Press Release

Poxel and Sumitomo Dainippon Pharma Announce the Approval of TWYMEEG® (Imeglimin hydrochloride) for the Treatment of Type 2 Diabetes in Japan

- **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, both as a monotherapy or as an add-on to other glucose lowering therapies**

- **The approval in Japan triggers a JPY 1.75 billion (approximately EUR 13.3 million, USD 15.9 million)[1] milestone payment to Poxel from Sumitomo Dainippon Pharma**

- **TWYMEEG's target product launch is anticipated in fiscal year 2021**[2]

- **The Japanese approval for TWYMEEG is supported by positive results from the Phase 3 TIMES program in over 1,100 patients in Japan**

LYON, France & OSAKA, Japan, June 23, 2021--(BUSINESS WIRE)-- POXEL SA (Euronext – POXEL - FR0012432516), a biopharmaceutical company focused on the development of innovative treatments for metabolic disorders, including type 2 diabetes and non-alcoholic steatohepatitis (NASH), and Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura; Securities Code: 4506, First Section of TSE), today announced that a new drug application for TWYMEEG® Tablets 500mg[3] (International Nonproprietary Name (INN): Imeglimin hydrochloride), for the treatment of type 2 diabetes, was approved in Japan on June 23. Japan is the first country in the world to approve Imeglimin. The TWYMEEG approval is supported by numerous 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, which included three pivotal trials to evaluate TWYMEEG's efficacy and safety in over 1,100 patients. In all three trials, TWYMEEG met its primary endpoints and objectives and was observed to exhibit a favorable safety and tolerability profile.

[1] Converted at the exchange rate as of June 21, 2021.
[2] Year noted is Fiscal Year from April to March, which is Sumitomo Dainippon Pharma's Fiscal Year.
[3] Dosage and administration: In general, for adults, 1,000 mg of Imeglimin hydrochloride is orally administered twice daily in the morning and evening.

"The TWYMEEG approval in Japan represents a major milestone for Poxel and the culmination of several years of clinical development work. This approval is a strong validation of our R&D capabilities and the international footprint that we have established. Our vision as a company is focused on developing and commercializing innovative drugs for metabolic diseases," said Thomas Kuhn, CEO of Poxel. "Going forward, we'll continue to support Sumitomo Dainippon Pharma in establishing TWYMEEG as a key treatment for type 2 diabetes in Japan, and in other countries where Sumitomo Dainippon Pharma has the rights to the product. Our efforts are also focused on our two first-in-class programs for the treatment of NASH, PXL770 and PXL065, as well as advancing earlier-stage opportunities from our adenosine monophosphate-activated protein kinase (AMPK) activator and deuterated thiazolidinediones (TZD) platforms in the arena of rare metabolic disorders."

The Phase 3 TIMES program was 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 TWYMEEG in Japan, China, South Korea, Taiwan and nine other Southeast Asian countries[4].The approval triggers a JPY1.75 billion (approximately EUR13.3 million, USD15.9 million) [5] milestone payment to Poxel. Furthermore, after product launch, Poxel is entitled to receive escalating double-digit royalties on net sales and sales-based payments of up to JPY26.5 billion (approximately EUR200 million, USD230 million)[6] in accordance with sales goals.

"We believe TWYMEEG is an important addition to our existing diabetes franchise through its differentiated dual mechanism of action and favorable efficacy and safety profile. Based on the clinical data obtained in Phase 2 and 3, we believe that it has the potential for use as a monotherapy, and in combination with other existing therapies, specifically complementing well our existing infrastructure in type 2 diabetes. This approval of TWYMEEG allows us to provide patients with type 2 diabetes the opportunity for greater flexibility in their treatment regimens," said Koichi Kozuki, Executive Officer, Drug Development Division of Sumitomo Dainippon Pharma. "We are committed to delivering new therapeutic options to help patients manage their disease."

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

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

[5] Converted at the exchange rate as of June 21, 2021.

[6] Converted at the exchange rate as of date of agreement.

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 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), and selected rare inherited disorders including adrenoleukodystrophy. In its mid-to-late-stage pipeline, the Company is currently advancing three drug candidates; several earlier-stage opportunities are also underway. Imeglimin, Poxel's first-in-class lead product, targets mitochondrial dysfunction. Poxel has a strategic partnership with Sumitomo Dainippon Pharma for TWYMEEG (Imeglimin) in Japan, China, South Korea, Taiwan and nine other Southeast Asian countries. A new drug application for TWYMEEG for the treatment of type 2 diabetes was approved in Japan. After successfully completing a Phase 2a proof-of-concept trial for the treatment of NASH, which met its primary endpoint and study objectives, for PXL770, a first-in-class direct adenosine monophosphate-activated protein kinase (AMPK) activator, Poxel plans to initiate a Phase 2b program in the second half of 2021. PXL770 could also have the potential to treat additional metabolic diseases. PXL065 (deuterium-stabilized R-pioglitazone), is in a streamlined Phase 2 trial for the treatment of NASH. Poxel also has additional earlier-stage programs from its AMPK activator and deuterated thiazolidinediones（TZD) platforms

targeting chronic and rare metabolic 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

In the context of the COVID-19 outbreak, which was declared a pandemic by the World Health Organization (WHO) on March 12, 2020, the Company is regularly reviewing the impact of the outbreak on its business.

As of the date of this press release, and based on publicly available information, the Company has not identified the occurrence of any material negative effect on its business due to the COVID-19 pandemic that remains unresolved. However, the Company anticipates that the COVID-19 pandemic could have further material negative impact on its business operations. The worldwide impact of COVID-19 may notably affect the Company's internal organization and efficiency, particularly in countries where it operates and where confinement measures are implemented by the authorities. In addition, COVID-19 may impact market conditions and the Company's ability to seek additional funding or enter into partnerships. Particularly, delays in the supply of drug substance or drug products, in the initiation or the timing of results of preclinical and/or clinical trials, as well as delays linked to the responsiveness of regulatory authorities could occur, which could potentially have an impact on the Company's development programs and partnered programs. The Company will continue to actively monitor the situation.

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 channeling our efforts into the research and development of new drugs, we aim to realize our mission and provide innovative and effective pharmaceutical solutions not only to people in Japan but also around the world. Sumitomo Dainippon Pharma's goal is to create innovative pharmaceutical products in the focus research areas of psychiatry and neurology, oncology, and regenerative medicine/cell therapy. For more detail, please visit our website. (URL:https://www.ds-pharma.com)

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