Poxel's Anti-diabetic Imeglimin Shows Significant Clinical Benefits in Type 2 Diabetes when Added to Sitagliptin

Phase II study achieved primary and secondary endpoints; Imeglimin brings incremental efficacy on top of sitagliptin; and is safe and well tolerated

Lyon, France, 5 November 2012, - Poxel SA today announced that in a Phase II study Imeglimin, a novel compound in development for Type 2 diabetes, showed incremental efficacy as an add-on therapy to sitagliptin, in patients inadequately controlled by sitagliptin monotherapy. The study achieved its primary endpoint of superiority in HbA_{1c} (blood sugar levels) reduction versus placebo ($p<0.001$), and the decrease in FPG (Fasting Plasma Glucose) was also statistically significant ($p<0.006$). Reduction in HbA_{1c} and FPG are two important measures of diabetes control.

Data from the Phase II trial assessed the clinical benefit of adding imeglimin to sitagliptin in 150 patients. The trial demonstrated that in 12 weeks, patients in the imeglimin-sitagliptin treatment group experienced 0.73% reduction in HbA_{1c} versus placebo. More patients responded to the imeglimin-sitagliptin treatment than to the sitagliptin-placebo treatment ($p<0.001$). The overall safety and tolerability profile in the imeglimin-sitagliptin group was excellent.

Professor Valdis Pirags, Principal Investigator, commented: *"I am pleased to see this study meeting its end-points. Imeglimin is effective as add-on therapy to sitagliptin with a great safety/tolerability profile. Combinability associated to safety is essential for new products to tackle type 2 diabetes."*

"The results from this add-on study are impressive. They do confirm the attractiveness of Imeglimin for both regulators and future prescribers: the molecule is unique and demonstrates its great efficacy potential in monotherapy as in combination with the two most important molecules on the treatment armamentarium today, metformin and sitagliptin", said Professor Harold Lebovitz, a prominent member of Poxel's scientific advisory board.

Thomas Kuhn, CEO of Poxel added: *"In just two years since our first round of financing, the Company has now completed two successful phase II clinical trials with Imeglimin. This second positive clinical trial demonstrates Imeglimin's potential to complement the efficacy of major drugs, which brings further value to our compound and added confidence in its further development. Within the type 2 diabetes landscape, Imeglimin is ahead in a race where new entrants have yet to prove their efficacy, their combinability and their safety."*

The full study results will be submitted soon to a diabetes peer-reviewed journal.

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 and has therefore a distinct mode of action compared to existing treatments for Type 2 diabetes. In that, it looks like the best partner to complement other treatments. Imeglimin phase 2a monotherapy results were published in *Diabetes, Obesity*

and Metabolism in April 2012. In October last year, 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 ($p<0.001$). It was presented as a poster during the 73rd edition of the American Diabetes Association meeting in Philadelphia last June and is already accepted for publication in *Diabetes Care*.

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 is not responding 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 urbanisation, 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 have 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 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 nearly double from $26 billion in 2011 to $48.8 billion in 2021.

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 drug candidates to clinical proof-of-concept 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 expertise.

Poxel's product pipeline consists of several first-in-class Type 2 diabetes candidates, including Imeglimin in Phase II development. A direct activator of AMPK is in pre-clinical development for the treatment of Type 2 diabetes.

For more information, please visit www.poxel.com

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