Press Release

Poxel Announces Grant of New Patent in Japan for the Use of Imeglimin in Type-2 Diabetic Patients with Renal Impairment

- **Newly granted patent covers Imeglimin's use in type-2 diabetic patients with renal impairment and has a patent term in Japan until 2039**
- **This patent further supports Poxel's strategy to maximize Imeglimin's commercial potential in Japan and beyond**

LYON, France, March 31, 2025 – 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 announced that the Japanese Patent Office has granted Poxel a new patent (n°7635474) covering the use of Imeglimin in type-2 diabetic patients with moderate to severe renal impairment until 2039.

Ahead of the anticipated outcome of the discussion between Sumitomo Pharma and regulatory authorities in Japan to revise TWYMEEG® package insert for patients with renal impairment with eGFR (estimated glomerular filtration rate) less than 45 ml/min/1.73m², this newly granted patent strengthens TWYMEEG®'s patent portfolio in Japan and protects its use in this population. Poxel previously also received the grant of this patent in China, the world's second largest type 2 diabetes market, strengthening ongoing discussions initiated by Poxel to develop Imeglimin beyond Japan[1].

"*This new patent approval in Japan is an additional feature that should further strengthen TWYMEEG's prescription strategy in a large patient population with high unmet need*", stated **Thomas Kuhn, Chief Executive Officer of Poxel**. *"With a significant number of type-2 diabetes patients also affected by renal impairment, the ability to offer a safe and effective treatment option is critical. We remain committed to advancing Imeglimin's potential in Japan and other key Asian markets."*

Previously, as announced on August 7, 2024, topline results obtained 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) conducted by Sumitomo Pharma in Japanese type 2 diabetic patients with renal impairment confirmed TWYMEEG®'s safety and tolerability profile, which is consistent with prior clinical studies in the general type 2 diabetes population. Based on these results, Sumitomo Pharma has initiated discussions with the regulatory authorities in Japan

[1] "*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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for revising TWYMEEG® package insert for patients with renal impairment with eGFR (estimated glomerular filtration rate) less than 45 mL/min/1.73m² and expects outcome in the first half of 2025.

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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Contacts - Investor relations / Media

NewCap
Aurélie Manavarere, Théo Martin / Arthur Rouillé
investors@poxelpharma.com
+33 1 44 71 94 94

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