JAPAN'S MHLW APPROVES PFIZER AND OPKO'S NGENLA® (SOMATROGON), A NEW LONG-ACTING TREATMENT FOR PEDIATRIC GROWTH HORMONE DEFICIENCY

〜NGENLA® offers a new once-weekly treatment option for children living with growth hormone deficiency〜

TOKYO and MIAMI (January 20, 2022) – Pfizer Japan Inc. and OPKO Health, Inc. (NASDAQ: OPK) announced today that the next generation long-acting growth hormone injection, NGENLA® (somatrogon) Inj. 24 mg Pens and 60 mg Pens, has been approved by the Ministry of Health, Labour and Welfare (MHLW) in Japan. NGENLA® is a once-weekly long-acting recombinant human growth hormone, for the indication of short statue due to growth hormone deficiency without closed epiphyses. NGENLA® provides patients with pediatric growth hormone deficiency (GHD) with a new option that reduces treatment frequency from daily injections to once-weekly injections.

This approval is based on the results of a Phase 3 study conducted in Japanese subjects and a global Phase 3 clinical study, both of which were conducted in subjects with pediatric GHD, and both of which compared the efficacy and safety of once-weekly NGENLA® with GENOTROPIN® (somatropin), a recombinant human growth hormone for injection administered once-daily. In both studies, NGENLA® showed comparable efficacy to GENOTROPIN in the primary endpoint of annual height velocity at 12 months. NGENLA® was generally well tolerated in both studies, with comparable safety to that of GENOTROPIN administered once-daily with respect to the types, numbers and severity of the adverse events observed between the treatment arms.

"We are pleased to receive approval for once-weekly NGENLA®, which offers a new treatment option for pediatric GHD patients that can help reduce the burden associated with daily growth hormone administration. We wish to express our gratitude to the patients and their families who participated in the clinical studies and to all the sites conducting these trials," said Taro Ishibashi, President of Pfizer R&D Japan G.K.

In 2014, Pfizer and OPKO Health entered into a worldwide agreement for the development and commercialization of somatrogon for the treatment of GHD. Under the agreement, OPKO is responsible for conducting the clinical program and Pfizer is responsible for registering and commercializing somatrogon for GHD.

【About NGENLA】

Product name	NGENLA® Inj.24mg Pens NGENLA® Inj.60mg Pens
General name	Somatrogon (recombination)
INDICATIONS	Short stature due to growth hormone deficiency without closed epiphyses
DOSAGE AND ADMINISTRATION	Generally, Somatrogon (recombination) 0.66 mg per kilogram body weight is administered once-weekly by subcutaneous injection.
Marketing Authorization Holder	Pfizer Japan Inc.

About the Japan Phase 3 Study
The Phase 3 study of NGENLA® in 44 treatment-naïve Japanese pre-pubertal children with pediatric GHD was a 12-month, open-label, randomized, active-controlled, parallel-group study of the efficacy and safety of weekly NGENLA® compared to recombinant human growth hormone (r-hGH), GENOTROPIN (somatropin) for injection treatment administered once-daily. Eligible patients were randomized in a 1:1 ratio to receive either once-weekly NGENLA® or GENOTROPIN administered once-daily (reference therapy, 0.025 mg/kg/day which is equivalent to 0.175 mg/kg/week). To obtain pharmacokinetic information of three different weekly doses in Japanese pediatric GHD patients, NGENLA® treated patients received 0.25 mg/kg/week for 2 weeks, followed by 0.48 mg/kg/week for 2 weeks followed by 0.66 mg/kg/week for the remaining 46 weeks.

About the Global Phase 3 Study
The Global Phase 3 study of NGENLA® in 224 treatment-naïve children with pediatric GHD in over 20 countries was a 12-month randomized, open-label, active-controlled study evaluating the safety and efficacy of weekly NGENLA® (somatrogon) injection compared to GENOTROPIN (somatropin) administered once-weekly. Eligible patients were randomized 1:1 into two arms: somatrogon administered at a dose of 0.66 mg/kg body weight once-weekly vs GENOTROPIN® (somatropin) administered at a dose of 0.034 mg/kg body weight once-daily.

About NGENLA® (somatrogon) injection
NGENLA® is a biologic product that is glycosylated and comprises the amino acid sequence of human growth hormone and one copy of the C-terminal peptide (CTP) from the beta chain of human chorionic gonadotropin (hCG) at the N-terminus and two copies of CTP (in tandem) at the C-terminus. The glycosylation and CTP domains account for the half-life of the molecule. NGENLA® was approved in Canada in October 2021 and in Australia in November 2021.

About GENOTROPIN
GENOTROPIN (somatropin) is a man-made, prescription treatment option, approved in the United States for children who do not make enough growth hormone on their own, have the genetic condition called Prader-Willi syndrome (PWS), were born smaller than most other babies, have the genetic condition called Turner syndrome (TS) or have idiopathic short stature (ISS). GENOTROPIN is also approved to treat adults with growth hormone deficiency. GENOTROPIN is taken by injection just below the skin and is available in a wide range of devices to fit a range of individual dosing needs. GENOTROPIN is just like the natural growth hormone that our bodies make and has an established safety profile.

About Growth Hormone Deficiency
Growth hormone deficiency is a rare disease characterized by the inadequate secretion of growth hormone from the pituitary gland and affects one in approximately 4,000 to 10,000 people[1,2]. In children, this disease can be caused by genetic mutations or acquired after birth[1,3]. Because the patient's pituitary gland secretes inadequate levels of somatropin, the hormone that causes growth, his or her height may be affected and puberty may be delayed[1,3,4]. Children may also experience other problems with physical health and mental well-being[3,4].

Pfizer Rare Disease
Rare disease includes some of the most serious of all illnesses and impacts millions of patients worldwide, representing an opportunity to apply our knowledge and expertise to help make a significant impact on addressing unmet medical needs. The Pfizer focus on rare disease builds on more than two decades of experience, a dedicated research unit focusing on rare disease, and a global portfolio of multiple medicines within a number of

disease areas of focus, including rare hematologic, neurologic, cardiac and inherited metabolic disorders.

Pfizer Rare Disease combines pioneering science and deep understanding of how diseases work with insights from innovative strategic collaborations with academic researchers, patients, and other companies to deliver transformative treatments and solutions. We innovate every day leveraging our global footprint to accelerate the development and delivery of groundbreaking medicines and the hope of cures.

OPKO Health, Inc.
OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large, rapidly growing markets by leveraging its discovery, development and commercialization expertise and novel and proprietary technologies. For more information, visit www.opko.com.

Pfizer Inc.: Breakthroughs that change patients' lives
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Disclosure Notice
The information contained in this release is as of January 20, 2022. Pfizer and OPKO assume no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about a product candidate, NGENLA (somatrogon), a once-weekly long-acting recombinant human growth hormone, including an approval by the Japanese Ministry of Health, Labour and Welfare, including its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any other jurisdictions for any potential indication for somatrogon; whether and when regulatory authorities in any jurisdictions may approve any applications that may be pending or filed (including the applications filed in the EU and the U.S.), which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether somatrogon will be commercially successful;

decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of somatrogon; uncertainties regarding the impact of COVID-19 on Pfizer's and OPKO's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's and OPKO's respective Annual Report on Form 10- K for the fiscal year ended December 31, 2020 and in their respective subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in their respective subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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