May 4, 2017

Poxel Announces Positive Top Line Results for Imeglimin Phase 2b Study in Japan for the Treatment of Type 2 Diabetes

- **Imeglimin Phase 2b trial in 299 Japanese patients achieved statistical significance for the primary and key secondary endpoints**
- **Imeglimin Phase 3 program in Japan is anticipated to initiate 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 drugs to treat metabolic diseases, including type 2 diabetes, announced today positive top line Phase 2b data results for Imeglimin for the treatment of type 2 diabetes in Japan.

The randomized, double-blind, placebo-controlled study of Imeglimin administered twice-daily for 24 weeks, demonstrated dose-dependent efficacy on two key measures of diabetes control in 299 Japanese patients. The trial achieved statistical significance ($p<0.0001$) for its primary endpoint of glycated hemoglobin A1c reduction versus placebo in all treatment groups at 24 weeks. In the study, hemoglobin A1c reduction was 0.52%, 0.94% and 1.00% for the 500 mg, 1000 mg and 1500 mg dose twice-daily, respectively. The level of reduction of hemoglobin A1c for Imeglimin was even more pronounced in the Japanese Phase 2b data than what has previously been shown in the U.S. and EU Phase 2b data.

For the study's key secondary endpoint of a decrease in Fasting Plasma Glucose (FPG), the top two Imeglimin doses of 1000 mg and 1500 mg achieved statistical significance ($p<0.0001$) versus placebo at 24 weeks. Analyses of data for the additional secondary endpoints are ongoing. In this study, Imeglimin was shown to be 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.

The Company anticipates meeting with the Pharmaceuticals and Medical Devices Agency in Japan during the third quarter, and pending feedback from the meeting, the Company plans to be in the position to advance Imeglimin into a Phase 3 program in Japan during the fourth quarter of 2017.

"The strong efficacy of Imeglimin observed in this study suggests that its innovative mechanism of action may play an important role in the treatment of type 2 diabetes and could be particularly well-suited for Japanese patients," said Pascale Fouqueray, MD, PhD, Executive Vice President, Early Development & Translational Medicine of Poxel. "Imeglimin has been successfully studied in over 1,200 subjects and has shown a differentiated product profile combined with favorable safety, and we believe that it has the potential to address the large and growing needs of the type 2 diabetes market."

"We are very pleased with these results and are actively preparing for the Imeglimin Phase 3 program in Japan. The Phase 3 program is anticipated to include 3 pivotal trials as well as non-pivotal studies in specific patient populations to further differentiate Imeglimin from other approved therapies in Japan," said Christophe Arbet-Engels, MD, PhD, MBA, Chief Medical Officer and Executive Vice President, Late Development & Medical Affairs of Poxel. "Diabetes is a growing health concern in Asia and with these data results we are encouraged that Imeglimin could become an innovative new treatment option for Japanese patients to manage their type 2 diabetes."

"This is a significant milestone for Poxel. Japan is a key focus and is an integral part of our business strategy, especially with the unique treatment paradigm for innovative therapies. In Japan, we believe Imeglimin may be a prime candidate for first-line treatment as monotherapy and as an add-on to other glucose lowering therapies for the treatment of patients with type 2 diabetes," said Thomas Kuhn, CEO of Poxel. "Japan represents the second largest single market for type 2 diabetes and is expected to grow to approximately $6 billion in annual sales in 2020*. Asia, in broader terms, is considered the most important geographic location with regards to treating the diabetes pandemic in the future."

Poxel anticipates presenting the full data results of the Phase 2b study in Japanese patients at scientific meetings during the second half of 2017.

Poxel will host an investor conference call today to discuss the Phase 2b data results at 7 pm Central European Summer Time (1 pm Eastern Daylight Time). To participate in the call, please use the dial-in numbers below.

FR: +33(0)170770944
UK: +44 - 2033679459
US: +1 855-402-7764

Replay Number:
FR: +33(0)172001500
UK: +44 - 2033679460
US: +1 877-642-3018
REF: 308776#

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 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

View source version on businesswire.com:
http://www.businesswire.com/news/home/20170503006386/en/

Poxel SA
Jonae R. Barnes, +1 617 818 2985
Senior Vice President, Investor Relations and Public Relations
jonae.barnes@poxelpharma.com
or
Investor relations / Media - EU/US
MacDougall Biomedical Communications
Gretchen Schweitzer or Stephanie May, + 49 89 2424 3494 or + 49 175 571 1562
smay@macbiocom.com
or
Investor relations / Media - France
NewCap
Florent Alba/Nicolas Mérigeau, + 33 1 44 71 98 55
poxel@newcap.fr

Source: Poxel SA