

January 14, 2021



Poxel Regains Imeglimin Rights From Metavant

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, as part of the previously communicated decision by Metavant not to advance Imeglimin into a Phase 3 program for strategic reasons, its partnership agreement with Metavant will be terminated, effective January 31, 2021. Metavant will return all rights to Imeglimin to Poxel, as well as all data, materials, and information, including FDA regulatory filings, related to the program. Metavant is not entitled to any payment from Poxel as part of the return of the program.

“We remain convinced of Imeglimin’s value as an innovative new drug for type 2 diabetes. A New Drug Application in Japan (J-NDA) is currently advancing through regulatory review with our partner Sumitomo Dainippon Pharma, and a target product launch is anticipated in fiscal year 2021¹. Moving forward, we are considering various options to advance Imeglimin in the US, Europe and other countries not covered by our agreement with Sumitomo Dainippon Pharma and we are looking forward to updating the market on our progress. In the meantime, we continue to remain focused on the further development of our metabolic disease pipeline,” said Thomas Kuhn, CEO of Poxel.

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. After successfully completing a Phase 2a proof-of-concept trial for the treatment of NASH, which met its primary endpoint and study objectives, for **PXL770**, a first-in-class direct adenosine monophosphate-activated protein kinase (AMPK) activator, Poxel plans to initiate a Phase 2b program in the second half of 2021. 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.

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

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20210114005819/en/>

Poxel SA

Aurélie Bozza

Investor Relations & Communication Director

aurelie.bozza@poxelpharma.com

+33 6 99 81 08 36

Investor relations / Media - EU/US

Trophic Communications

Stephanie May or Valeria Fisher

may@trophic.eu or fisher@trophic.eu
+49 171 185 56 82 or +49 175 804 1816

Investor relations / Media - France

NewCap

Emmanuel Huynh or Arthur Rouillé

poxel@newcap.eu

+33 1 44 71 94 94

Source: Poxel SA