News Release

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FDA Approves PIMJETMI® (pimicotinib) for Patients with Tenosynovial Giant Cell Tumor

- **PIMJETMI is a new once-daily oral systemic treatment option for certain U.S. patients with symptomatic tenosynovial giant cell tumor (TGCT)**
- **In the Phase 3 MANEUVER trial, PIMJETMI demonstrated early[1] and durable[2] tumor response with clinically meaningful improvements in all clinical outcome assessments, including physical function and pain**
- **PIMJETMI has shown high objective response rate (ORR) with a manageable safety profile**

Darmstadt, Germany, November 10, 2026 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, announced today that the U.S. Food and Drug Administration (FDA) has approved PIMJETMI® (pimicotinib), a once-daily oral colony stimulating factor-1 receptor (CSF-1R) inhibitor, as a systemic treatment for adults with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection may cause worsening functional limitation or severe morbidity.

"People living with TGCT have long faced difficult treatment decisions as they navigate a disease that can significantly affect their daily lives including their mobility," said Danny Bar-Zohar, CEO Healthcare and Member of the Executive

Board of Merck KGaA, Darmstadt, Germany. "Translating scientific innovation into clinically meaningful advances for people living with rare tumors is a strategic imperative for our company, as we continue our commitment to addressing significant unmet needs. With the approval of PIMJETMI in the U.S., we strengthen our leadership position and growing portfolio in rare tumors and bring real hope to patients and their families."

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 population. It has been reported that up to half of people with TGCT can be initially misdiagnosed, resulting in delays in the 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.

"The results of the Phase 3 MANEUVER trial demonstrate that PIMJETMI elicits durable[2] tumor response with a manageable tolerability profile," said Vinod Ravi, MD, MS, MBA, Department of Sarcoma Medical Oncology, Division of Cancer Medicine, UT MD Anderson, an investigator on the MANEUVER trial. "This combination of efficacy and safety data will potentially address the needs of people living with TGCT in a once-daily treatment option."

FDA approval is based on primary and longer-term results from the global Phase 3 MANEUVER study. PIMJETMI demonstrated a statistically significant improvement in objective response rate (ORR) at week 25 as assessed by blinded independent review committee (BIRC) based on RECIST v1.1 compared with placebo (56% vs. 3% for placebo; $p<0.0001$). PIMJETMI also demonstrated clinically meaningful and statistically significant improvements as compared to placebo across secondary endpoints relevant to patients' daily lives, improving relative range of motion ($p=0.0003$), physical functioning ($p=0.0074$), and pain ($p<0.0001$). The MANEUVER study was presented at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting. In the longer-term follow up (median 14.3 months for patients initially randomized to pimicotinib) presented at the European Society for Medical Oncology (ESMO) Congress in 2025, the median duration of response was

not reached. The majority (77%) of patients with response at 25 weeks maintained clinical benefit after an additional 12 months of follow up, demonstrating the durability[2] of response with PIMJETMI.

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.

“TGCT can profoundly affect patients' daily lives through persistent pain, swelling, and loss of joint function,” said Sydney Stern, PhD, MS, TGCT Support, a Program of the Life Raft Group. “For symptomatic patients who are not likely to benefit from surgery alone, there remains need for treatment options which are tolerable and effectively address the burden of disease, shrink their TGCT, and improve pain and function.”

The FDA approval of PIMJETMI builds on growing momentum for the Merck KGaA, Darmstadt, Germany rare tumors portfolio that included two other drug approvals in the past three years including OGSIVEO®, the first FDA-approved treatment for adults with progressing desmoid tumors who require systemic therapy. The PIMJETMI approval follows its approval in China by the National Medical Products Administration (NMPA) in December 2025, in Canada by Health Canada in June 2026 for the treatment of adult patients with symptomatic TGCT, as well as in Switzerland by its own independent national regulatory authority, the Swissmedic in October 2026.In May 2025, Merck KGaA, Darmstadt, Germany launched in the U.S. TGCT & Me, a free app created with insights from patients, HCPs, and a patient advocacy group to help people navigate life with TGCT.

