May 23, 2024

Company Name: AnGes Inc.
Presentative: Ei Yamada, President & CEO

Notice of Launch Date for Zokinvy (Orphan Drug) for the Treatment of Progeria

AnGes announced that Zokinvy, a drug for the treatment of premature aging, was listed in the NHI Drug Price Standard on April 17, 2024, and that it is scheduled to be launched. In this announcement, we announced that we would be making preparations for the start of sales by the end of May 2024, and we are now pleased to announce that we have decided to set the launch date as May 27, 2024.

As a result of this decision, sales of Zokinvy will be recorded from the second quarter of the current fiscal year. However, a certain amount of sales of Zokinvy has already been included in the sales forecast for the current fiscal year, which was announced on March 14, 2024. Accordingly, there is no change in the consolidated earnings forecast for the current fiscal year as a result of this decision.

For details, please refer to the attached press release.

May 23, 2024
Company Name: AnGes Inc.
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AnGes, Inc. will launch Zokinvy for the treatment of Hutchinson-Gilford-Progeria syndrome and Processing-Deficient Progeroid Laminopathy, an ultra-rare disease, on May 23, which is the “Day of Intractable Diseases”

On May 23, the “Day of Intractable Diseases,” AnGes, Inc. will launch Zokinvy (Orphan Drug) for the treatment of Hutchinson-Gilford Progeria Syndrome (HGPS) and processing-deficient progeroid laminopathies (PDPL) among Progeria on May 27, 2024.

Zokinvy was approved and marketed in the United States in November 2020, and subsequently approved in the European Union and the United Kingdom. We obtained exclusive rights to market the product in Japan in May 2022, received orphan drug designation by the Ministry of Health, Labour and Welfare in March 2023, obtained manufacturing and marketing approval on January 18, 2024, and was listed on the NHI drug price standard on April 17, 2024.

About Zokinvy

Zokinvy (generic name: lonafarnib) was approved by the U.S. Food and Drug Administration (FDA) in November 2020, the European Union in July 2022, and the United Kingdom in August 2022 for the treatment of HGPS and PDPL.

Zokinvy inhibits the accumulation of farnesylated mutant proteins (which cause nuclear destabilization and premature aging) that impair the structure and function of the nuclear envelope in children and young adults with HGPS and PDPL. Zokinvy is a first-in-class disease-modifying agent, and its efficacy was investigated in HGPS and PDPL in children and young adults. In patients with HGPS, Zokinvy reduced mortality by 72% and increased mean survival by 4.3 years. Many patients have been treated with Zokinvy for more than 10 years, and the most commonly reported side effects are gastrointestinal (Vomiting, diarrhea, nausea), mostly mild or moderate .

In our company, the number of ultra-rare patients expected to use Zokinvy in Japan is expected to be approximately a few.

About HGPS and PDPL

Hutchinson-Gilford Progeria Syndrome (HGPS) and Processing-Deficient Progeroid Laminopathy (PDPL) are each a very rare and lethal genetic premature aging disease with an accelerated mortality rate from a young age. HGPS is caused by a point mutation in the LMNA gene that produces a farnesylated mutant protein, progerin. PDPL is caused by mutations in the LMNA and ZMPSTE24 genes, which produce a farnesylated protein similar to progerin and accelerate aging. Both forms of the disease cause premature aging symptoms such as severe growth retardation, scleroderma-like skin, generalized lipodystrophy, alopecia, joint contractures, skeletal dysplasia, accelerated atherosclerosis, and death at a young age due to atherosclerotic disease (myocardial infarction or stroke), and the average age of HGPS is reported to be 14.5 years.