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Poxel and Sumitomo Dainippon Pharma Announce Initiation of Phase 3 Program for Imeglimin, an Investigational Therapeutic Agent for Type 2 Diabetes, in Japan

- **Start of Phase 3 program for Imeglimin in Japan on track as planned**
- **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.**

LYON, France & OSAKA, Japan--(BUSINESS WIRE)-- POXEL SA (Euronext – POXEL - FR0012432516, hereinafter called "Poxel"), a biopharmaceutical company focused on the development of innovative treatments for metabolic disorders, including type 2 diabetes, and Sumitomo Dainippon Pharma Co., Ltd (Head Office: Osaka, Japan; Representative Director, President and CEO: Masayo Tada; Securities Code: 4506, First Section of TSE, hereinafter called "Sumitomo Dainippon Pharma"), announced today the initiation of the Phase 3 program for Imeglimin, an investigational therapeutic agent for type 2 diabetes, in Japan. Referred to as TIMES (**T**rials of **IM**eglimin for **E**fficacy and **S**afety), the Imeglimin Phase 3 program in Japan will include three pivotal trials to evaluate Imeglimin's efficacy and safety in approximately 1,100 patients. In December 2017, the first patient was included in the TIMES 1 trial, a multicenter, double-blind, placebo-controlled, randomized, monotherapy study in over 200 Japanese patients with type 2 diabetes.

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The TIMES program is a joint development effort between Poxel and Sumitomo Dainippon Pharma. The companies announced on October 30, 2017, a strategic partnership for the development and commercialization of Imeglimin in Japan, China, South Korea, Taiwan and nine other Southeast Asian countries.*

"Initiation of the TIMES program is a major milestone for Poxel and for the development of Imeglimin with our partner Sumitomo Dainippon Pharma. Based on the success of our Phase 2 program, we have a clear roadmap for the Phase 3 TIMES program," said Thomas Kuhn, CEO of Poxel. "Our near-term focus in Japan is the successful execution of TIMES, and, to this end, we will work closely with our colleagues at Sumitomo Dainippon Pharma to

support the Japanese New Drug Application submission."

"Our commitment to diabetes patients is to continue to innovate and provide the best medicines to help them manage their disease. We are pleased to be working closely with Poxel and initiating the TIMES registration studies," said Nobuyuki Hara, Director, Executive Officer; Drug Development Division of Sumitomo Dainippon Pharma. "Diabetes is a significant area for us in Japan and we believe that Imeglimin will be a very important addition to our existing diabetes franchise."

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., EU 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, will consist of three pivotal trials involving approximately 1,100 patients. The TIMES program will include 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. We have successfully completed our Phase 2 clinical program for our first-in-class lead product, Imeglimin, which targets mitochondrial dysfunction, in the U.S., EU and Japan, and have initiated the Phase 3 TIMES program in Japan. Our second program, PXL770, a direct AMPK activator, is in Phase 1 development. We intend to generate further growth through strategic partnerships and pipeline development. (Euronext: POXEL, www.poxelpharma.com)

About Sumitomo Dainippon Pharma

Sumitomo Dainippon Pharma defines its corporate mission as "to broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide". By pouring all our efforts into the research and development of new drugs, we aim to provide innovative and effective pharmaceutical solutions to people not only in Japan but also around the world in order to realize our corporate mission. Sumitomo Dainippon Pharma aims to create innovative pharmaceutical products in the Psychiatry & Neurology area and the Oncology area, which have been designated as the focus therapeutic areas. Sumitomo Dainippon Pharma has also positioned Psychiatry & Neurology, Diabetes/Cardiovascular and Speciality areas as our focus marketing areas in Japan. For more detail, please visit our website. (URL:http://www.ds-pharma.com)

*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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