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Poxel Announces Completion of Patient Enrollment for TIMES 1 Trial in the Phase 3 Registration Program for Imeglimin, an Investigational Therapeutic Agent for Type 2 Diabetes, in Japan

- **Phase 3 TIMES 1 data readout is on track for the second quarter of 2019**
- **Japanese New Drug Application submission for Imeglimin targeted in 2020**
- **Diabetes is a fast-growing market in Asia and Japan is the second largest single market for type 2 diabetes outside of the U.S.; it is expected to grow to approximately $6 billion in 2020[1]**

LYON, France--(BUSINESS WIRE)-- POXEL SA (Euronext – POXEL - FR0012432516), a biopharmaceutical company focused on the development of innovative treatments for metabolic diseases, including type 2 diabetes and non-alcoholic steatohepatitis (NASH), announced today that patient enrollment for the TIMES 1 trial in the Phase 3 program for Imeglimin, an investigational therapeutic agent for type 2 diabetes, in Japan has been completed. Referred to as TIMES (**T**rials of **IM**eglimin for **E**fficacy and **S**afety), the Imeglimin Phase 3 registration program in Japan includes three pivotal trials to evaluate the efficacy and safety of Imeglimin in approximately 1,100 patients. The TIMES 1 trial is a multicenter, double-blind, placebo-controlled, randomized, monotherapy study in over 200 Japanese patients with type 2 diabetes.

“We continue to make progress advancing all three pivotal Phase 3 TIMES trials for Imeglimin in Japan and completing patient enrollment of the TIMES 1 trial is another important clinical milestone that takes us one step closer to the Phase 3 data readout in 2019,” said Thomas Kuhn, CEO of Poxel. “Enrollment of the TIMES 2 and TIMES 3 trials is anticipated to be completed during the second half of 2018. Our near-term focus in Japan is the successful execution of TIMES, and, to this end, we are working closely with our colleagues at Sumitomo Dainippon Pharma to support the Japanese New Drug Application submission anticipated in 2020.”

The TIMES program is a joint development effort between Poxel and Sumitomo Dainippon Pharma. The companies entered into a strategic partnership in October 2017 for the development and commercialization of Imeglimin in Japan, China, South Korea, Taiwan and nine other Southeast Asian countries.[2]

Imeglimin is an orally-available drug candidate with a novel mechanism of action that has been observed in clinical studies to demonstrate glucose lowering benefits by simultaneously targeting all three key organs, which play an important role in the treatment of type 2 diabetes, the liver, muscles and the pancreas. Imeglimin has demonstrated in preclinical studies the potential to address mitochondrial dysfunction, which is believed to be at the core of type 2 diabetes pathophysiology. Imeglimin has completed Phase 1 and Phase 2 development in over 1,200 subjects in the U.S., Europe and Japan.

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 approximately 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 study 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 will include other standard glycemic and non-glycemic parameters.

TIMES 2: A Phase 3, 52-week, open-label, parallel-group study to assess the long-term safety and efficacy of Imeglimin in Japanese patients with type 2 diabetes. In this study, 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.

TIMES 3: A Phase 3, 16-week, double-blind, placebo-controlled, randomized study 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.

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 will be responsible for Imeglimin's development and commercialization in countries outside of Poxel's partnership with Sumitomo Dainippon Pharma, including the U.S. and Europe. Our second program, PXL770, a first in class direct adenosine monophosphate-activated protein kinase (AMPK) activator, is in Phase 1 and we plan on developing it for the treatment of NASH. PXL770 could also have the potential to treat additional metabolic diseases. We intend to generate further growth through strategic partnerships and pipeline development. (Euronext: POXEL, www.poxelpharma.com)

[1]Source: Oppenheimer & Co. estimates.
[2]including: Indonesia, Vietnam, Thailand, Malaysia, The Philippines, Singapore, Republic of the Union of Myanmar, Kingdom of Cambodia and Lao People's Democratic Republic.

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