September 4, 2024

Kissei Pharmaceutical Co., Ltd.
(Code 4547, Tokyo Stock Exchange Prime Market)

Licensing Agreement for "olutasidenib", an Acute Myeloid Leukemia Drug

Kissei Pharmaceutical Co., Ltd. (Head Office: Matsumoto City, Nagano Prefecture; Chairman and CEO: Mutsuo Kanzawa; hereinafter "Kissei") announced that it has entered into an agreement with Rigel Pharmaceuticals, Inc. (Head Office: USA; President and CEO: Raul Rodriguez; hereinafter "Rigel") to acquire exclusive development and commercialization rights for the acute myeloid leukemia (AML) drug "olutasidenib (generic name)".

Under this agreement, Kissei will acquire exclusive development and sales rights for olutasidenib in Japan, South Korea and Taiwan.

By inhibiting IDH1[*1], olutasidenib suppresses the inhibition of normal differentiation of stem and progenitor cells and the promotion of neoplastic transformation caused by IDH1 gene mutations, thereby restoring normal cell differentiation. The drug was approved in the United States in December 2022 for the treatment of adult patients with relapsed or refractory AML with a susceptible IDH1 mutation[*2] as detected by an FDA-approved test and is sold by Rigel.

We are working to expand our product portfolio in the areas of urology, nephrology and dialysis, as well as areas with high unmet medical needs. Through this agreement, Kissei aims to further strengthen its efforts in treating rare diseases and to provide this drug to patients suffering from AML as soon as possible.

The upfront payment arising from this transaction has been incorporated into the consolidated financial results forecast for the fiscal year ending March 31, 2025, announced on May 7, 2024.

＜Reference＞

*1: About IDH1 (Isocitrate Dehydrogenase-1)

IDH1 is a cytoplasmic metabolic enzyme that catalyzes the oxidative decarboxylation of isocitrate to α-ketoglutarate (α-KG) in the citric acid cycle. Mutations in the IDH1 gene are thought to promote DNA methylation, which inhibits normal cell differentiation of stem and progenitor cells and promotes neoplastic transformation.

*2: IDH1 mutation-positive relapsed/refractory AML

AML is a highly diverse blood malignancy characterized by the autonomous clonal proliferation of immature myeloid cells that have impaired differentiation and maturation ability. As a result of the abnormal proliferation of leukemia cells in the bone marrow, normal hematopoietic function is significantly inhibited, resulting in various symptoms associated with leukopenia, anemia, and thrombocytopenia. If appropriate treatment is not given, it is a serious disease that can become fatal within a short period of time due to infection or bleeding. The number of AML patients in Japan is estimated to be approximately 11,000[1)].

Treatment for this disease involves induction therapy, such as the combination of anthracyclines and cytarabine, but 10-40% of patients do not achieve remission[2)] and approximately half of patients relapse[3),] so they move on to salvage therapy for relapsed/refractory disease.

The intended indication for this drug is relapsed/refractory AML that is IDH1 mutation-positive, expected to be 6-9% of AML patients[4)].

1) Ministry of Health, Labor and Welfare 2020 Patient Survey, 2) Blood (2015) 126 (3): 319-27., 3) Leukaemia Care. Relapse in Acute Myeloid Leukaemia (AML). Version 3., 4) NCCN Guidelines 2024 V3

About Rigel Pharmaceuticals, Inc.

Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) is a biotechnology company dedicated to discovering, developing and providing novel therapies that significantly improve the lives of patients with hematologic disorders and cancer. Founded in 1996, Rigel is based in South San Francisco, California. For more information on Rigel, the Company's marketed products and pipeline of potential products, visit www.rigel.com.