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Poxel Announces Additional Positive Phase 2 Results Establishing Unique Glucose-Control Features of Imeglimin in Type 2 Diabetes

--Imeglimin improves both fasting and post-prandial glucose control by increasing glucose-dependent insulin secretion and improving insulin action--

--New trial confirms Phase 2b clinical trial results and dual novel mechanistic approach--

LYON, France--(BUSINESS WIRE)-- POXEL SA (Euronext:POXEL), a biopharmaceutical company developing innovative drugs to treat type 2 diabetes, today announced positive results from a new Phase 2 trial evaluating Imeglimin, the Company's first-in-class oral anti-diabetic agent. The results demonstrate that Imeglimin met the primary and secondary endpoints with statistical significance, while confirming safety and efficacy. This Phase 2 trial was an 18-week, randomized, placebo controlled trial in 59 subjects that were treated with either 1500mg of Imeglimin twice daily or placebo.

In this trial, Imeglimin improves both fasting and post-prandial glucose control by increasing glucose-dependent insulin secretion and by improving insulin action. This unique profile translates into a significant HbA1c (glucose control) reduction of 0.62% (p=0.013) versus placebo, confirming Phase 2b and add-on therapy trial results. A significant effect on post-prandial glucose (reduction of 804 mmol.h/L, p=0.001) and on fasting plasma glucose was shown after treatment with Imeglimin (reduction of 1.22mmol/L, p=0.022). Imeglimin was also able to significantly increase insulin secretion and insulin sensitivity indexes in response to glucose during a challenge test.

"In this sophisticated study, Poxel succeeded in showing for the first time in a single trial Imeglimin's ability to target both insulin secretion and insulin sensitivity with a balanced effect between fasting plasma glucose and post-prandial glucose," commented Harold E. Lebovitz, Professor of Medicine in the Division of Endocrinology and Metabolism/Diabetes at State University of NY, Health Sciences Center, Brooklyn, and a member of Poxel's Scientific Advisory Board. "This distinctive mode of action clearly sets Imeglimin apart from other anti-diabetic agents as it is able to beneficially act on both key defects of type 2 diabetes."

Consistent with the previously released Phase 2b results, as well as results from earlier trials evaluating Imeglimin as an add-on therapy to metformin or sitagliptin, Imeglimin

demonstrated in this Phase 2 trial a favorable safety and tolerability profile with less subjects presenting one or more adverse events (AE) when treated with Imeglimin compared to placebo (27% versus 59%). Only one treatment-related AE (hyperglycemia) was described for the Imeglimin group, versus five in the placebo group. No drug-related serious AEs, hypoglycemia, or gastrointestinal events occurred in the Imeglimin group and no subject discontinued the trial for safety reasons.

“These results are highly encouraging, as the data from this trial further strengthen Imeglimin’s unique profile for managing type 2 diabetes” added Thomas Kuhn, CEO of Poxel. “Through these successful results, which greatly complement our previous data, we made another important step towards achieving our strategic goals.”

Full results from the Company’s US and EU Phase 2b Imeglimin study for which Poxel has presented topline data in December 2014, will be presented at the upcoming American Diabetes Association (ADA) 75th Scientific Sessions in Boston, MA on June 6 and 7, 2015.

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 2011, 366 million people around the world had diabetes. This total is expected to rise to 552 million in 2030. Each year a further 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 $31 billion in 2012 to $48.8 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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