November 20, 2020

Poxel Provides Update on Metavant Partnership with Imeglimin

- **For strategic reasons, Metavant has decided not to advance Imeglimin into a Phase 3 program**
- **Metavant will actively explore options for a potential out-licensing of Imeglimin rights for a period of 60 days; Metavant intends to return Imeglimin rights to Poxel if they are unable to reach an agreement on material terms within this period**
- **No impact on Sumitomo Dainippon Pharma partnership; Following successful completion of the Phase 3 program, a New Drug Application for Imeglimin in Japan (J-NDA) is currently advancing through regulatory review with a target product launch anticipated in fiscal year 2021[1]**
- **Imeglimin is a first-in-class drug candidate with a unique dual mechanism of action with the potential to treat type 2 diabetes across several stages of the current treatment paradigm, both as a monotherapy or as an add-on to other glucose lowering therapies, and could be a treatment option for the sensitive patient populations, such as those with chronic kidney disease**

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 Metavant has conducted a strategic review and has decided not to move forward with the development of Imeglimin. This decision was not based on any efficacy, safety or other data generated through the partnership.

“As a novel first-in-class drug candidate that aims to address type 2 diabetes across several stages of the current treatment paradigm, Imeglimin has already successfully completed the Phase 3 TIMES program in Japan under a partnership with Sumitomo Dainippon Pharma, and it is currently under regulatory review to request approval for manufacturing and marketing for the treatment of type 2 diabetes in Japan. Based on the outcome of those trials, we see this compound as a novel and innovative potential therapy that could benefit patients with type 2 diabetes globally. Today’s announcement does not impact the agreement for Imeglimin with Sumitomo Dainippon Pharma. Moving forward, we are preparing to explore various options to advance Imeglimin into a Phase 3 development program in the US, Europe and other countries currently covered under the Metavant agreement,” said Thomas Kuhn, CEO of Poxel. “In addition to advancing our two Phase 2 programs, PXL770 and PXL065, for the treatment of NASH, we remain fully committed to Imeglimin and our vision of developing innovative drugs for metabolic diseases.”

“Although we are not planning for continued development of Imeglimin at this time, we continue to believe that Imeglimin has a potentially unique profile with a novel mechanism of action, and we are encouraged by the positive results generated by Metavant and by Sumitomo Dainippon Pharma in Japan,” said Paul Strumph, MD, Chief Medical Officer of Metavant.

Metavant will not be entitled to any payment from Poxel in the event that rights to Imeglimin are returned to Poxel. Poxel anticipates no impact to its projected cash runway and that its cash and cash equivalents will continue to be sufficient to fund operations through 2022 based on its current business plan. As of September 30, 2020, Poxel had cash and cash equivalents of EUR 41.5 million (USD 48.6 million).

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 dual 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 Poxel and Sumitomo Dainippon Pharma Strategic Partnership

Poxel and Sumitomo Dainipppon Pharma have a strategic partnership for the development and commercialization of Imeglimin in Japan, China, South Korea, Taiwan and nine other Southeast Asian countries.[2] The Imeglimin Phase 3 TIMES program was successfully completed in December 2019. On July 30, 2020, Poxel announced that Sumitomo Dainippon Pharma submitted a J-NDA to the Pharmaceuticals and Medical Devices Agency (PMDA) to request approval for manufacturing and marketing of Imeglimin for the treatment of type 2 diabetes. The Imeglimin J-NDA is supported by numerous preclinical and clinical trials, including the Phase 3 TIMES (**T**rials of **IM**eglimin for **E**fficacy and **S**afety) program in Japan. The TIMES program was a joint development effort between Poxel and Sumitomo Dainippon Pharma Co., Ltd. and it included three pivotal trials to evaluate Imeglimin’s efficacy and safety in over 1,100 patients. In all three trials, Imeglimin met its primary endpoints and objectives and was observed to exhibit a favorable safety and tolerability profile.

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. **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 streamlined Phase 2 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.

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

[2] including Indonesia, Vietnam, Thailand, Malaysia, The Philippines, Singapore, Republic of the Union of Myanmar, Kingdom of Cambodia and Lao People's Democratic Republic.

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