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New Clinical Results for an Anti-Diabetic Compound in Development at Poxel

Poxel's Novel Compound Imeglimin Shows Significant Benefits in Type 2 Diabetes When Added to Metformin

LYON, FRANCE -- (MARKET WIRE) -- 10/26/11 -- Poxel SA today announced that Imeglimin, a novel compound in development for Type 2 diabetes, showed incremental efficacy as an add-on therapy to metformin, the reference first-line treatment, in patients inadequately controlled by metformin monotherapy. The study achieved its primary endpoint of superiority in HbA1c reduction versus placebo (p less than 0.001), and the decrease in FPG (Fasting Plasma Glucose) was also statistically significant (p less than 0.001). Reduction in HbA1c and FPG are two important measure of diabetes control.

Data from this Phase II trial assessing the clinical benefit of adding imeglimin to metformin demonstrate that in 12 weeks, patients in the imeglimin-metformin treatment group experience a -0.65 % reduction in HbA1c versus baseline. Moreover, the initial results indicated a trend towards reduced BMI (body mass index) and waist circumference, further indications of diabetes control. The overall safety and tolerability profile in the Imeglimin-metformin group was good.

Professor Valdis Pirags, Principal Investigator, commented, "I am pleased to see how positive these findings are. The results are exciting and we wait to further contribute to the development of this compound."

"The results from this add-on study are extremely encouraging, and I am confident that further development trials will reinforce the conclusion that Imeglimin is a safe and efficacious treatment option for diabetic people. There is still a need for new medications to control their disease," said Professor Harold Lebovitz, a distinguished member of Poxel's scientific advisory board.

Thomas Kuhn, CEO of Poxel added, "Based on all data available to date, Imeglimin has the potential to become the second-line treatment of choice for Type 2 diabetes, either as a monotherapy or in combination with other treatments. These new clinical data represent an additional key milestone in the development of Imeglimin and add to the value of our lead compound."

The full study results will be presented at leading diabetes congresses in 2012.

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, the muscle, and the pancreas and has therefore a distinct mode of action compared to existing treatments for Type 2 diabetes. Imeglimin has shown a significant anti-diabetic efficacy combined with an excellent tolerance in earlier monotherapy clinical trials.

About Type 2 Diabetes

Type 2 diabetes is defined by a failure of sensitive tissues to respond to insulin, a hormone involved in glucose and fatty acid metabolism. The World Health Organization (WHO) estimates that Type 2 diabetes comprises 90% of diabetic patients worldwide. There are increasing reports of children developing Type 2 diabetes, which mainly occurs after the age of 40 years.

The International Diabetes Federation estimates that in 2009, 285 million people around the world have diabetes. This total is expected to rise to 438 million within 20 years. 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 disease impacts industrialized countries most strongly, but changes in lifestyle, including in developing countries, have led to a dramatic increase in obesity worldwide, a significant risk factor for developing Type 2 diabetes. The worldwide pharmaceutical market for Type 2 diabetes, 75% of which is represented by oral anti-diabetics, is expected to nearly double from $20 billion in 2009 to $36 billion in 2019.

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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