The application for PIMJETMI was reviewed under Project Orbis, an international initiative of the FDA Oncology Center of Excellence. Application reviews are ongoing for partners of Project Orbis, an international framework for collaboration.

[1] In the global Phase 3 MANEUVER clinical trial, the effect of pimicotinib had an early onset, with 41.3 % (26 of 63) of patients experiencing objective response to therapy after 13 weeks.

[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 PIMJETMI 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 USA, 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 PIMJETMI (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 include tumor volume score (TVS), relative range of motion, 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 PIMJETMI® (pimicotinib)

PIMJETMI, developed by Abbisko Therapeutics, is a novel, orally administered, highly selective and potent small-molecule inhibitor of CSF-1R. PIMJETMI 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. PIMJETMI has received priority medicine (PRIME) designation from the European Medicines Agency (EMA). Merck KGaA, Darmstadt, Germany, holds worldwide commercialization rights for PIMJETMI.

PIMJETMI Important Safety Information from the US FDA-Approved Label

Approved Use

PIMJETMI (pimicotinib) is a prescription medicine used to treat adults with symptomatic tenosynovial giant cell tumor (TGCT) when surgery may make the symptoms worse or cause severe problems.

It is not known if PIMJETMI is safe and effective in children.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about PIMJETMI?

PIMJETMI can cause serious side effects, including liver problems. Increased liver enzymes in your blood are common with PIMJETMI. Your healthcare provider will do blood tests to check for liver problems:

- before starting treatment with PIMJETMI,
- every month for the first 3 months,
- then every 3 months for the rest of the first year after starting treatment and as needed thereafter during treatment with PIMJETMI.

If you develop liver problems during treatment with PIMJETMI, your healthcare provider may temporarily stop treatment, decrease your dose, or permanently stop treatment depending on how severe your liver problems are.

- Tell your healthcare provider right away if you develop any signs or symptoms of liver problems during treatment with PIMJETMI including yellowing of your skin or the white part of your eyes, dark urine, lack or loss of appetite, pain or tenderness on the upper right side of your stomach-area (abdomen), feeling overly tired, nausea, vomiting, fever, rash and itching.

Before taking PIMJETMI, tell your healthcare provider about all of your medical conditions, including if you:

- have or had liver problems.
- are pregnant or plan to become pregnant. PIMJETMI can harm your unborn baby.

  Females who are able to become pregnant:
  - Your healthcare provider will do a pregnancy test before you start treatment with PIMJETMI.
  - Use effective birth control (contraception) during treatment and for 2 weeks after your last dose of PIMJETMI.

- Tell your healthcare provider right away if you become pregnant or you think you may be pregnant during treatment with PIMJETMI.

Males with female partners who are able to become pregnant:

- Use effective birth control (contraception) during treatment and for 2 weeks after your last dose of PIMJETMI.
- Tell your healthcare provider right away if your female partner becomes pregnant or thinks she may be pregnant during treatment with PIMJETMI.

- Tell your healthcare provider if you are breastfeeding or plan to breastfeed. It is not known if PIMJETMI passes into your breast milk. **Do not** breastfeed during treatment with PIMJETMI and for 2 weeks after your last dose of PIMJETMI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking PIMJETMI with certain other medicines may affect the way that PIMJETMI or the other medicine works and may increase your risk of side effects.

What are the possible side effects of PIMJETMI?
PIMJETMI can cause serious side effects.
The most common side effects of PIMJETMI include:

- itching
- rash
- swelling of your face
- swelling around your eyes
- tiredness
- nausea
- headache
- swelling of your hands and feet
- change in certain blood tests

PIMJETMI may cause fertility problems, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility. These are not all the possible side effects of PIMJETMI. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Please see full US Prescribing Information and Medication Guide available at http://www.PIMJETMI.com.

