

Sanwa Kagaku Kenkyusho Co., Ltd.

February 27, 2026

Ministry Of Health, Labour and Welfare Grants Orphan Drug Designation in Japan to Paltusotine (SK-5307) for Acromegaly and Pituitary Gigantism

On February 28, 2022, Sanwa Kagaku Kenkyusho Co., Ltd. (Headquarters: Nagoya, Aichi Prefecture; President and CEO: Shusaku Isono; Suzuken Group; hereinafter "SKK ") 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), a selective somatostatin receptor (SSTR)2 agonist, in Japan for acromegaly and neuroendocrine tumors, including carcinoid syndrome.

SKK is pleased to announce that paltusotine has been designated as an orphan drug by the Ministry of Health, Labour and Welfare for acromegaly and pituitary gigantism.

A Phase 2/3 clinical study of paltusotine in acromegaly is ongoing in Japan, and positive initial results were announced on January 15, 2026*. Based on these results, SKK is preparing to submit an NDA for its use in Japan. Through the development of paltusotine, SKK aims to provide acromegaly and pituitary gigantism patients with a new treatment option—the first orally administered SSTR agonist in Japan.

Currently, paltusotine is approved for use in the USA as PALSONIFY™. It is not 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.

* [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](#)

About Orphan Drug/Medical Device Designation

In Japan, drugs and medical devices can be designated as orphan drugs or medical devices based on the Article 77-2 of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics if they are intended for use in less than 50,000 patients in Japan and for which there is a high medical need. They are designated by the Minister of Health, Labour and Welfare based on the opinion of the

Pharmaceutical Affairs and Food Sanitation Council (PAFSC). For details on support measures and other information about orphan drug/medical device designation, please refer to the MHLW website. [Ministry of Health, Labour and Welfare: Pharmaceuticals and Medical Devices](#)

About Acromegaly

Acromegaly is a serious disease caused by benign pituitary adenomas that secrete excess growth hormone. 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 SSTR2 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. (SKK)

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' QOL, based on its corporate philosophy of "delivering people-friendly medicines to 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 development for congenital adrenal hyperplasia and ACTH-dependent Cushing's syndrome, and CRN09682, a nonpeptide drug conjugate candidate that is being developed to treat SSTR2 expressing neuroendocrine tumors and other SSTR2 expressing solid tumors. 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.

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.

< Inquiries about the release >

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