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News Release

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Not intended for UK-based media

October 17, 2025

Pimicotinib Treatment Demonstrates Deep and Durable Tumor Responses and Continued Improvements in Pain and Function for Patients with TGCT

- **With median follow-up of 14.3 months, pimicotinib demonstrated increasing ORR over time, from 54% at Week 25 to 76.2%**
- **Global Phase 3 MANEUVER study demonstrated ongoing improvements in key secondary endpoints including pain and function**
- **Application for marketing authorization under review by China National Medical Products Administration (NMPA), with additional applications planned in the U.S. and other markets**

Darmstadt, Germany, October 17, 2025 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced the presentation of longer-term results from the global Phase 3 MANEUVER trial evaluating pimicotinib, an investigational colony stimulating factor-1 receptor (CSF-1R) inhibitor in development by Abbisko Therapeutics Co., Ltd., for the treatment of patients with tenosynovial giant cell tumor (TGCT). This latest analysis showed that, with a median follow-up of 14.3 months, the objective response rate (ORR) for people treated with pimicotinib from the beginning of the study increased considerably to 76.2% (95% CI: 63.8, 86.0) by blinded independent review committee (BICR) per

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RECIST v1.1, from 54% at Week 25. The study also showed continued clinically meaningful improvements in key secondary endpoints related to patient outcomes such as pain and function. The safety profile was consistent with previously reported data. The results are being presented today in the Sarcoma mini-oral session at the European Society for Medical Oncology (ESMO) Congress 2025 (Presentation # 2690MO).

"With the initial results of the global MANEUVER study presented earlier this year at ASCO, pimicotinib demonstrated the highest objective response rate seen in a Phase 3 clinical trial of a systemic therapy in TGCT," said Prof. Niu Xiaohui, Director of the Bone and Soft Tissue Tumour Diagnosis and Research Centre at Beijing Jishuitan Hospital. "These latest findings build on those impressive results, showing that these tumor responses not only persist but deepen over time. Importantly, we also see continued improvements beyond one year in the patient-reported symptoms and functional outcomes that truly make a difference in patients' abilities to go about their daily lives. Together, these findings indicate the potential for pimicotinib to be a best-in-class systemic treatment for patients with TGCT."

"TGCT causes pain, stiffness, and loss of range of motion, affecting patients' ability to participate in activities of daily living and with their families or communities. Ultimately, this affects everyone and takes a mental and physical toll," said Sydney Stern, PhD, MS, TGCT Support, a Program of the Life Raft Group. "Patients benefit from more options that address their symptoms and shrink the disease. Importantly, addressing their symptoms enables patients to be the parents, partners, carers, and people they want to be without wondering when their TGCT will take over their life again."

The latest analysis of the global Phase 3 MANEUVER trial includes results from 63 patients who received pimicotinib for 24 weeks in Part 1 and then continued on pimicotinib in the open-label phase of the trial. With a median follow-up of 14.3 months, tumor responses continued to improve:

- ORR per BIRC based on RECIST v1.1 increased to 76.2% (95% CI: 63.8, 86.0), from 54% at Week 25.

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- ORR per BIRC based on tumor volume score (TVS), an endpoint designed specifically for TGCT, increased to 74.6% (95% CI: 62.1, 84.7), from 61.9% at Week 25.
- At the time of the data cutoff, the median duration of response was not reached (range: 0.03-19.81 months), with 93.7% of pimicotinib-treated patients experiencing a reduction in tumor size by BIRC per RECIST v1.1 at longer-term follow up.

Pimicotinib also demonstrated clinically meaningful improvements with longer-term follow-up up to week 73 in key patient-reported measures including range of motion, pain, stiffness and physical function that significantly impact people living with TGCT:

- For relative range of motion, pimicotinib showed a mean change from baseline of 23.9% (increased from 15.6% at week 25).
- Mean change from baseline continued to show improvements in physical function as measured by the patient-reported PROMIS-PF scale, and reductions in stiffness and pain as measured by the Worst Stiffness Numeric Scale Rating and Brief Pain Inventory worst pain rating, respectively.

The analysis also includes results for patients who were initially randomized to receive placebo in Part 1, then switched to pimicotinib in the open label part of the study (n=31). These patients experienced a clear benefit from pimicotinib treatment, with an ORR of 64.5% both by BICR per RECIST v1.1 and by TVS with a median follow-up of 8.5 months after switching to pimicotinib.

At longer-term follow-up, in patients who had received pimicotinib throughout the study, there were no new safety signals, and no evidence of cholestatic hepatotoxicity, drug-induced liver injury or hair/skin hypopigmentation. Most treatment-emergent adverse events remained mild in severity and were manageable.

"These longer-term results highlight the potential of pimicotinib to transform care by providing a systemic therapy that delivers meaningful, lasting benefit not only in terms of reducing tumor burden but in helping patients regain function and live with reduced pain," said Victoria Zazulina, M.D., Head of Development Unit, Oncology,

for the Healthcare business of Merck KGaA, Darmstadt, Germany. "Guided by this robust global study—conducted across North America, Europe and China—we are working with regulatory authorities as we seek to make this treatment available to patients as quickly as possible."

An application for marketing authorization of pimicotinib as a Class 1 innovative drug for adult patients with TGCT has been accepted for review by the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA). Additional applications are planned in the U.S. and other markets around the world.

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).

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 (ABSK021), which is being developed by Abbisko Therapeutics, is a novel, orally administered, highly selective and potent small-molecule inhibitor of

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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 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.

Advancing the Future of Cancer Care

At Merck KGaA, Darmstadt, Germany, we strive every day to improve the futures of people living with cancer. Building on our 350-year global heritage as pharma pioneers, we are focusing our most promising science to target cancer's deepest vulnerabilities, pursuing differentiated molecules to strike cancer at its core. By developing new therapies that can help advance cancer care, we are determined to create a world where more cancer patients will become cancer survivors. Learn more at www.emdgroup.com.

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.

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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