Press Release

Sanwa Kagaku Kenkyusho Co., Ltd.
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Presentation of Treatment Period I in the Japanese Phase 2/3 Clinical Study of Paltusotine (SK-5307) in Patients with Acromegaly and Pituitary Gigantism at The 22nd International Congress of Endocrinology / The 99th Annual Congress of The Japan Endocrine Society

Sanwa Kagaku Kenkyusho Co., Ltd. (Headquarters: Nagoya-shi, Aichi, hereinafter "our company") announced the presentation of the Efficacy and Safety of Treatment Period I (12 weeks) of a Phase 2/3 clinical study (PA 9001 Study) paltusotine in patients with acromegaly and pituitary gigantism was conducted in Japan.

Dr. Yutaka Takahashi, Professor in Department of Diabetes and Endocrinology, Nara Medical University, presented a poster at The 22nd International Congress of Endocrinology / The 99th Annual Congress of The Japan Endocrine Society, held at the Kyoto International Conference Center, Japan, on June 2−6, 2026.

【Poster Title】
Efficacy and Safety of Paltusotine in Patients with Acromegaly/ Gigantism: A Phase II/III Trial in Japan.

Study Design
In this multicenter, double-blinded, fixed-dose, parallel-group study, 34 patients with acromegaly and pituitary gigantism were randomized to receive 20 mg, 40 mg, or 60 mg of paltusotine once daily for 12 weeks to evaluate efficacy and safety. The washout period was set to at least two weeks for each treatment when a previous treatment was present.

Study Results
Eleven patients each received paltusotine 20 mg and 60 mg, and 12 patients received 40 mg. One patient was diagnosed with gigantism, and the remaining patients had acromegaly. Fifteen patients were male, age was 58.4 ± 14.4 years, previous treatments included somatostatin analog in 15 and dopamine agonist in 7. For the primary endpoint, the change from baseline in serum IGF-I[*1] concentration relative to the upper limit of the age- and sex-

specific reference range (upper limit of normal; ULN) at 12 weeks was −0.88 x ULN (95% confidence interval: −1.03 – −0.73) overall and −0.88 x ULN (95% confidence interval: −1.15 – −0.62), −0.84 x ULN (95% confidence interval: −1.09 – −0.59), and −0.92 x ULN (95% confidence interval: −1.18 – −0.66) in the 20 mg, 40 mg and 60 mg groups of paltusotine, respectively. Overall and each group of primary endpoints revealed significant reduction. For the secondary endpoint, the proportion of patients with IGF-I ≤1 x ULN was 70.6% overall and a substantial proportion of trial participants achieved IGF-I normalization with paltusotine.
Adverse events occurred in 79.4%, 81.8%, 75.0%, and 81.8% in the overall group and 20 mg, 40 mg and 60 mg groups of paltusotine, respectively, while adverse drug reactions occurred in 50.0%, 36.4%, 50.0% and 63.6% in the same groups, respectively. Most adverse events were gastrointestinal symptoms (primarily diarrhea). Paltusotine was well tolerated with no notable safety concerns or issues. These results are consistent with previous global clinical studies of paltusotine[*2].

The complete results from this study (52 weeks) will be submitted for presentation at scientific conferences and for publication in a peer-reviewed journal. If approved, paltusotine will become Japan's first orally administered somatostatin receptor (SSTR) agonist.

Paltusotine is approved in the USA for the treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option. In the European Union, it is approved as PALSONIFY™ for the medical treatment of adult patients with acromegaly. A marketing authorization application is currently under review in Japan (submitted by our company) and in Brazil (submitted by Crinetics).

*1 IGF-I is an insulin-like growth factor-1 secreted by the liver and is a major biomarker used by endocrinologists in the management of acromegaly. In general, patients with acromegaly and pituitary gigantism have high levels of IGF-I, and reducing these levels is an important therapeutic strategy.
*2 Crinetics' Once-Daily Oral Paltusotine Achieved the Primary and All Secondary Endpoints in the Phase 3 PATHFNDR-2 Study in Acromegaly Patients - March 19, 2024
https://crinetics.com/crinetics-once-daily-oral-paltusotine-achieved-the-primary-and-all-secondary-endpoints-in-the-phase-3-pathfndr-2-study-in-acromegaly-patients/

【About Acromegaly】
Acromegaly is a serious disease caused by benign pituitary adenomas that typically stimulate growth hormone production. Excessive growth hormone causes the liver to secrete IGF-I. Excessive production of these hormones causes the symptoms and findings of acromegaly, including abnormal growth of hands and feet, facial changes, arthritis, carpal tunnel syndrome, joint pain, deepening of the voice with enlargement of the vocal cords, fatigue, sleep apnea, enlargement of the heart, liver, and other organs, and changes in glucose and lipid metabolism. Regarding treatment, surgical removal of the pituitary adenoma is generally indicated as the first-line treatment for most patients with acromegaly. However, medical treatment may be considered for patients who are not candidates for surgery or who cannot achieve treatment goals with surgery. As for medical treatment, long-acting somatostatin

analogs, which are administered by depot injection once every four weeks, are widely used as standard medical treatment.

【About PALSONIFY™ (Paltusotine)】

PALSONIFY, a selectively-targeted somatostatin receptor type 2 (SST2) nonpeptide agonist, is the first and only once-daily, oral therapy approved for the treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option. In Phase 3 studies, once-daily, oral PALSONIFY maintained IGF-1 levels and symptom control in patients with acromegaly who were switched from monthly injectable medications (PATHFNDR-1) and rapidly decreased IGF-1 levels and symptom burden in medically untreated acromegaly patients (PATHFNDR-2). IGF-1 is the primary biomarker endocrinologists use to manage acromegaly patients. Paltusotine is also in Phase 3 clinical development for carcinoid syndrome associated with neuroendocrine tumors (CAREFNDR). Results from a Phase 2 study in carcinoid syndrome demonstrated rapid and sustained reductions in flushing episodes and bowel movement frequency, which are the most common symptoms of carcinoid syndrome.

PALSONIFY is approved in the U.S. for the first-line treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option. It is also approved for use in the EU for the medical treatment of adult patients with acromegaly. It’s being investigated for the treatment of patients with acromegaly and pituitary gigantism in Japan.

【About Sanwa Kagaku Kenkyusho Co., Ltd.】

Sanwa Kagaku Kenkyusho is a subsidiary of Suzuken, one of Japan's leading pharmaceutical wholesalers, and is headquartered in Nagoya, Aichi. Sanwa Kagaku Kenkyusho is a pharmaceutical company that handles everything from research and development to sales and provides ethical drugs and diagnostics, mainly in the areas of diabetes and the kidney. The mission of Sanwa Kagaku Kenkyusho is to develop and deliver pharmaceuticals that contribute to improving patients' quality of life (QOL), based on its corporate philosophy of "Patient-friendly medicines for people around the world."

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