Press Release

Poxel Announces Imeglimin Phase 2b Initiation in Japan

First Clinical Site of Imeglimin Phase 2b Trial Opened in Japan, Validating the Start of the Clinical Development in this Country

PXL770 Phase 1 Trial on Track for First Read-out Mid-2016

Lyon, France, December 14, 2015 – POXEL SA (Euronext – POXEL - FR0012432516), a biopharmaceutical company focused on the development of innovative drugs to treat type 2 diabetes, today provided an update on the clinical development of its two lead pipeline assets: Imeglimin, the first in a new class of oral anti-diabetic agents, and PXL770, a direct activator of the adenosine monophosphate-activated kinase (AMPK). The first Phase 2b clinical trial site for Imeglimin has been opened in Japan, starting the planned rapid late-stage clinical development program for Imeglimin in the Japanese market. For PXL770, preparations for the start of a Phase 1 trial in Germany are on track to obtain first clinical data by mid-2016.

"The progress of our two lead assets strengthens Poxel's leading position in bringing innovative treatments to patients with type 2 diabetes. The next 12 to 18 months will be an exciting time in terms of generating key clinical data," said Thomas Kuhn, CEO of Poxel. "We are very pleased to have fruitful and ongoing interactions with the Japanese regulators on the clinical program that would enable Poxel to reach a New Drug Application in Japan in an efficient and streamlined manner, building on our robust clinical trial development program for Imeglimin in the EU/US and our strong cash position."

Thomas Kuhn added: "The PXL770 program is designed to demonstrate a differentiated safety and efficacy profile that may serve type 2 diabetes patients who also suffer from lipid abnormalities, a significant portion of all type 2 diabetes patients. Based on the site initiation schedule, we are on track to obtain the first read-out by mid-2016."

Imeglimin – On track with the start of Phase 2b in Japan

The first trial site has been opened, thereby kicking off the Phase 2b study of Imeglimin in Japan, the second largest single market for type 2 diabetes. Supervised by Professor Ueki, Department of Diabetes and Metabolic Disease, University of Tokyo, this double-blinded, placebo-controlled Phase 2b trial has been designed to include up to 300 naïve and pre-treated patients. Primary endpoint of the trial will be efficacy as measured by change in glycated haemoglobin HbA1c concentrations. Poxel expects data from this trial in the first half of 2017. Additionally, Poxel has also already started regulatory discussions with the PMDA for a subsequent Phase 3 program design and protocol.

PXL770 – Clinical development on track for first clinical data in mid-2016

Poxel recently presented promising preclinical results for PXL770 at the World Congress on Insulin Resistance, Diabetes and Cardiovascular Diseases in Los Angeles in November 2015. The Phase 1 trial will have three stages; the first will evaluate safety tolerability and pharmacokinetics of single ascending doses of PXL770, the second will evaluate safety, tolerability and pharmacokinetics after multiple ascending doses, and the third stage will investigate efficacy and target engagement triggered by PXL770. First data is expected by mid-year 2016.

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 in monotherapy and to complement other treatments such as metformin or sitagliptin.

About PXL770

PXL770 directly activates adenosine monophosphate-activated protein kinase (AMPK), an enzyme that acts as an energy sensor and regulator, maintaining cellular homeostasis, thus playing an important role in the management of diabetes. In addition to its anti-diabetic properties, PXL770 has the potential to treat lipid-related abnormalities, which are present in a vast majority of diabetic patients and are the cause of cardiovascular incidents among this population.

About Poxel

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 started Phase 2b development in Japanese patients. 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)

Contacts

Investor relations / Media - EU/US
MacDougall Biomedical Communications
Gretchen Schweitzer or Stephanie May
smay@macbiocom.com
+ 49 89 2424 3494 or + 49 172 861 8540

Investor relations / Media - France
NewCap
Florent Alba/Nicolas Mérigeau
poxel@newcap.fr
+ 33 1 44 71 98 55