Sumitomo Pharma

Press Release

August 7, 2024

Sumitomo Pharma Co., Ltd.

# Sumitomo Pharma Announces Topline Results from Post-Marketing Clinical Study on TWYMEEG® for the Treatment of Type 2 Diabetes in Japan

Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Toru Kimura) announced today that topline results were obtained from a 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), ("the Study") in Japanese type 2 diabetic patients with renal impairment for TWYMEEG® Tablets 500 mg (generic name: imeglimin hydrochloride, "the Drug") being sold in Japan, based on the Risk Management Plan.

The Study was an open-label, uncontrolled, long-term study in 60 Japanese type 2 diabetic patients with renal impairment, who had no experience of type 2 diabetes treatment other than diet and exercise therapy or insufficient glycemic management in monotherapy with a hypoglycemic agent excluding insulin formulation.
The Drug was administered at 500 mg twice-daily to patients with estimated glomerular filtration rate (eGFR) 15 mL/min/1.73 $m^2$ or higher to less than 45 mL/min/1.73 $m^2$, or at 500 mg once-daily to those with eGFR less than 15 mL/min/1.73$m^2$ in monotherapy or in combination therapy with a hypoglycemic agent excluding insulin formulation, to evaluate safety and tolerability when administered orally for 52 weeks.

The incidence of adverse events in the Study was 68.3% (41 of 60 subjects) and most of the adverse events were mild or moderate in severity. The incidence of serious adverse events was 16.7% (10 of 60 subjects) and causality with the Drug could be ruled out in all cases. No adverse events leading to death occurred. The incidence of adverse events leading to study treatment discontinuation was 6.7% (4 of 60 subjects).
No significant differences were found in the incidence of adverse events, their types and severities in the Study from the previous clinical studies, demonstrating that the Drug was safe and tolerable in Japanese type 2 diabetic patients with renal impairment.

At present, administration of the Drug is not recommended for patients with renal impairment with eGFR less than 45 mL/min/1.73$m^2$. Based on the results of the Study, Sumitomo Pharma plans to consult with regulatory authorities on revising the package insert in fiscal 2024 regarding administration for patients with renal impairment with eGFR less than 45 mL/min/1.73$m^2$.

Reference

Overview of "TWYMEEG® Tablets 500 mg"

| | |
|---|---|
| **[**Brand name**]** | TWYMEEG® Tablets 500 mg |
| **[**Generic name**]** | imeglimin hydrochloride |
| **[**Standard/Content**]** | TWYMEEG® Tablets 500 mg: 500 mg of imeglimin hydrochloride in one tablet |
| **[**Indications**]** | Type 2 diabetes |
| **[**Dosage/Administration**]** | In general, for adults, it is generally administered as a 1,000 mg dose twice-daily as imeglimin hydrochloride, orally once in the morning and once in the evening. |

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.

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