OGSIVEO Indication
OGSIVEO is indicated for adult patients with progressing desmoid tumors who require systemic treatment.

OGSIVEO Important Safety Information
Warnings And Precautions

Diarrhea: Diarrhea, sometimes severe, can occur in patients treated with OGSIVEO. Diarrhea occurred in 84% of patients treated with OGSIVEO, and included Grade 3 events in 16% of patients. Median time to first diarrhea event was 9 days (range: 2 to 434 days). Monitor patients and manage using antidiarrheal medications. Modify dose as recommended.
Ovarian Toxicity: Female reproductive function and fertility may be impaired in patients treated with OGSIVEO. Impact on fertility may depend on factors like duration of therapy and state of gonadal function at time of treatment. Long-term effects of OGSIVEO on fertility have not been established. Advise patients on the potential risks for ovarian toxicity before initiating treatment. Monitor patients for changes in menstrual cycle regularity or the development of symptoms of estrogen deficiency, including hot flashes, night sweats, and vaginal dryness.
Hepatotoxicity: ALT or AST elevations occurred in 30% and 33% of patients, respectively. Grade 3 ALT or AST elevations (>5 x ULN) occurred in 6% and 2.9% of patients. Monitor liver function tests regularly and modify dose as recommended.
Non-Melanoma Skin Cancers: New cutaneous squamous cell carcinoma and basal cell carcinoma occurred in 2.9% and 1.4% of patients, respectively. Perform dermatologic evaluations prior to initiation of OGSIVEO and routinely during treatment.
Electrolyte Abnormalities: Decreased phosphate (65%) and potassium (22%) occurred in OGSIVEO-treated patients. Phosphate <2 mg/dL occurred in 20% of patients. Grade 3 decreased potassium occurred in 1.4% of patients. Monitor phosphate and potassium levels regularly and supplement as necessary. Modify dose as recommended.
Embryo-Fetal Toxicity: OGSIVEO can cause fetal harm when administered to pregnant women. Oral administration of nirogacestat to pregnant rats during the period of organogenesis resulted in embryo-fetal toxicity and death at maternal exposures below human exposure at the recommended dose of 150 mg twice daily. Advise pregnant women of the potential risk to a fetus. Advise females and males of reproductive potential to use effective contraception during treatment with OGSIVEO and for 1 week after the last dose.

Adverse Reactions
The most common (≥15%) adverse reactions were diarrhea (84%), ovarian toxicity (75% in the 36 females of reproductive potential), rash (68%), nausea (54%), fatigue (54%), stomatitis (39%), headache (30%), abdominal pain (22%), cough (20%), alopecia (19%), upper respiratory tract infection (17%), and dyspnea (16%).
Serious adverse reactions occurred in 20% of patients who received OGSIVEO. Serious adverse reactions occurring in ≥2% of patients were ovarian toxicity (4%).
The most common laboratory abnormalities (≥15%) were decreased phosphate, increased urine glucose, increased urine protein, increased AST, increased ALT, and decreased potassium.

Drug Interactions
CYP3A Inhibitors and Inducers: Avoid concomitant use with strong or moderate CYP3A inhibitors (including grapefruit products, Seville oranges, and starfruit) and strong or moderate CYP3A inducers.
Gastric Acid Reducing Agents: Avoid concomitant use with proton pump inhibitors and H2 blockers. If concomitant use cannot be avoided, OGSIVEO can

be staggered with antacids (e.g., administer OGSIVEO 2 hours before or 2 hours after antacid use).
Consult the full Prescribing Information prior to and during treatment for important drug interactions.

Use in Specific Populations
Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with OGSIVEO and for 1 week after the last dose.
OGSIVEO may reduce the effectiveness of hormonal contraceptives. Addition of a barrier method is recommended for females using hormonal contraceptives.

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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