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Poxel Announces Positive Results for Thorough QT Safety Clinical Study of Imeglimin

LYON, France--(BUSINESS WIRE)-- POXEL SA (Euronext – POXEL - FR0012432516), a biopharmaceutical company focused on the development of innovative treatments for type 2 diabetes, today announced that it has successfully completed a thorough QT/QTc (TQT) cardiac safety study on Imeglimin in 55 healthy subjects. This study assesses a drug's risk of QT prolongation and its proarrhythmic potential, which is a heart conduction disorder that can cause serious irregular heart rhythms (arrhythmias), and is a standard component of all clinical development programs for new molecular entities.

Imeglimin showed no effect on the QT/QTc interval at a dose of 2250 mg and at a higher dose of 6000 mg. In addition, this study also showed that Imeglimin had a consistent pharmacokinetic profile at the doses tested. In previous Phase 1 and Phase 2 clinical studies in over 850 subjects, Imeglimin showed no effect on the QT/QTc interval.

"These important safety study results for Imeglimin are additive to the overall excellent safety profile that we are continuing to see and to published data suggesting beneficial protective effects on diabetic cardiomyopathy and vascular dysfunction, which are major complications of type 2 diabetes," said Thomas Kuhn, CEO of Poxel. "During 2017, we expect to present further differentiating data demonstrating Imeglimin's potential for cardiovascular-related benefits, and we are on track to deliver results from the 300-patient Phase 2b study in Japan during the second quarter of 2017 that will support the start of our Phase 3 program in Japan."

About Imeglimin

Imeglimin is the first clinical candidate in a new chemical class of oral anti-diabetic agents called the Glimins. Imeglimin acts on the three main target organs involved in glucose homeostasis: the liver, muscle, and the pancreas. Imeglimin has a unique mechanism of action (MOA) that targets mitochondrial bioenergetics. This MOA has the potential for glucose lowering benefits, as well as the potential to prevent endothelial 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

Poxel uses its development expertise in metabolism to advance a pipeline of drug candidates focused on the treatment of type 2 diabetes. We have successfully completed our Phase 2 clinical program for our first-in-class lead product, Imeglimin, which targets mitochondrial dysfunction, in the U.S. and EU and have fully enrolled a Phase 2b clinical study in 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)

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