November 26, 2019

Poxel Announces Positive Topline Results for Imeglimin Phase 3 Trial (TIMES 3 36-week) for the Treatment of Type 2 Diabetes in Japan

- **Imeglimin in combination with insulin was observed to demonstrate consistent and sustained efficacy in the TIMES 3 36-week, open-label extension period**
- **These results build upon the positive results from the 16-week double-blind, placebo-controlled part of the TIMES 3 trial announced in June 2019**
- **Imeglimin in combination with insulin was observed to show a favorable safety and tolerability profile throughout the 52 weeks of treatment in TIMES 3**
- **Phase 3 results from the TIMES 2 trial are anticipated around the end of 2019**
- **Imeglimin Japanese New Drug Application (JNDA) targeted for 2020**

Poxel will host an investor conference call today to discuss the results at 1:00 pm EST (7:00 pm CET). To participate in the call, please use the dial-in numbers: US: +1 646-722-4916 France: +33 172-727-403 UK: +44 207-194-3759 Access Code: 18698372#. *For a replay of the call, please use: US: +1 646-722-4969 FR: +33 170-710-160 UK: +44 203-364-5147 Access Code: 418889018#.*

Lyon, France, November 26, 2019 – POXEL SA (Euronext – POXEL – FR0012432516), a biopharmaceutical company focused on the development of innovative treatments for metabolic disorders, including type 2 diabetes, announced today positive topline Phase 3 results from the 36-week, open-label extension period of the TIMES 3 trial, which evaluated Imeglimin in combination with insulin for the treatment of type 2 diabetes. Referred to as TIMES (**T**rials of **IM**eglimin for **E**fficacy and **S**afety), the Imeglimin Phase 3 program in Japan includes three pivotal trials to evaluate Imeglimin's efficacy and safety in over 1,100 patients.

"I am very excited to contribute to the development of a new and innovative potential treatment option for Japanese patients with type 2 diabetes," said Professor Hirotaka Watada, MD, PhD, Department of Metabolism and Endocrinology, Juntendo University Graduate School of Medicine, Tokyo, Japan. "Given the efficacy of Imeglimin observed in this insulin-treated population combined with the favorable safety and tolerability profile, I believe it has the potential to provide a new treatment option to help manage glycemic control in these patients."

As previously announced, the 16-week, double-blind placebo-controlled randomized portion of the TIMES 3 trial was observed to demonstrate efficacy and achieved statistical significance ($p<0.0001$) for its primary endpoint, defined as a change of glycated hemoglobin

A1c (HbA1c) from baseline versus placebo at week 16, with a mean HbA1c placebo-corrected change from baseline of -0.60%.

In the open-label extension period, which was not placebo-controlled, 208 Japanese patients who completed the first 16 weeks of the study were administered 1,000 mg Imeglimin orally twice-daily as well as insulin therapy for the next 36 weeks. The HbA1c decrease observed at the end of the open-label extension period was:

- -0.64% versus baseline in patients receiving Imeglimin and insulin for 52 weeks (Imeglimin and insulin for 16 weeks followed by Imeglimin and insulin for 36 weeks).
- -0.54% versus baseline in patients receiving Imeglimin and insulin for the last 36 weeks only (placebo and insulin for 16 weeks followed by Imeglimin and insulin for 36 weeks).
- The results of this study were observed to demonstrate sustained efficacy of Imeglimin as an add-on therapy to insulin.

Overall, the safety and tolerability profile of Imeglimin was observed to be favorable for the entire portion of the 52-week trial. In the first 16-week double-blind placebo-controlled treatment period, the incidence of treatment emergent adverse events was similar to the placebo group. In the 36-week extension period, the safety and tolerability profile was consistent with the first part of the trial. There were no episodes of severe hypoglycemia events and the majority of the hypoglycemia events reported were mild.

"Despite efforts to manage type 2 diabetes with diet and oral agents, many patients transition to insulin therapy as a natural part of the disease progression. We are very pleased with the sustained efficacy observed for Imeglimin over a one-year period in combination with insulin," said Thomas Kuhn, CEO of Poxel. “These data demonstrate efficacy with a favorable safety and tolerability profile in a different patient population than the TIMES 1 monotherapy trial and we are looking forward to the TIMES 2 results evaluating Imeglimin in combination with marketed therapies available in Japan. We are continuing to work very closely with our partner, Sumitomo Dainippon Pharma, in preparing for the Japanese New Drug Application and the TIMES 3 results bring us one step closer to achieving that goal.”

Poxel anticipates presenting full data results from the Phase 3 TIMES 3 trial at an upcoming scientific meeting.

About the Phase 3 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 is a joint development effort between Poxel and Sumitomo Dainippon Pharma Co., Ltd. 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 and East Asian countries[1]. 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 topline results were 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, glinide, alpha-glucosidase inhibitor, thiazolidine and GLP1 receptor agonist. The TIMES 2 topline 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 topline results were reported on June 25, 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 pancreas, muscles, and the liver, 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 is a **dynamic biopharmaceutical company** that uses its extensive expertise in developing **innovative drugs for metabolic diseases**, with a focus on **type 2 diabetes** and **non-alcoholic steatohepatitis (NASH)**. In its mid-to-late stage pipeline, the Company is currently advancing three drug candidates as well as earlier-stage opportunities. **Imeglimin**, Poxel's first-in-class lead product, targets mitochondrial dysfunction. Together, with its partner Sumitomo Dainippon Pharma, Poxel is 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. Poxel also established a partnership with Roivant Sciences for Imeglimin's development and commercialization in countries outside of the 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 clinical testing and being developed for the treatment of NASH. Poxel also has additional earlier-stage programs targeting metabolic, specialty and rare diseases. The Company intends to generate further growth through strategic partnerships and pipeline development. Listed on Euronext Paris, Poxel is headquartered in

Lyon, France, and has subsidiaries in Boston, MA, and Tokyo, Japan. For more information, please visit: www.poxelpharma.com.

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[1] including Indonesia, Vietnam, Thailand, Malaysia, The Philippines, Singapore, Republic of the Union of Myanmar, Kingdom of Cambodia and Lao People's Democratic Republic.