May 20, 2021

Poxel Presents New Results of Imeglimin Phase 2 and 3 Clinical Studies in Japan at the 64th Annual Meeting of the Japan Diabetes Society (JDS)

- **Kaku et al. Long-term efficacy and safety in Phase 3 study with Imeglimin as mono- and add-on therapy in Japanese T2DM patients: results from TIMES 2 trial**
- **Hata et al. Post hoc analysis of Phase 2 and 3 studies of Imeglimin – similar efficacy and consistent safety in patients with different backgrounds, including elderly patients and those with renal impairment**
- **Kondo et al. Post hoc analyses of Phase 2 and 3 studies of Imeglimin – similar efficacy in patients with impaired insulin secretion or impaired insulin sensitivity**

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 presentations of new results from Imeglimin Phase 2 and 3 clinical studies at the 64th Annual Meeting of the Japan Diabetes Society, which is being held virtually (May 20-22, 2021).

Imeglimin is a novel agent that acts on both key defects in type 2 diabetes (T2DM) by improving insulin secretion in response to glucose and insulin sensitivity through a unique mode of action. These new results (summarized below) were obtained and presented by Poxel's clinical development team in collaboration with its partner, Sumitomo Dainippon Pharma and leading diabetologists in Japan.

- **TIMES 2 : Long-term efficacy and safety in Phase 3 study with Imeglimin as a mono- and add-on therapies in Japanese T2DM: results from TIMES 2 trial**
  - Open-label, non-placebo controlled, multicenter study to assess the long-term safety/efficacy of Imeglimin for 52 weeks as a mono- and add-on to other available individual antidiabetic therapies in Japanese T2DM patients
  - Adverse events were generally mild and consistent with known safety/tolerability profile; there was no severe hypoglycemia
  - Changes from baseline in HbA1c ranged from -0.56 ± 0.08 to -0.92 ± 0.11% in patients receiving Imeglimin added to other oral antidiabetics

- **Post hoc analysis of Phase 2 and 3 studies of Imeglimin – efficacy and safety in patients with different backgrounds, including elderly patients and those with renal impairment**

- Further analysis of data derived from key subgroups - based on age, renal function or body mass index (BMI) - from the completed Japanese Phase 2b and TIMES1 Phase 3 trial
- Imeglimin treatment produced similar efficacy (HbA1c reduction) regardless of age, renal function, and BMI; the safety profile was also consistent in each subgroup and in comparison with the broader population

- **Post hoc analyses of Phase 2 and 3 studies of Imeglimin – efficacy in patients with impaired insulin secretion or impaired insulin sensitivity**
  - Further analysis of data derived from the completed Japanese Phase 2b, TIMES 1 and TIMES 2 Phase 3 trials
  - Subpopulations of patients with greater or lesser degrees of insulin resistance and impaired insulin secretion were identified using standard indices (the value of HOMA-IR, QUICKI and HOMA-β at baseline, respectively or combination of these indices)
  - The effect of Imeglimin to decrease HbA1c was similar in patient subgroups with predominant insulin resistance or impaired insulin secretion

“In TIMES 2, which was the largest of our pivotal Phase 3 trials, we found that Imeglimin produced clinically meaningful and sustained reductions in HbA1c both as a monotherapy and when added to other commonly used antidiabetics” said Pascale Fouqueray, Executive Vice President of Clinical Development and Regulatory Affairs at Poxel. “Consistent with Imeglimin’s dual mechanism of action, it was also important to confirm that Imeglimin could perform well across the spectrum of pathophysiologic defects in insulin action and secretion. We are also very pleased that Imeglimin appears similarly safe and effective in subgroups with greater unmet medical need – in particular elderly patients and those with modest degrees of reduced renal function.”

Imeglimin will be also discussed in Symposium 21 “New therapies utilizing metformin and concomitant use of new drugs,” on May 22.

“We are proud of our work in Japan and we are especially pleased by our strong partnership with Sumitomo Dainippon Pharma, the leading pharmaceutical company in Japan when it comes to delivering solutions to patients with diabetes,” commented Thomas Kuhn, CEO of Poxel. “We look forward to the completion of the J-NDA review of Imeglimin and based on a typical 12-month review by the PMDA, we believe Imeglimin could be approved in mid-2021 with an anticipated product launch by our partner Sumitomo Dainippon Pharma in Fiscal Year 2021[1].”

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)**, and selected rare inherited disorders including adrenoleukodystrophy. In its mid-to-late-stage pipeline, the Company is currently advancing three drug candidates; several earlier-stage opportunities are also underway. **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.

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