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Not intended for UK-based media

January 12, 2026

FDA Accepts New Drug Application for Pimicotinib for the Treatment of Tenosynovial Giant Cell Tumor

Darmstadt, Germany, January 12, 2026 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, announced today that the U.S. Food and Drug Administration (FDA) has accepted the company's new drug application (NDA) for pimicotinib as a systemic treatment for patients with tenosynovial giant cell tumor (TGCT). The application is based on the primary results and longer-term follow-up of the global Phase 3 MANEUVER study, which demonstrated deep and durable tumor responses and meaningful improvements in clinical outcomes with pimicotinib.

"With pimicotinib, we have an opportunity to significantly advance care for people living with TGCT, a painful and debilitating disease that has few effective and well-tolerated treatment options beyond surgery," said David Weinreich, Global Head of R&D and Chief Medical Officer for the Healthcare business of Merck KGaA, Darmstadt, Germany. "Based on clinical trial results showing not only a reduction in tumor burden, but also the ability to help alleviate symptoms like pain and stiffness in the global Phase 3 MANEUVER study, we are confident in the important role pimicotinib can play for TGCT patients in the U.S. and worldwide."

News Release

The application is based on primary and longer-term results from the global Phase 3 MANEUVER study. In this trial, once-daily pimicotinib demonstrated a statistically significant improvement in the primary endpoint of objective response rate (ORR) assessed by blinded independent review committee (BIRC) by RECIST v1.1 compared with placebo at week 25. The study also demonstrated statistically significant and clinically meaningful improvements in all secondary endpoints related to key patient-reported outcomes in TGCT, including improvements in active range of motion and physical function and reductions in stiffness and pain. These findings were presented at the 2025 ASCO Annual Meeting. Longer-term results with median follow-up of 14.3 months presented at ESMO Congress 2025 showed ORR continued to increase over time among patients treated with pimicotinib from the beginning of the study.

TGCT is a rare, locally aggressive tumor occurring in or around the joint leading to progressive swelling, stiffness and reduced mobility of the affected joint, significantly impacting daily activities and quality of life in what is typically an otherwise healthy population. If left untreated or in recurrent cases, TGCT may result in irreversible damage to the bone, joint and surrounding tissues. A significant need remains for highly effective and well-tolerated treatments beyond surgery that can not only shrink tumors but also alleviate pain and restore function.

In December 2025, pimicotinib was approved by the China National Medical Products Administration (NMPA) for the treatment of adult patients with symptomatic TGCT for which surgical resection will potentially cause functional limitation or relatively severe morbidity. Additional applications are under review by regulatory bodies in other markets.

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 U.S. and Canada (n=21).

News Release

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 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).

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. Pimicotinib is approved in China 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. 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.

Merck KGaA
Darmstadt, Germany

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