September 9, 2019

Poxel Announces Symposium Presentation for Imeglimin at 55th Annual Meeting of the European Association for the Study of Diabetes

Detailed Imeglimin Phase 3 TIMES 1 results to be presented at EASD; session chaired by Ralph DeFronzo, M.D., leading academic diabetes expert

LYON, France--(BUSINESS WIRE)-- POXEL S.A. (Euronext – POXEL – FR0012432516), a biopharmaceutical company dedicated to the development of innovative treatments for metabolic disorders, including type 2 diabetes and non-alcoholic steatohepatitis (NASH), announced today that it will be attending and presenting a session at the 55th Annual Meeting of the European Association for the Study of Diabetes (EASD), held at the Fira Barcelona Gran Via conference center in Barcelona, Spain from September 16 – 20, 2019.

The session will be chaired by leading academic diabetes expert, Ralph DeFronzo, M.D., Professor of Medicine and Chief of the Diabetes Division at UT Health San Antonio and Deputy Director of the Texas Diabetes Institute, part of University Health System, San Antonio, Texas. The purpose of the session will be to discuss the therapeutic potential of Poxel's lead drug candidate, Imeglimin, a novel treatment approach for type 2 diabetes in various patient populations, and to present the detailed Phase 3 TIMES 1 results in Japanese patients. The session will be followed by an open Q&A.

Session Details

Session Title: Imeglimin: a first-in-class oral medication with a unique mechanism of action targeting mitochondrial bioenergetics

Speakers and Lecture Titles:

Ralph DeFronzo, M.D., Professor of Medicine and Chief of the Diabetes Division at UT Health San Antonio and Deputy Director of the Texas Diabetes Institute, part of the University Health System, San Antonio, Texas: The role of mitochondrial dysfunction in the pathophysiology of diabetes (Oral Presentation # S22.1)

Julie Dubourg, M.D., Medical Director at Poxel: Clinical evidence to support the safety and efficacy of Imeglimin in various populations of patients with type 2 diabetes (Oral Presentation # S22.2)

Date & Time: Wednesday, September 18, 2019, 12 pm – 1 pm CEST

Location: Ochoa Hall

The presentation will also be available on the EASD virtual meeting website, which can be accessed via the following link:

https://www.easd.org/virtualmeeting/home.html#!contentsessions/3117.

About the TIMES Program
TIMES (**T**rials of **Im**eglimin for **E**fficacy and **S**afety), the Phase 3 program for Imeglimin for the treatment of type 2 diabetes in Japan, consists of three pivotal trials involving over 1,100 patients. The TIMES program includes the following three trials that will be performed using the dose of 1,000 mg twice daily:

TIMES 1: A Phase 3, 24-week, double-blind, placebo-controlled, randomized, monotherapy trial to assess the efficacy, safety and tolerability of Imeglimin in Japanese patients with type 2 diabetes, using the change in HbA1c as the primary endpoint. Secondary endpoints of the trial include fasting plasma glucose, other standard glycemic and non-glycemic parameters. The TIMES 1 trial met its primary and secondary endpoints and the top-line data was reported on April 9, 2019.

TIMES 2: A Phase 3, 52-week, open-label, parallel-group trial to assess the long-term safety and efficacy of Imeglimin in Japanese patients with type 2 diabetes. In this trial, Imeglimin will be administrated orally as a monotherapy or combination therapy with existing hypoglycemic agents, including a DPP4 inhibitor, SGLT2 inhibitor, biguanide, sulphonylurea and GLP1 receptor agonist. The TIMES 2 results are expected around the end of 2019.

TIMES 3: A Phase 3, 16-week, double-blind, placebo-controlled, randomized trial with a 36-week open-label extension period to evaluate the efficacy and safety of Imeglimin in combination with insulin in Japanese patients with type 2 diabetes and inadequate glycemic control on insulin therapy. The TIMES 3 16-week portion of the trial met its primary endpoint with a favorable safety and tolerability profile observed and the top-line data was reported on June 25, 2019. The TIMES 3 36-week open label results are expected around the end of 2019.

About Imeglimin:
Imeglimin is the first clinical candidate in a new chemical class of oral agents called Glimins by the World Health Organization. Imeglimin has a unique mechanism of action (MOA) that targets mitochondrial bioenergetics. Imeglimin acts on all three key organs which play an important role in the treatment of type 2 diabetes: the liver, muscles and the pancreas, and it has demonstrated glucose lowering benefits by increasing insulin secretion in response to glucose, improving insulin sensitivity and suppressing gluconeogenesis. This MOA has the potential to prevent endothelial and diastolic dysfunction, which can provide protective effects on micro- and macro-vascular defects induced by diabetes. It also has the potential for protective effect on beta-cell survival and function. This unique MOA offers the potential opportunity for Imeglimin to be a candidate for the treatment of type 2 diabetes in almost all stages of the current anti-diabetic treatment paradigm, including monotherapy or as an add-on to other glucose lowering therapies.

About Poxel SA
Poxel uses its development expertise in metabolism to advance a pipeline of drug candidates focused on the treatment of metabolic disorders, including type 2 diabetes and non-alcoholic steatohepatitis (NASH). We have successfully completed the Phase 2 clinical program for our first-in-class lead product, Imeglimin, which targets mitochondrial dysfunction, in the U.S., Europe and Japan. Together, with our partner Sumitomo Dainippon Pharma, we are conducting the Phase 3 **T**rials of **IM**eglimin for **E**fficacy and **S**afety (TIMES) program for the treatment of type 2 diabetes in Japan. Our partner Roivant Sciences is responsible for Imeglimin's development and commercialization in countries outside of Poxel's partnership with Sumitomo Dainippon Pharma, including the U.S. and Europe. PXL770, a first in class direct adenosine monophosphate-activated protein kinase (AMPK) activator, is in a Phase 2a proof-of-concept program for the treatment of NASH. PXL770 could also have the potential to treat additional metabolic diseases. PXL065 (deuterium-stabilized R-pioglitazone), a mitochondrial pyruvate carrier (MPC) inhibitor, is in Phase 1 and being developed for the treatment of NASH. Poxel also has additional earlier-stage programs, including deuterated drug candidates for metabolic, specialty and rare diseases. We intend to generate further growth through strategic partnerships and pipeline development. (Euronext: POXEL, www.poxelpharma.com)

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Poxel SA
Jonae R. Barnes
Senior Vice President, Investor Relations and Public Relations
jonae.barnes@poxelpharma.com
+1 (617) 818-2985

Investor relations / Media - EU/US
Trophic Communications
Stephanie May or Joanne Tudorica
may@trophic.eu or tudorica@trophic.eu
+49 89 238 877 34 or +49 171 185 56 82

Investor relations / Media - France
NewCap
Alexia Faure/Arthur Rouillé
poxel@newcap.eu
+33 1 44 71 98 55

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