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Two-Year Data of Pimicotinib Demonstrated Durable Tumor Control and Sustained Improvement in TGCT Symptoms and Joint Function

- **Improvements in symptoms of pain, stiffness, and range of motion were sustained through two years**
- **Tumor responses remained robust¹ and durable²**

Not intended for UK-based media

Darmstadt, Germany, October 26, 2026 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced new two-year follow up results from the Phase 3 MANEUVER study evaluating pimicotinib in patients with tenosynovial giant cell tumor (TGCT). The study showed that among patients initially randomized to pimicotinib, improvements in symptoms and joint function were observed as early as Week 5, sustained through two years, and continued to improve over time. Tumor responses remained robust¹ and durable,² and the safety profile was consistent with previous analyses. The findings are being presented today in the Sarcoma poster session at **the European Society for Medical Oncology (ESMO) Congress 2026 (Presentation # 3747P)**.

"For people living with TGCT, the impact of the disease is often felt through persistent limitations in mobility, physical function and the ability to carry out everyday activities," said Vinod Ravi, MD, MS, MBA, Department of Sarcoma Medical Oncology, Division of Cancer Medicine, UT MD Anderson, an investigator on the MANEUVER trial. "What is encouraging about these two-year findings is the consistency of improvements, not only in the durability of tumor response, but





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across the symptoms and functional outcomes that matter to patients. Together with the observed safety profile, these results provide important insight into the potential for pimicotinib to deliver meaningful benefit over time."

The new analysis in patients initially randomized to pimicotinib found that at Week 97, mean changes from baseline were 19.6% in range of motion, -3.9 in stiffness (as measured by the Worst Stiffness Numeric Scale Rating), -3.1 in pain (as measured by the Brief Pain Inventory worst pain rating) and +7.4 in physical function (as measured by the patient-reported PROMIS-PF scale).

Tumor responses also remained robust¹ and durable² through two years. Objective Response Rate (ORR) by blinded independent review committee (BIRC) per RECIST v1.1 was 76.2% (95% CI: 63.8, 86.0), remaining unchanged from the one-year analysis, while ORR per BIRC based on tumor volume score (TVS) increased from 74.6% at one year to 77.8% (95% CI: 65.5, 87.3) at two years. Median duration of response was not reached at the time of analysis, and median treatment duration was 22.6 months (range: 1.8-33.6 months) at the March 1, 2026 data cutoff. Fifty-four percent of patients initially randomized to pimicotinib remained on treatment at two years.

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.

"These two-year findings add to the growing body of evidence from the MANEUVER study demonstrating the potential for pimicotinib to meaningfully address some of the burden of TGCT," said David Weinreich, MD, MBA, Global Head of R&D and Chief Medical Officer for the Healthcare business of Merck KGaA, Darmstadt, Germany. "The sustained improvements observed across symptoms, physical function and tumor control reinforce the potential of pimicotinib to address aspects of TGCT that can affect patients every day. These results add to our evolving understanding of



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the long-term benefit that pimicotinib may provide for people living with this debilitating rare tumor."

TGCT is a rare, locally aggressive tumor occurring in or around the joints leading to progressive worsening of symptoms including pain and reduced mobility of the affected joint, significantly impacting physical function in what is typically an otherwise healthy and young adult population. Patient-reported experiences indicate that up to half of people with TGCT may initially receive an incorrect diagnosis, which can delay appropriate disease management.³ If left untreated or in recurrent cases, TGCT may result in cumulative morbidity and irreversible damage to the bone, joint and surrounding tissues.

Pimicotinib was approved in China by the China National Medical Products Administration (NMPA) in December 2025 and in Canada by Health Canada in June 2026 for the treatment of adult patients with symptomatic TGCT. A regulatory application is currently under review by the U.S. Food and Drug Administration (FDA) and other regulatory agencies.

¹ 54% ORR as assessed by BIRC based on RECIST v1.1 at week 25 vs. 3% with placebo; $p < 0.0001$.

² The majority (77%) of patients with response at 25 weeks maintained this clinical benefit after an additional 12 months of treatment.

³ Stern S, et al. Localized and diffuse tenosynovial giant cell tumor: real-world results from a patient observational registry. *Future Oncol.* 2025;21(12):1501-1510.

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 were eligible for systemic therapy and have not received prior anti-CSF-1/CSF-1R therapy.

The ongoing study is being conducted by Abbisko Therapeutics and enrolled patients globally in U.S., Canada and Europe (n=49) and China (n=45).

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. In addition to the primary endpoint of ORR at week 25, as measured by RECIST v1.1 by BICR, secondary endpoints



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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, all eligible patients from either arm could continue to the open-label Part 2 and receive up to 24 weeks of pimicotinib 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, selective and potent small-molecule inhibitor of CSF-1R. Pimicotinib has been approved for the treatment of adult patients with symptomatic TGCT for which surgical resection will potentially cause functional limitation or relatively severe morbidity by China National Medical Products Administration (NMPA) and Health Canada. 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.

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 2025, Merck KGaA, Darmstadt, Germany, generated sales of € 21.1 billion in 65 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.

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