

## News Release

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## **Merck KGaA, Darmstadt, Germany, Strengthens Oncology Portfolio Through Commercialization Agreement With Abbisko for Phase III Asset, Pimicotinib**

- **Pimicotinib (ABSK021) is currently in a global Phase III study in tenosynovial giant cell tumor (TGCT)**
- **Merck KGaA, Darmstadt, Germany to receive an exclusive commercial license in mainland China, Hong Kong, Macau and Taiwan with option for rest of world**
- **Pimicotinib has been granted Breakthrough Therapy Designation by China NMPA and U.S. FDA and PRIME Designation by the EMA for treatment of TGCT**

Darmstadt, Germany, December 4, 2023 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced a license agreement with Abbisko Therapeutics Co. Ltd, Shanghai, China, for pimicotinib (ABSK021), which is currently being evaluated in a Phase III study for the treatment of tenosynovial giant cell tumor (TGCT). TGCT is a benign tumor of the joints that can cause swelling, pain, stiffness, and limited mobility of the affected joints. Treatment options for this disease, which can seriously affect patients' quality of life, are very limited. The agreement grants Merck KGaA, Darmstadt, Germany a license to



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commercialize pimicotinib in mainland China, Hong Kong, Macau and Taiwan, with an option for rest of world.

“We have the opportunity through our partnership with Abbisko to deliver a first-in-class treatment for a critically underserved patient population in China and potentially beyond,” said Andrew Paterson, Chief Marketing Officer for the Healthcare business sector of Merck KGaA, Darmstadt, Germany. “Pimicotinib provides an opportunity to address a significant unmet medical need and for us to expand our commercial footprint in oncology in China, the second largest pharmaceutical market in the world.”

Pimicotinib is an orally administered, highly selective and potent small-molecule antagonist of colony stimulating factor-1 receptor (CSF-1R) currently being evaluated in a global Phase III clinical trial as a potential therapy for TGCT. No drugs are currently approved in China for the disease, and only one medicine has been approved in the U.S.

In a recent Phase Ib trial, pimicotinib demonstrated clinically meaningful and sustained antitumor activity, with an overall response rate at one-year follow-up of 87.5% (28/32, including 3 complete responses) among patients receiving the 50mg QD dose, as determined by the Independent Review Committee based on Response Evaluation Criteria in Solid Tumors v1.1 (RECIST 1.1). The ongoing randomized, double-blind, placebo-controlled Phase III MANEUVER trial is evaluating the efficacy and safety of pimicotinib 50 mg QD in patients with unresectable TGCT.

“The collaboration with Merck KGaA, Darmstadt Germany, is an important milestone in advancing the global commercialization process of pimicotinib, and provides a new model for the commercialization path of Abbisko’s pipeline in the future,” said Dr. Xu Yao-chang, Chairman of Abbisko Therapeutics. “We are pleased to collaborate with a leading multinational pharmaceutical company, jointly accelerating the global approval and commercialization pace of pimicotinib and striving to bring new treatment options to patients as soon as possible.”

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Under the terms of the agreement, Merck KGaA, Darmstadt, Germany will receive an exclusive license to commercialize pimicotinib in mainland China, Hong Kong, Macau and Taiwan, with an exclusive commercialization option in the rest of the world. Abbisko will continue to develop pimicotinib. In addition, Merck KGaA, Darmstadt, Germany has the option to co-develop pimicotinib in additional indications under certain conditions. Merck KGaA, Darmstadt, Germany will provide Abbisko with an upfront payment of \$70 million and upon exercising the option, will provide Abbisko an option fee. Abbisko will receive additional payments for the achievement of certain regulatory and commercial milestones as well as double-digit tiered royalties on net sales by Merck KGaA, Darmstadt, Germany.

### **About Pimicotinib (ABSK021)**

Pimicotinib (ABSK021), which was independently 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 designations (BTD) by China National Medical Products Administration (NMPA) and the U.S. Food and Drug Administration (FDA) and priority medicine (PRIME) designation from the European Medicines Agency (EMA) for the treatment of patients with TGCT that are not amenable to surgery.

A Phase Ia dose escalation study for pimicotinib has been completed in the U.S., and the global Phase III MANEUVER clinical trial of pimicotinib for the treatment of TGCT is underway in China, the U.S., Canada, and Europe.

In addition to TGCT, Abbisko Therapeutics is actively exploring the potential of pimicotinib in treating other indications including many types of solid tumors. Abbisko also has obtained approval from NMPA to conduct Phase II clinical studies in chronic graft-versus-host disease and advanced pancreatic cancer.

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### **About Merck KGaA, Darmstadt, Germany**

Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across life science, healthcare and electronics. More than 64,000 employees work to make a positive difference to

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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 2022, Merck KGaA, Darmstadt, Germany, generated sales of € 22.2 billion in 66 countries.

The company holds the global rights to the name and trademark "Merck" internationally. The only exceptions are the United States and Canada, where the business sectors of Merck KGaA, Darmstadt, Germany, operate as MilliporeSigma in life science, EMD Serono in healthcare and EMD Electronics in electronics. Since its founding in 1668, scientific exploration and responsible entrepreneurship have been key to the company's technological and scientific advances. To this day, the founding family remains the majority owner of the publicly listed company.