

March 13, 2018



## **Poxel Announces Initiation of TIMES 2 and TIMES 3 Trials for the Phase 3 Program for Imeglimin, an Investigational Therapeutic Agent for Type 2 Diabetes, in Japan**

- **Imeglimin Phase 3 TIMES 1, TIMES 2 and TIMES 3 trials are underway in Japan**
- **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<sup>1</sup>**

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 the initiation of the TIMES 2 and TIMES 3 trials for the Phase 3 program for Imeglimin, an investigational therapeutic agent for type 2 diabetes, in Japan. Referred to as TIMES (Trials of IMeglimin for Efficacy and Safety), the Imeglimin Phase 3 program in Japan includes three pivotal trials to evaluate Imeglimin's efficacy and safety in approximately 1,100 patients.

“Over the last few months, we have made significant progress advancing the TIMES program for Imeglimin in Japan with the initiation of all three pivotal Phase 3 trials. We are on track for the Phase 3 data readout in 2019,” said Thomas Kuhn, CEO of Poxel. “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 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.<sup>2</sup> Through this partnership, the TIMES 1 trial in Japan was initiated in December 2017.

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 (Trials of Imeglimin for Efficacy and Safety), 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 administered 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., EU and Japan. Together, with our partner Sumitomo Dainippon Pharma, we are conducting the Phase 3 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. We intend to generate further growth through strategic partnerships and pipeline development. (Euronext: POXEL, [www.poxelpharma.com](http://www.poxelpharma.com))

<sup>1</sup>Source: Oppenheimer & Co. estimates.

<sup>2</sup>including: Indonesia, Vietnam, Thailand, Malaysia, The Philippines, Singapore, Republic of the Union of Myanmar, Kingdom of Cambodia and Lao People's Democratic Republic.

View source version on businesswire.com:

<http://www.businesswire.com/news/home/20180313005167/en/>

### **Poxel SA**

Jonae R. Barnes, +1 617-818-2985

Senior Vice President, Investor Relations and Public Relations

[jonae.barnes@poxelpharma.com](mailto:jonae.barnes@poxelpharma.com)

or

### **Investor relations / Media - EU/US**

Trophic Communications

Gretchen Schweitzer, +49 89 238 877 34

or

Stephanie May, +49 171 185 56 82

[may@trophic.eu](mailto:may@trophic.eu)

or

### **Investor relations / Media - France**

NewCap

Florent Alba/Nicolas Merigeau, +33 1 44 71 98 55

[poxel@newcap.fr](mailto:poxel@newcap.fr)

Source: Poxel SA