Press Release

Sanwa Kagaku Kenkyusho Co., Ltd.
January,15,2026

Topline Data from Treatment Period I in the Japanese Phase 2/3 Clinical Study of Paltusotine (SK-5307) in Patients with Acromegaly and Pituitary Gigantism

Information on pharmaceutical products (including products under development) contained in this press release is for the purpose of disclosing corporate information and is not intended for the purpose of advertising or medical advice. These descriptions are based on our company's judgment based on information currently available and contain risks and uncertainties. Please note that the actual results may differ from these descriptions due to various factors.

On February 28, 2022, Sanwa Kagaku Kenkyusho Co., Ltd. (Headquarters: Nagoya-shi, Aichi, hereinafter “our company”) entered a license agreement with Crinetics Pharmaceuticals, Inc. (Headquarters: San Diego, California, USA, hereinafter "Crinetics") of the United States for exclusive development and commercialization rights for paltusotine (development code, SK-5307) in Japan for acromegaly and neuroendocrine tumors including carcinoid syndrome. The top-line data of Treatment Period 1 (12 weeks) of a Phase 2/3 clinical study (PA 9001 Study) paltusotine in patients with acromegaly and pituitary gigantism currently being conducted in Japan have been obtained.

In the 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 study’s primary endpoint is a change from baseline in IGF-1 levels[*1]. Key secondary endpoints include: the proportion of patients with IGF-1 ≤1 x ULN (upper limit of normal) and the proportion of patients with IGF-1≤ 1.3 x ULN.

The top-line data obtained in this study confirmed the efficacy of paltusotine in patients with acromegaly and pituitary gigantism. For the primary endpoint, paltusotine treatment resulted in a rapid and sustained decrease in IGF-1 levels from baseline. For key secondary endpoints, a substantial proportion of trial participants achieved IGF-1 normalization with paltusotine.
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 will be submitted for presentation at scientific conferences and

for publication in peer-reviewed journals. Based on these results, SKK is preparing to submit paltusotine for approval in Japan at a date to be determined. If approved, it will become Japan's first orally administered somatostatin receptor (SSTR) agonist.

Paltusotine is approved for use in the USA as PALSONIFY™. It is not currently approved for use in any other global markets. In addition to investigating paltusotine for potential use in Japan, a Marketing Authorization Application submitted by Crinetics is currently under review for its use in the European Union.

*1 IGF-1 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-1, 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-1. 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 Paltusotine】

Paltusotine is a selectively-targeted somatostatin receptor type 2 (SST2) nonpeptide agonist, and the first and only once-daily, oral therapy approved in the United States for the treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option. It was discovered and designed by Crinetics Pharmaceuticals to provide a once-daily oral treatment option for patients with acromegaly and carcinoid syndrome associated with neuroendocrine tumors.

【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."

【About Crinetics Pharmaceuticals】

Crinetics Pharmaceuticals is a global pharmaceutical company committed to transforming the treatment of endocrine diseases and endocrine-related tumors through science rooted in patient needs. Crinetics is focused on discovering, developing, and commercializing novel therapies, with a core expertise in targeting G-protein coupled receptors (GPCRs) with small molecules that have specifically tailored pharmacology and properties.

Crinetics' lead product, PALSONIFY™ (paltusotine), is the first once-daily, oral treatment approved by the U.S. FDA for the treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option. Paltusotine is also in clinical development for carcinoid syndrome associated with neuroendocrine tumors. Crinetics' deep pipeline of 10+ disclosed programs includes late-stage investigational candidate atumelnant, which is currently in late-stage development for congenital adrenal hyperplasia and ACTH-dependent Cushing's syndrome. Additional discovery programs address a variety of endocrine conditions such as neuroendocrine tumors, Graves' disease (including Graves' hyperthyroidism and Graves' orbitopathy, or thyroid eye disease), polycystic kidney disease, hyperparathyroidism, diabetes, obesity, and GPCR-targeted oncology indications.

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