Press Release

Poxel Announces Product Launch in Japan for TWYMEEG® as Treatment for Type 2 Diabetes

LYON, France, September 10, 2021 – POXEL SA (Euronext: POXEL - FR0012432516), a clinical stage biopharmaceutical company developing innovative treatments for chronic serious diseases with metabolic pathophysiology, including non-alcoholic steatohepatitis (NASH) and rare disorders, today announced with its partner, Sumitomo Dainippon Pharma, the product launch of TWYMEEG®[1] (Imeglimin hydrochloride) 500mg tablets for the treatment of type 2 diabetes in Japan is planned for September 16, 2021. TWYMEEG is Poxel's first product to reach commercialization and Japan is the first country where the product has been approved. Poxel has received a milestone payment of JPY1.75 billion (EUR13.2 million, USD15.8 million)[2] from Sumitomo Dainippon Pharma in July for the approval of TWYMEEG in Japan. Additionally, as part of the license agreement with Sumitomo Dainippon Pharma, Poxel is entitled to receive escalating double-digit royalties on net sales (based on Poxel's current forecast) and sales-based payments of up to JPY26.5 billion (approximately EUR200 million, USD230 million)[3] in accordance with sales goals. In October 2017, Poxel and Sumitomo Dainippon Pharma entered into a strategic partnership for the development and commercialization of TWYMEEG in Japan, China, South Korea, Taiwan and nine other Southeast Asian countries (Indonesia, Vietnam, Thailand, Malaysia, The Philippines, Singapore, Republic of the Union of Myanmar, Kingdom of Cambodia and Lao People's Democratic Republic).

TWYMEEG is a first-in-class drug with a unique dual mechanism of action for the treatment of type 2 diabetes across the continuum of the current treatment paradigm. It has been approved as a monotherapy and as an add-on treatment to other glucose lowering therapy regimens. The product launch follows the approval by the Japanese regulatory agency in June of this year, which was based on positive results from various preclinical and clinical studies, including the Phase 3 TIMES (**T**rials of **IM**eglimin for **E**fficacy and **S**afety) program managed jointly by Poxel and Sumitomo Dainippon Pharma. The program included three pivotal trials to evaluate TWYMEEG's efficacy and safety in over 1,100 patients. TWYMEEG met its primary endpoints and objectives, exhibiting a favorable safety and tolerability profile.

"We are immensely proud to have brought TWYMEEG to patients in Japan through our fruitful partnership with Sumitomo Dainippon Pharma, a leading company in the diabetes field in Japan. This launch speaks volumes to our ability to develop and commercialize innovative drugs for metabolic diseases," said Thomas Kuhn, CEO of

[1] Dosage and administration: In general, for adults, 1,000 mg of Imeglimin hydrochloride is orally administered twice daily in the morning and evening.
[2] Currency exchange rate at the date of the approval (23 June 2021).
[3] Currency exchange rate at the date of the agreement (30 Oct 2017).

Poxel. “Harnessing the momentum of this achievement, we will continue increasing our focus on rare metabolic disease programs to complement our NASH pipeline, accelerating and expanding upon our existing platforms and proven capabilities. Our mission of bringing innovative therapeutics to patients living with metabolic diseases remains unchanged and our recent achievements underscore our ability to deliver on our goals.”

About TWYMEEG (INN: Imeglimin hydrochloride)

Imeglimin is the first agent in a new chemical class of tetrahydrotriazine-containing molecules. It is thought that TWYMEEG shows a glucose lowering effect by both a pancreatic action that promotes glucose concentration-dependent insulin secretion and an extra-pancreatic action that improves glucose metabolism in the liver and skeletal muscle (suppression of gluconeogenesis and improvement of glucose uptake) through an action on mitochondria. This mechanism of action (MOA) has the potential to prevent endothelial and diastolic dysfunction, which could provide protective effects on micro- and macrovascular defects induced by diabetes. It also has the potential for protective effects 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 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, out of which the non-control individuals were administered the dose of 1,000mg twice daily. Preliminary results of the three trials were announced in press releases dated April. 4, 2019 (TIMES1), December 20, 2019 (TIMES2), and June 25, 2019 (TIMES3).

- TIMES1: A Phase 3, 24-week, double-blind, placebo-controlled, randomized, monotherapy trial that assessed the efficacy, safety, and tolerability of imeglimin in Japanese patients with type 2 diabetes.

- TIMES2: A Phase 3, 52-week, open-label, parallel-group trial that assessed the long-term safety and efficacy of imeglimin in Japanese patients with type 2 diabetes. In this trial, imeglimin was administered orally as combination therapy with approved hypoglycemic agents, including a DPP-4 inhibitor, an SGLT2 inhibitor, metformin, a sulphonylurea, a glinide, an alpha-glucosidase inhibitor, a thiazolidinedione, and a GLP1 receptor agonist or as monotherapy.

- TIMES3: A Phase 3, 16-week, double-blind, placebo-controlled, randomized trial with a 36-week open-label extension period that evaluated the efficacy and safety of imeglimin in combination with insulin in Japanese patients with type 2 diabetes and

Japanese patients with type 2 diabetes on insulin therapy with inadequate glycemic control.

About Poxel SA

Poxel is a clinical stage biopharmaceutical company developing innovative treatments for chronic serious diseases with metabolic pathophysiology, including non-alcoholic steatohepatitis (NASH) and rare disorders. Poxel has clinical and earlier-stage programs from its adenosine monophosphate-activated protein kinase (AMPK) activator and deuterated TZD platforms targeting chronic and rare metabolic diseases. For the treatment of NASH, PXL065 (deuterium-stabilized *R*-pioglitazone) is in a streamlined Phase 2 trial (DESTINY1). PXL770, a first-in-class direct AMPK activator, has successfully completed a Phase 2a proof-of-concept trial for the treatment of NASH, which met its objectives. For the rare inherited metabolic disorder, adrenoleukodystrophy (ALD), the company intends to initiate Phase 2a proof of concept studies with PXL065 and PXL770 in patients with adrenomyeloneuropathy (AMN). TWYMEEG (Imeglimin), Poxel's first-in-class lead product that targets mitochondrial dysfunction, has been approved for the treatment of type 2 diabetes in Japan. With this approval, Poxel is entitled to receive sales-based payments and royalties from Sumitomo Dainippon Pharma. Poxel has a strategic partnership with Sumitomo Dainippon Pharma for Imeglimin in Japan, China, South Korea, Taiwan and nine other Southeast Asian countries. 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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