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Poxel Announces Positive Top Line Results for Its Antidiabetic Agent Imeglimin in a Phase 2b Dose-Ranging Trial

Phase 2b trial achieved primary and secondary glycemic endpoints; Results indicate Imeglimin's target dose for phase 3 development and confirm the product's safety and tolerability

LYON, France--(BUSINESS WIRE)-- Poxel SA today announced that Imeglimin, a novel compound in development to treat Type 2 Diabetes, demonstrated dose-dependent efficacy on two key measures of diabetes control in a phase 2b trial conducted in both treatment-naïve patients and patients previously treated with a diabetes monotherapy. The trial achieved its primary endpoint of HbA_{1c} reduction versus placebo ($p<0.001$), and significant decrease in FPG (Fasting Plasma Glucose) ($p<0.006$) at a dose of 1500mg, which will be the dose Poxel will advance into a phase 3 development program.

This phase 2b trial assessed the efficacy and safety profile of 4 doses of Imeglimin in 382 patients after 24-week treatment. In addition to the HbA1C and FPG reductions obtained with the 1500mg dose, the number of responders (defined as patients achieving an HbA1C below 7% at the end of the treatment) was statistically significant ($p=0.005$) and no patient required rescue therapy ($p=0.01$) during the trial's duration. The overall safety and tolerability profile was positive in all Imeglimin groups, with a similar overall incidence of adverse events between treatment groups and placebo group. The trial reported no serious adverse events related to the treatment with Imeglimin. Poxel anticipates reporting final analysis of the trial data at an international scientific meeting in 2015.

Professor Valdis Pirags, Principal Investigator and member of the Faculty of Medicine University of Latvia, commented, "*These data further support the therapeutic profile of Imeglimin we have reported to date and provide hope at a time when physicians are seeking new therapeutic options for helping patients to control their disease.*"

"Imeglimin shows great promise with this positive phase 2b trial for both its success in meeting the trial's endpoints and its safety/tolerability profile. These data confirm the potential of this agent that was also demonstrated as an add-on treatment to the two main marketed products, metformin and sitagliptin," said Professor Harold Lebovitz, Professor of Medicine in the Division of Endocrinology and Metabolism/Diabetes at State University of NY, Brooklyn, and a prominent member of Poxel's Scientific Advisory Board.

Thomas Kuhn, CEO of Poxel added, *"With this initial analysis, Poxel has reached a key milestone, confirming the potential of its most advanced asset, Imeglimin, and allowing the company to advance to late-stage clinical trials. These results are also instrumental in achieving our goals as a company."*

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 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 the mitochondria bioenergetics. This distinct mode of action compared to existing treatments for Type 2 Diabetes makes Imeglimin a prime candidate to complement other treatments. Imeglimin phase 2a monotherapy results were published in *Diabetes, Obesity and Metabolism* in April 2012. In October 2011, Poxel reported phase 2 results of Imeglimin as add-on therapy to metformin in patients inadequately controlled with metformin monotherapy. This study achieved its primary end-point of superiority in HbA1c reduction versus placebo ($p<0.001$). The study results are published in *Diabetes Care*. In November 2012, Poxel reported phase 2 results of Imeglimin as add-on therapy to sitagliptin in patients inadequately controlled with sitagliptin monotherapy. This study achieved its primary end-point of superiority in HbA1c reduction versus placebo ($p<0.001$). The study results are published in *Diabetes Care*.

About Poxel SA

Poxel, founded in 2009, is a biopharmaceutical company developing innovative first-in-class drugs, with a primary focus on Type 2 Diabetes. The company develops novel treatments before seeking pharmaceutical industry partners. Poxel was spun out from Merck Serono and now operates independently as a lean organization with strong in-house drug development and business expertise.

Poxel's product pipeline consists of several first-in-class Type 2 Diabetes candidates, including Imeglimin, a direct activator of AMPK, which is close to phase 1 development, and several early-stage assets for the treatment of Type 2 Diabetes.

For more information, please visit www.poxel.com

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