April 8, 2025

Poxel Announces Regulatory Approval by Japanese Authorities to Expand TWYMEEG® Package Insert to Include Type 2 Diabetes Patients with Renal Impairment

- **Approval by the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan enables TWYMEEG® (Imeglimin) to be prescribed to type-2 diabetic patients with moderate to severe renal impairment. This approval is based on the results of the Phase 4 TWINKLE study**
- **Sumitomo Pharma to immediately start promoting the use of the product in this new patient population, further supporting efforts to maximize TWYMEEG opportunity in Japan**
- **This regulatory milestone could also support Poxel's strategy and ongoing discussions to develop and commercialize Imeglimin outside of Japan**

LYON, France--(BUSINESS WIRE)-- Regulatory News:

POXEL SA (Euronext : POXEL - FR0012432516), a clinical stage biopharmaceutical company developing innovative treatments for chronic serious diseases with metabolic pathophysiology, including metabolic dysfunction-associated steatohepatitis (MASH) and rare metabolic disorders, today announces that the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan has approved the revision of TWYMEEG® package insert for patients with renal impairment with eGFR (estimated glomerular filtration rate) less than 45 mL/min/1.73m^2.

This approval follows positive topline results from the post-marketing clinical study TWINKLE (**TW**YMEEG® in d**i**abetic patients with re**n**al impairment: A post-mar**k**eting **l**ong-t**e**rm study) in Japanese type 2 diabetic patients with renal impairment, which confirmed TWYMEEG®'s safety and tolerability profile, as announced last August[1]. Based on these results, discussions with the Japanese regulatory authorities were initiated by Sumitomo Pharma, resulting in the approval that will be officially implemented by Sumitomo Pharma as of April 8, 2025.

"The approval of the revised TWYMEEG® package insert from the regulatory authorities in Japan is a major milestone for Sumitomo Pharma allowing us to address a key patient population, particularly elderly individuals with renal impairment, who are faced with limited

treatment options. TWYMEEG® is an important asset in our existing diabetes franchise, and we remain fully committed to support its sales trajectory, building on the safety and tolerability profile observed from TWINKLE study", stated **Koichi Kozuki, Executive Officer, Corporate Regulatory Compliance & Quality Assurance Division, Senior Vice President, Head of Corporate Regulatory Compliance & Quality Assurance Division of Sumitomo Pharma.**

"*This regulatory achievement, combined with recent patent approvals, further strengthens TWYMEEG®'s prescription strategy in a large patient population with high unmet medical need*", added **Thomas Kuhn, Chief Executive Officer of Poxel**. *"Given the high prevalence of renal impairment among type-2 diabetic patients, this approval further strengthens the product's commercial potential in other Asian territories."*

This milestone builds on the newly granted patent (n°7635474) by the Japanese Patent Office to Poxel[2] covering the use of Imeglimin in type-2 diabetic patients with moderate to severe renal impairment until 2039, strengthening TWYMEEG®'s patent portfolio in Japan and protecting its use in this population. Poxel previously received the grant of this patent in China[3], the world's second largest type-2 diabetes market, further supporting ongoing discussions initiated by Poxel to develop Imeglimin beyond Japan.

About TWYMEEG®

TWYMEEG® is the first agent in a class of tetrahydrotriazine-containing molecules. It is thought that the Drug 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 acting on mitochondria. The Drug has the potential to prevent endothelial and diastolic dysfunction, which could provide protective effects on micro- and macrovascular defects induced by diabetes. It may also have protective effects on pancreatic β cell survival and function. Owing to its unique mechanism of action, the Drug is widely used for glucose lowering in the treatment of type 2 diabetes, either as monotherapy or as an add-on to other therapies for this purpose.

In October 2017, Sumitomo Pharma concluded a development and commercialization partnership agreement for Japan, Chinese mainland, Taiwan, Korea and nine Southeast Asian countries with Poxel SA (Head Office: Lyon, France; CEO: Thomas Kuhn) and started selling the Drug in Japan in September 2021.

In September 2024, Sumitomo Pharma and Poxel amended this agreement, whereby Poxel received the rights back from Sumitomo for all territories under the agreement except Japan.

About Sumitomo Pharma Co., Ltd.

Sumitomo Pharma Group defines its 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, the Group aims to provide innovative and valuable pharmaceutical and healthcare solutions to people in Japan and around the world in order to realize its Mission. The Group will remain committed to research and development with the aim of continually

discovering excellent pharmaceuticals, regenerative medicine/cell therapy, non-pharmaceutical products, and others with a focus on the Psychiatry & Neurology and Oncology as priority disease areas.

For more details, please visit website: www.sumitomo-pharma.com

About Poxel SA

Poxel is a **clinical stage biopharmaceutical company** developing **innovative treatments for chronic serious diseases with metabolic pathophysiology**, including **metabolic dysfunction-associated steatohepatitis (MASH)** and rare disorders. For the treatment of MASH, **PXL065** (deuterium-stabilized *R*-pioglitazone) met its primary endpoint in a streamlined Phase 2 trial (DESTINY-1). In rare diseases, development of **PXL770**, a first-in-class direct adenosine monophosphate-activated protein kinase (AMPK) activator, is focused on the treatment of adrenoleukodystrophy (ALD) and autosomal dominant polycystic kidney disease (ADPKD). **TWYMEEG®** (Imeglimin), Poxel's first-in-class product that targets mitochondrial dysfunction, is now marketed for the treatment of type 2 diabetes in Japan by Sumitomo Pharma and Poxel expects to receive royalties and sales-based payments. Poxel has a strategic partnership with Sumitomo Pharma for Imeglimin in Japan. 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] *"Sumitomo Pharma and Poxel Announce Topline Results from Post-Marketing Clinical Study on TWYMEEG® for the Treatment of Type 2 Diabetes in Japan", August 7, 2024*

[2] *"Poxel Announces Grant of New Patent in Japan for the Use of Imeglimin in Type-2 Diabetic Patients with Renal Impairment", on March 31, 2025*

[3] *"Poxel Announces the Grant of Patent in China Protecting the Use of Imeglimin for Type-2 Diabetic Patients with Renal Impairment", on January 20, 2025*

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