaurès, 69007 Lyon, France.

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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