News Release

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Merck KGaA, Darmstadt, Germany, Exercises Option with Abbisko, Giving Company Worldwide Commercialization Rights for Pimicotinib

Darmstadt, Germany, March 28, 2025 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced it has exercised its option with Abbisko Therapeutics Co. Ltd, Shanghai, China for commercialization of pimicotinib in the U.S. and rest of world and will pay Abbisko an option fee of $85 million. Under the agreement signed in 2023 for the commercialization rights in Mainland China, Hong Kong, Macau, and Taiwan, Merck KGaA, Darmstadt, Germany, now holds worldwide commercialization rights for pimicotinib. The companies recently reported positive topline results from the global Phase III MANEUVER study, demonstrating pimicotinib significantly improved the primary endpoint of objective response rate versus placebo (54.0% vs. 3.2% at week 25, $p<0.0001$) in the treatment of patients with tenosynovial giant cell tumor (TGCT). The companies also will explore pimicotinib in additional indications, such as chronic graft-versus-host disease (cGvHD).

"Today marks a significant milestone in our partnership with Abbisko as we work together to deliver a potentially best-in-class therapy for patients with TGCT around the world," said Andrew Paterson, Chief Marketing Officer for the Healthcare business sector of Merck KGaA, Darmstadt, Germany. "This collaboration underscores our commitment to advancing new treatment options in rare oncology

for patients who need them. With this important step forward, we aim to transform the treatment landscape and offer hope to those living with TGCT, who today have very limited treatment options."

TGCT is a non-malignant and often recurring tumor of the joints that can cause high morbidity associated with swelling, pain, stiffness, and limited mobility of the affected joints, significantly impacting daily activities and quality of life in the primarily working-age population that it affects. If left untreated or in recurrent cases, TGCT can result in irreversible damage to the bone, joint and surrounding tissues. This highlights the need for well-tolerated and effective systemic treatments that can impact tumor growth while relieving the symptoms of the disease.

About MANEUVER

The pivotal Phase III MANEUVER study is a three-part, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of pimicotinib in patients with TGCT, who are eligible for systemic therapy and have not received prior anti-CSF-1/CSF-1R therapy. The study is being conducted in China (n=45), Europe (n=28), and the US and Canada (n=21).

In the double-blind Part 1, 94 patients were randomized 2:1 to receive either 50 mg QD of pimicotinib (n=63) or placebo (n=31) for 24 weeks. The primary endpoint is objective response rate (ORR) at week 25, as measured by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 by blinded independent central review in the intent-to-treat (ITT) population. Secondary endpoints include tumor volume score, active range of motion, stiffness by Numeric Rating Scale (NRS), pain by Brief Pain Inventory (BPI), and physical function measured by Patient-Reported Outcomes Measurement Information System (PROMIS).

After the double-blind Part 1, eligible patients may continue to the open-label Part 2 for up to 24 weeks of dosing, results of which are expected in mid-2025. Patients who complete Part 2 may then enter the open-label extension phase (Part 3) for extended treatment and safety follow-up.

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About Pimicotinib (ABSK021)

Pimicotinib (ABSK021), which is being developed by Abbisko Therapeutics, is a novel, orally administered, highly selective and potent small-molecule inhibitor of CSF-1R. Pimicotinib has been granted breakthrough therapy designation (BTD) for the treatment of inoperable TGCT by China National Medical Products Administration (NMPA) and the US Food and Drug Administration (FDA), and priority medicine (PRIME) designation from the European Medicines Agency (EMA).

Advancing the Future of Cancer Care

At Merck KGaA, Darmstadt, Germany, we strive every day to improve the futures of people living with cancer. Our research explores the full potential of promising mechanisms in cancer research, focused on synergistic approaches designed to hit cancer at its core. We are determined to maximize the impact of our standard-of-care treatments and to continue pioneering novel medicines. Our vision is to create a world where more cancer patients will become cancer survivors.

About Merck KGaA, Darmstadt, Germany
Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across life science, healthcare and electronics. More than 62,000 employees work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. From providing products and services that accelerate drug development and manufacturing as well as discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2024, Merck KGaA, Darmstadt, Germany, generated sales of € 21.2 billion in 65 countries.