September 14, 2017

Poxel Presents Results for Imeglimin Phase 2b Study in Japan for the Treatment of Type 2 Diabetes at the European Association for the Study of Diabetes 53rd Annual Meeting

- **Imeglimin Phase 2b trial in 299 Japanese patients achieved statistically significant results for its primary and secondary endpoints**
- **Poxel recently completed the End of Phase 2 Meeting for Imeglimin with Japanese regulators and plans to initiate the Phase 3 program in the fourth quarter of 2017**
- **The Japanese diabetes market is fast-growing and anticipated to reach approximately $6B by 2020***

LYON, France--(BUSINESS WIRE)-- POXEL SA (Euronext – POXEL - FR0012432516), a biopharmaceutical company focused on the development of innovative therapies for metabolic disorders, including type 2 diabetes, announced that results from the Imeglimin Phase 2b study in Japan will be presented today in the Novel Approaches to Glucose-Lowering Session in Poster 843 from 1:15-2:15 pm in the Poster Hall at the European Association for the Study of Diabetes (EASD) 53rd Annual Meeting. This scientific meeting is being held from September 11-15th in the Parque das Nações, at the International Fair of Lisbon in Portugal.

"The strong efficacy and favorable safety profile of Imeglimin observed in this study suggests that it could be particularly well-suited for Japanese patients," said Professor Kohjiro Ueki, MD, PhD, Director, Diabetes Research Center, Research Institute, National Center for Global Health and Medicine, Tokyo, Japan. "Diabetes is a growing health concern in Asia and Imeglimin has the potential to become an innovative new treatment option for Japanese patients to manage their type 2 diabetes."

"Japan is a key focus and an integral part of our business strategy. We believe that Imeglimin's unique profile could be very attractive given the specific needs of this important marketplace and the pathophysiology of Japanese patients," said Thomas Kuhn, CEO of Poxel. "Due to Imeglimin's safety and efficacy profile, it has the potential to be used as first-line therapy for type 2 diabetes in Japan for treatment naïve patients or in combination with other glucose lowering therapies, as well as for the elderly and sensitive populations."

“We recently met with the Pharmaceuticals and Medical Devices Agency in Japan for the Imeglimin End of Phase 2 Meeting to discuss our Phase 3 program. Based on the interactions with Japanese regulators and feedback from this meeting, we plan to initiate the Phase 3 program for Imeglimin in Japan during the fourth quarter of this year,” continued Thomas Kuhn.

Imeglimin Results for the Phase 2b Study in Japan

The Phase 2b randomized, double-blind, placebo-controlled study tested three doses of Imeglimin (500 mg, 1000 mg and 1500 mg) administered twice-daily for 24 weeks in 299 Japanese patients for the treatment of type 2 diabetes. In this study, the primary endpoint achieved statistical significance ($p<0.0001$) for the change from baseline in glycated hemoglobin (HbA1c) versus placebo in all treatment groups at 24 weeks. Placebo-adjusted HbA1c reduction was 0.52%, 0.94% and 1.00% for the 500 mg, 1000 mg and 1500 mg dose twice-daily, respectively.

In this study, consistent, statistically significant ($p<0.0001$) decreases at the top two doses in the key secondary endpoints of fasting plasma glucose, glycated albumin and percentage of patients reaching a target HbA1c of less than 7% were also achieved. A statistically significant dose dependent (500 mg $p=0.008$,1000 mg $p=0.0008$, and 1500 mg $p<0.0001$) improvement of the homeostasis model assessment of beta-cell function (HOMA-B), a marker of beta cell function in fasting condition, was also observed. In addition, there was a significant decrease in two of the most relevant liver enzymes, alanine aminotransferase (ALT) and gamma-glutamyl transferase (GGT), which are considered biomarkers in liver disease. The ALT and GGT results are consistent with previously published data in animal models.

“We are extremely pleased with the robust efficacy shown in this study. We believe that Imeglimin’s positive effect on beta cell function is very meaningful and could be particularly important for Japanese patients with type 2 diabetes,” said Pascale Fouqueray, MD, PhD, Executive Vice President, Early Development & Translational Medicine of Poxel. “The additional data demonstrating an improvement in liver enzymes are promising and could represent an added benefit to type 2 diabetes patients who are at a high risk for liver disease.”

Overall, the study showed that Imeglimin was safe and well tolerated and the adverse event profile was consistent to what was observed in the U.S. and EU Phase 1 and 2 programs. No serious adverse events related to Imeglimin were reported. There was no difference in the overall incidence of patients presenting with at least one treatment emergent adverse event between treatment and placebo groups. Of particular note, in this study, the safety and efficacy of Imeglimin in patients with mild to moderate chronic kidney disease was similar to patients with normal renal function. In addition, no weight gain from Imeglimin was observed.

The poster titled “Imeglimin monotherapy in Japanese patients with type 2 diabetes: results from a randomized, 24-week, double-blind, placebo-controlled, phase IIb trial” is available on the Company’s website under “Scientific Publications” or by using the following link http://www.poxelpharma.com/en_us/product-pipeline/posters.

About Imeglimin

Imeglimin is the first clinical candidate in a new chemical class of oral agents called the Glimins. Imeglimin has a unique mechanism of action (MOA) that targets mitochondrial

bioenergetics. Imeglimin acts on the three main target organs involved in glucose homeostasis: the liver, muscle, and the pancreas. This MOA has the potential for glucose lowering benefits, as well as the potential to prevent endothelial and diastolic dysfunction, which can provide protective effects on micro- and macro-vascular defects induced by diabetes. The additional protective effect on beta-cell survival and function may lead to a delay in disease progression. This unique mode of action compared to existing treatments for type 2 diabetes makes Imeglimin a prime candidate in all stages of the current anti-diabetic treatment paradigm, including monotherapy or as an add-on to other glucose lowering therapies for the treatment of patients with type 2 diabetes.

About Poxel SA
Poxel uses its development expertise in metabolism to advance a pipeline of drug candidates focused on the treatment of metabolic disorders, including type 2 diabetes. We have successfully completed a Phase 2 clinical program for our first-in-class lead product, Imeglimin, which targets mitochondrial dysfunction, in the U.S., EU and Japan. Our second program, PXL770, a direct AMPK activator, is in Phase 1 development. We intend to generate further growth through strategic partnerships and pipeline development. (Euronext: POXEL, www.poxel.com)

* Source: Oppenheimer & Co. estimates

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Source: POXEL SA