June 6, 2015

Poxel's Novel Anti-diabetic Agent Imeglimin Meets Glycemic Endpoints in Phase 2b Dose-Ranging Trial

--Full Data Analysis Confirming Advantageous Profile of First-in-Class Type 2 Diabetes Treatment Presented at the ADA 75th Scientific Sessions--

BOSTON--(BUSINESS WIRE)-- POXEL SA (Euronext: POXEL), a biopharmaceutical company developing innovative drugs to treat type 2 diabetes, today presented data at the American Diabetes Association (ADA) 75th Scientific Sessions showing that its lead candidate, the first-in-class oral anti-diabetic agent Imeglimin, has met glycemic endpoints in a dose-ranging study conducted in 382 subjects, with a statistically significant reduction in the HbA1c (plasma glucose) of 0.63 percent. These results provide a full analysis of the trial's top line data as announced in December 2014 and corroborate beneficial safety and tolerability data seen for Imeglimin in all previously conducted trials. The data were selected for presentation on a Guided Audio Poster Tour in addition to the main poster presentation.

"This positive Phase 2b trial confirms that Imeglimin holds great promise through both its success in meeting the trial's endpoints and its excellent safety/tolerability profile," said Professor Harold Lebovitz, Professor of Medicine in the Division of Endocrinology and Metabolism/Diabetes at State University of NY, Brooklyn, and a member of Poxel's Scientific Advisory Board. "The study underscores Imeglimin's potential as a truly innovative treatment for type 2 diabetes, as both an effective monotherapy and combination therapy with the current standard of care."

The study assessed the efficacy and tolerability of four doses of Imeglimin versus placebo in type 2 diabetes patients that were either naïve to treatment (25%) or previously managed with oral monotherapies (75%), mainly metformin. After a wash-out run-in period of three to six weeks, 382 subjects were randomized and treated for 24 weeks in a double-blind manner. The primary efficacy endpoint was the placebo-subtracted dose-dependent reduction in HbA1c from baseline. The study was conducted in eight countries, both in Europe and in the US.

A statistically significant dose-dependent decrease in HbA1c (-0.63%, $P<0.001$) was observed, with the maximal effect being reached at the dose of 1500 mg twice daily after 18 weeks of treatment. Significant placebo-subtracted reductions in fasting plasma glucose (FPG) were also observed for the 1500 mg (–1.25 mmol/L or 22.5 mg/dL, $P=0.001$) and 2000 mg groups (–0.81 mmol/L or 14.6 mg/dL, $P=0.029$). A significantly greater proportion of patients achieved an HbA1c ≤7% with in the 1500 mg group (33.3%, $P=0.005$), compared with placebo. No subjects required rescue treatment during the course of the study.

All doses of Imeglimin were well tolerated with a safety profile comparable to placebo. No treatment-emergent serious adverse events related to Imeglimin or placebo were reported in the study at this dose.

“Importantly, the study confirms that at 1500 mg twice-daily Imeglimin is most active and well-tolerated, making it the optimal dose for Phase 3 development,” said Pascale Fouqueray, MD/PhD, CMO of Poxel, who presented the study. “With these promising results for Imeglimin, Poxel has achieved a major clinical development milestone and we are grateful for the validation of presenting the study at ADA amongst the global experts in diabetes research”.

About Imeglimin

Imeglimin is the first in an entirely novel chemical class of oral anti-diabetic agents, the Glimins. Imeglimin’s unique mechanism of action targets mitochondria bioenergetics, thus improving mitochondrial function, resulting in improving both glucose-dependent insulin secretion and insulin action. Additionally, Imeglimin is able to fully protect beta cells or endothelial cells from death induced by oxidative stress. Imeglimin acts on three main target organs involved in glucose homeostasis: the liver, muscle, and the pancreas. This distinct mode of action compared to existing treatments for type 2 diabetes makes Imeglimin a prime candidate to complement other treatments. Imeglimin has recently been evaluated in a large Phase 2b study in Europe and the US, a second 18-week Phase 2 trial in Europe, as well as in a Phase 1 trial in Japanese subjects.

About Type 2 Diabetes

Type 2 Diabetes is the most common type of diabetes. It usually occurs in adults, but is increasingly seen in children and adolescents. In Type 2 Diabetes, the body is able to produce insulin but it is either not sufficient or the body does not respond to its effects, leading to a build-up of glucose in the blood. Type 2 Diabetes is a major cause of both cardiovascular and kidney diseases. The number of people with Type 2 Diabetes is rising rapidly worldwide. This rise is associated with economic development, ageing populations, increasing urbanization, dietary changes, reduced physical activity and changes in other lifestyle patterns. The International Diabetes Federation estimates that in 2014, 387 million people around the world had diabetes. This total is expected to rise to 592 million in 2035. Each year an additional 7 million people develop diabetes. The current market is dominated by a few product classes and significant unmet needs remain for both physicians and patients. The worldwide pharmaceutical market for Type 2 Diabetes, 60% of which is represented by oral anti-diabetics, is expected to increase from $26 billion in 2011 to $49 billion in 2021 (source: IMS audits).

About Poxel SA

Poxel uses its unique development expertise in metabolism to advance a pipeline of truly novel products currently focused on type 2 diabetes. Our first-in-class lead product, Imeglimin, targeting mitochondrial dysfunction, has successfully completed Phase 2 development in the US and EU and has entered clinical development in Japanese subjects. We are advancing our second program, PXL770, a direct AMPK activator, through clinical proof-of-concept. We will generate further growth through strategic partnerships and pipeline development. (Euronext: POXEL, www.poxel.com)

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