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News Release

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Pimicotinib Approved as Systemic Treatment in China for Tenosynovial Giant Cell Tumor

- **First regulatory approval in the world for pimicotinib based on positive data from global Phase 3 MANEUVER study**
- **In MANEUVER, pimicotinib significantly improved objective response rate at week 25 (54% vs. 3.2% for placebo), while providing clinically meaningful and statistically significant improvements across all patient-reported outcomes**
- **With longer-term follow-up, 3 out of 4 patients treated with pimicotinib achieved response per RECIST v1.1, and treatment continued to be well-tolerated**
- **Approval strengthens company's leadership in rare tumors, with additional ongoing regulatory filings for pimicotinib underway globally**

Darmstadt, Germany, December 22, 2025 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, announced today that following Priority Review, the China National Medical Products Administration (NMPA) has approved pimicotinib for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause functional limitation or relatively severe morbidity. Pimicotinib, a colony stimulating factor-1 receptor (CSF-1R) inhibitor developed by Abbisko Therapeutics Co., Ltd., Shanghai,

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China, is the first Chemical Drug Class 1 approved in China for the treatment of TGCT.

"We are continuing to deliver on our commitment to improving the lives of patients with rare tumors with this first-in-the-world regulatory approval of pimicotinib," said Danny Bar-Zohar, CEO Healthcare and Member of the Executive Board of Merck KGaA, Darmstadt, Germany. "This approval is a significant step forward in further strengthening our leadership in rare tumors, while offering patients the opportunity to change the course of their disease and help alleviate symptoms that impact their daily lives. We are now working to make pimicotinib available to patients in China as quickly as possible, as we continue to progress applications with regulatory authorities in additional markets."

TGCT is a rare, locally aggressive tumor of the joint leading to progressive swelling, stiffness and reduced mobility of the affected joint, significantly impacting daily activities and quality of life in the otherwise healthy population that it affects. If left untreated or in recurrent cases, TGCT can result in irreversible damage to the bone, joint and surrounding tissues. Historically TGCT may have been known by several different names, including pigmented villonodular synovitis (PVNS).

The approval of pimicotinib by the China NMPA is based on results from the global Phase 3 MANEUVER study, in which pimicotinib demonstrated the highest objective response rate (ORR) based on RECIST v1.1 seen in a Phase 3 trial of a systemic TGCT treatment, as well as meaningful improvements in clinical outcomes. At week 25, pimicotinib demonstrated a statistically significant improvement in the primary endpoint of ORR assessed by blinded independent review committee (BIRC) based on RECIST v1.1 compared with placebo at week 25 (54.0% vs. 3.2% for placebo; $p<0.0001$). Pimicotinib also demonstrated clinically meaningful and statistically significant improvements across secondary endpoints relevant to patients' daily lives, improving relative range of motion ($p=0.0003$) and physical function measured by PROMIS-PF scale ($p=0.0074$) and reducing worst stiffness ($p<0.0001$) and worst pain ($p<0.0001$). These findings were presented at the 2025 ASCO Annual Meeting. Longer-term results presented at the ESMO Congress 2025 showed that with a median follow-up of 14.3 months, ORR per RECIST v1.1 increased

considerably among patients treated with pimicotinib from the beginning of the study, to 76.2% (95% CI: 63.8, 86.0).

"Many people living with TGCT in China have faced a long and difficult journey due to the lack of approved options beyond surgery, which may not address the needs of patients whose tumors recur or are not amenable to resection," said Prof. Niu Xiaohui, Director of the Bone and Soft Tissue Tumour Diagnosis and Research Centre at Beijing Jishuitan Hospital. "With the approval of pimicotinib based on the results of the global MANEUVER study, healthcare professionals in China will soon have the opportunity to prescribe their patients an effective and well-tolerated systemic treatment option, offering a much-needed advance in how they manage this challenging condition."

In MANEUVER, pimicotinib was well-tolerated, with no evidence of cholestatic hepatotoxicity or hair/skin hypopigmentation. During the randomized, double-blind treatment phase of the trial, treatment-emergent adverse events (TEAEs) leading to treatment discontinuation occurred in one patient (1.6%) treated with pimicotinib; TEAEs leading to dose reduction occurred in 7.9% (n=5) of pimicotinib-treated patients.

About MANEUVER

The pivotal global Phase 3 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 require systemic therapy and have not received prior anti-CSF-1/CSF-1R therapy. The study is being conducted by Abbisko Therapeutics 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 was 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 (BICR) in the intent-to-treat (ITT) population. Secondary endpoints include ORR per tumor volume score (TVS), relative 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-PF).

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After the double-blind Part 1, eligible patients could continue to the open-label Part 2 for up to 24 weeks of further treatment. Patients who completed Part 2 could then enter the open-label extension phase (Part 3) for extended treatment and safety follow-up.

About pimicotinib (ABSK021)

Pimicotinib, developed by Abbisko Therapeutics, is a novel, orally administered, highly selective and potent small-molecule inhibitor of CSF-1R. It has been granted breakthrough therapy designation (BTD) for the treatment of inoperable TGCT by the U.S. Food and Drug Administration (FDA), and priority medicine (PRIME) designation from the European Medicines Agency (EMA). Merck KGaA, Darmstadt, Germany, holds worldwide commercialization rights for pimicotinib.