Press Release

Poxel Announces Patient Enrollment Completed for Imeglimin Phase 2b Clinical Trial in Type 2 Diabetes in Japan

Rapid patient enrollment supports Imeglimin development in second largest market for type 2 diabetes

Lyon, France, June 30, 2016 – POXEL SA (Euronext – POXEL - FR0012432516), a biopharmaceutical company focused on the development of innovative drugs to treat type 2 diabetes, today announced that it has completed patient enrollment for the Phase 2b clinical trial of Imeglimin in type 2 diabetes patients in Japan. Imeglimin is the first in a new class of oral anti-diabetic agents targeting mitochondrial bioenergetics and has completed Phase 2 development in over 850 patients in the United States and Europe.

The dose-ranging, randomized, double-blind, placebo-controlled Phase 2b study in Japan is supervised by Professor Kohjiro Ueki, MD, PhD, Department of Diabetes and Metabolic Disease at the University of Tokyo and been designed to include approximately 300 naïve and pre-treated patients. Following recruitment and a six-to-ten week washout period, patients are randomized into 24 weeks of treatment. The primary endpoint of the trial is efficacy measured by change in glycated haemoglobin HbA1c concentrations.

“I am pleased to report that we have reached another important clinical milestone as we continue to advance Imeglimin into late-stage development in Japan,” said Thomas Kuhn, CEO of Poxel. “As the second largest single market for type 2 diabetes with approximately $4 billion in annual sales and growing, Japan is a key focus for Poxel and we are excited with our progress. We are on track to report the Phase 2b results during the first half of next year.”

“Imeglimin’s dual mechanism of action clearly differentiates it from other anti-diabetic agents. In clinical trials to date, Imeglimin has been observed to act on the key defects of type 2 diabetes and improve insulin sensitivity and insulin secretion, and it is also expected to slow disease progression by protecting beta cell dysfunction and death,” said Pascale Fouqueray, MD, PhD, Executive Vice President, Clinical Development of Poxel. “We believe that Imeglimin has the potential to address the large inherent needs of the type 2 diabetes market.”

Poxel has worked in close collaboration with the Japanese Pharmaceutical and Medical Device Agency (PMDA) to plan for the Phase 3 development program in Japan, which Poxel expects to be in the position to initiate during the second half of 2017.

Poxel’s Imeglimin program in Japan is being supported by a Japanese Scientific Advisory Board (SAB) in diabetes research. The SAB members have worked with Poxel in guiding the Company’s regulatory interactions and clinical development plans. The members include:

- Pr. M. Kasuga, President of the National Center for Global Health and Medicine in Tokyo;
- Pr. K. Ueki, Professor of the Department of Molecular Sciences on Diabetes of Tokyo University; and
- Pr. H. Watada, Professor of the Department of Medicine, Metabolism and Endocrinology of the Juntendo University in Tokyo

New data were presented on Imeglimin during two poster presentations at the American Diabetes Association's 76th Scientific Sessions, held June 10th–14th in New Orleans, Louisiana. Two preclinical studies highlighted Imeglimin's novel and unique mechanism of action and further elucidated the specific pathways through which Imeglimin may improve insulin secretion and action. The posters can be found in the Our Science/Scientific Publications section of the Company's website.

About Imeglimin

Imeglimin is the first in a new chemical class of oral anti-diabetic agents, the Glimins. Imeglimin acts on three main target organs involved in glucose homeostasis: the liver, muscle, and the pancreas. Imeglimin's unique mechanism of action targets mitochondrial bioenergetics. This distinct mode of action compared to existing treatments for type 2 diabetes makes Imeglimin a prime candidate in monotherapy and to complement other treatments, such as metformin or sitagliptin.

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 trials for our first-in-class lead product, Imeglimin, which targets mitochondrial dysfunction, in the U.S. and EU and have entered Phase 2b clinical development in Japanese patients. We are advancing our second program, PXL770, a direct AMPK activator, which is in Phase 1 development. We intend to generate further growth through strategic partnerships and pipeline development. (Euronext: POXEL, www.poxel.com).

Contacts

Poxel SA
Jonae R. Barnes
Senior Vice President, Investor Relations and Public Relations
jonae.barnes@poxelpharma.com
+1 617 818 2985

Investor relations / Media - EU/US
MacDougall Biomedical Communications
Gretchen Schweitzer or Stephanie May
smay@macbiocom.com
+ 49 89 2424 3494 or + 49 175 571 1562

Investor relations / Media - France
NewCap
Florent Alba/Nicolas Mérigeau
poxel@newcap.fr
+ 33 1 44 71 98 55