First Patient In for Poxel's Imeglimin Phase IIb Monotherapy Trial to Treat Type 2 Diabetes

Lyon, France, March 7, 2013, - Poxel SA, today announced the initiation of a phase IIb clinical trial of Imeglimin, a novel compound in development for Type 2 diabetes. The first patient was included in the trial which will span USA and Europe. The trial will assess the dose-response of Imeglimin at four dose levels compared to placebo in Type 2 diabetes patients after 24 weeks of treatment, using the change in glycosylated hemoglobin (HbA1c) as the primary endpoint.

Over 350 patients are expected to be tested in the multi-center, double-blind, placebo-controlled, randomized study with five parallel groups, four Imeglimin groups and one placebo group. Secondary endpoints of the trial include the optimal dose and activity of Imeglimin compared to placebo on other glycemic and non-glycemic parameters. Furthermore, this phase IIb trial will assess the tolerability and safety of Imeglimin compared to placebo.

Thomas Kuhn, CEO of Poxel noted: "This is a very important milestone for Imeglimin and Poxel; we have already proved Imeglimin as an excellent add-on therapy to the standard treatments for Type 2 diabetes. With this trial including over 350 patients, it is our intention to confirm Imeglimin's efficacy in monotherapy, and complete our data package for partnering discussions."

The main patient inclusion criteria for the trial are: either men or women aged between 18 and 75 years of age with Type 2 diabetes, who at the time of screening are either not on anti-diabetic agents or treated with oral anti-diabetic monotherapy, including metformin, sulfonylurea, dipeptidyl peptidase 4 (DPP- 4) inhibitors, glinide or acarbose. Some patients presenting with a mild to moderate renal impairment will also be recruited in the trial.

Imeglimin represents a new treatment option for Type 2 diabetic patients, for whom a significant unmet need remains. To date more than 400 subjects have been treated in clinical trial settings, which proved Imeglimin effective, safe and well tolerated.

About Imeglimin

Imeglimin is the first in a new chemical class of oral anti-diabetic agents, the Glimins. Imeglimin has a mitochondrian-based mechanism of action, targeting the respiratory chain. Through this new mechanism, Imeglimin acts on the three key defects of Type 2 diabetes, inhibiting hepatic gluconeogenesis, increasing muscle glucose uptake and restoring normal insulin secretion. Imeglimin phase IIa monotherapy results were published in *Diabetes, Obesity and Metabolism* in April 2012. In November 2012, Poxel reported phase II results of Imeglimin as an add-on therapy to sitagliptin in patients inadequately controlled with sitagliptin monotherapy. The study achieved its primary endpoint of reducing HbA1c from baseline to week 12 vs. placebo plus sitagliptin. Specifically, Imeglimin led to a significant reduction in HbA1c compared to placebo ($p<0.001$). Imeglimin also met the secondary end- point of reducing fasting plasma glucose (FPG) from baseline to week 12 vs. placebo ($p<0.006$). In October 2011, Poxel reported phase II 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 ($p<0.001$). This trial was published online ahead of print in *Diabetes Care*. Thanks to its mode of action and its great safety and tolerability profile, Imeglimin appears as an excellent partner to complement current major anti-diabetic treatments.

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 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 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. It 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 products, including Imeglimin in phase II development. Recently, Imeglimin has also shown significant clinical benefits in Type 2 diabetes, when added to sitagliptin. The Phase II study achieved the primary and secondary endpoints. Previously, Imeglimin has shown incremental efficacy as an add-on therapy to metformin, in patients inadequately controlled by monotherapy. In addition, Poxel develops direct AMPK activator compounds with one being close to entering phase I clinical trials for the treatment of Type 2 diabetes.

For more information, please visit www.poxel.com.

Media Contacts

Poxel SA
Mrs. Pascale Malgouyres
Business Development and Marketing Director
Phone: +33 437 372 012
Email: pascale.malgouyres@poxelpharma.com

MC Services AG
Mr. Raimund Gabriel
Managing Partner
Phone: +49 89 2102 280
Email: raimund.gabriel@mc-services.eu