

Sanwa Kagaku Kenkyusho Co., Ltd.

April 15, 2026

## Notice Regarding the Submission of an NDA for “Paltusotine,” a Treatment for Acromegaly and Pituitary Gigantism

Sanwa Kagaku Kenkyusho Co., Ltd. (Headquarters: Nagoya, Aichi Prefecture; President and CEO: Shusaku Isono; Suzuken Group; hereinafter "SKK ") today submitted an NDA for Paltusotine (development code: SK-5307) as a treatment for acromegaly and pituitary gigantism.

This NDA is based on positive efficacy and safety results in two global Phase III clinical trials\*<sup>1,2</sup> conducted in patients with acromegaly, as well as in a Phase II/III clinical trial\*<sup>3</sup> conducted in Japan in patients with acromegaly and pituitary gigantism.

\*1 <https://crinetics.com/crinetics-paltusotine-achieved-primary-and-secondary-endpoints-in-phase-3-pathfndr-1-acromegaly-study/>

\*2 <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/>

\*3 <https://skk-net.com/information/item/press20260115.pdf>

SKK entered a license agreement with Crinetics Pharmaceuticals, Inc. (Headquarters: San Diego, California, USA; hereinafter "Crinetics") of the United States on February 25, 2022, for exclusive development and commercialization rights for paltusotine in Japan for acromegaly and neuroendocrine tumors (NETs), and carcinoid syndrome resulting from NETs.

Paltusotine has already been approved in the United States under the brand name PALSONIFY™ and is currently under review in the European Union (EU) for treating acromegaly. Through the development of paltusotine, SKK aims to provide patients with a new treatment option, which is Japan's first orally administered SSTR2 agonist.

### 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. Paltusotine has been designated as an orphan drug by the Ministry of Health, Labour and Welfare for the treatment of acromegaly and pituitary gigantism.

#### 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.

<For inquiries regarding this release>

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