News Release

Your Contact
Media Relations
gangolf.schrimpf@emdgroup.com
Phone: +49 6151 72-9591

Investor Relations
investor.relations@emdgroup.com
Phone: +49 6151 72-3321

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European Medicines Agency Validates Application for Tepotinib for the Treatment of Advanced NSCLC with METex14 Skipping Alterations

Darmstadt, Germany, November 26, 2020 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced that the European Medicines Agency (EMA) has validated for review, the application for tepotinib for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition factor gene (*MET*) exon 14 (*MET*ex14) skipping alterations. With this validation, the application is complete, and the EMA will now begin the review procedure.

Tepotinib is a highly selective oral MET inhibitor that is administered once daily.[1] The application to EMA is based on results from the pivotal Phase II VISION study (NCT02864992) evaluating tepotinib as monotherapy in patients with advanced NSCLC with *MET*ex14 skipping alterations, prospectively assessed by liquid biopsy (LBx) or tissue biopsy (TBx). In the ongoing study, the patient population is generally characterized as elderly, with a median age of 74.0 years, and as having poor clinical prognosis typical of NSCLC with *MET*ex14 skipping alterations. Data from the primary analysis of the VISION study were published in *The New England Journal of Medicine (NEJM)* on May 29, 2020.[2]

Lung cancer is estimated to be the second most common cancer in Europe, and the leading cause of cancer-related mortality, responsible for 388,000 deaths in 2018.[3]

Frankfurter Strasse 250
64293 Darmstadt · Germany
Hotline +49 6151 72-5000
www.emdgroup.com

Head of Media Relations -6328
Spokesperson: -9591 / -8908 /
-45946 / -55707

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*MET*ex14 skipping occurs in approximately 3–4% of NSCLC cases and correlates with aggressive tumor behavior and poor clinical prognosis.[4] Currently, there are no treatments available in Europe for patients with advanced NSCLC harboring *MET*ex14 skipping alterations.

Tepotinib became the first oral MET inhibitor indicated for the treatment of advanced NSCLC harboring *MET* gene alterations to receive a regulatory approval globally, with its approval in Japan in March 2020 through the SAKIGAKE program. Recently, the FDA granted Orphan Drug Designation (ODD) to tepotinib and the FDA is reviewing the application under Priority Review and through the Real-Time Oncology Review pilot program.

About tepotinib
Tepotinib is an oral MET inhibitor that inhibits the oncogenic *MET* receptor signaling caused by *MET* (gene) alterations. Discovered and developed in-house at Merck KGaA, Darmstadt, Germany, it has a highly selective mechanism of action, with the potential to improve outcomes in aggressive tumors that have a poor prognosis and harbor these specific alterations.[1]
Additional Clinical Investigations: Tepotinib is also being investigated in the Phase II INSIGHT 2 study in combination with osimertinib in *MET* amplified, advanced or metastatic NSCLC harboring activating *EGFR* mutations that has progressed following first-line treatment with osimertinib, and in the Phase II PERSPECTIVE study in combination with cetuximab in RAS/BRAF wild-type left-sided metastatic colorectal cancer patients having acquired resistance to anti-EGFR antibody targeting therapy due to *MET* amplification.

References
1. Bladt F, et al. *Clin Cancer Res*. 2013;19:2941-2951.
2. Paik PK et al. Tepotinib in non–small-cell lung cancer with *MET* exon 14 skipping mutations. *N Engl J Med* 2020 May 29; [e-pub]. (https://doi.org/10.1056/NEJMoa2004407)
3. Ferlay J, et al. *Eur J Cancer.* 2018;103:356–387.
4. Reungwetwattana T, et al. *Lung Cancer*. 2017;103:27–37.

About Merck KGaA, Darmstadt, Germany
Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across healthcare, life science and performance materials. Around 57,000 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 advancing gene editing technologies and discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2019, Merck KGaA, Darmstadt, Germany generated sales of € 16.2 billion in 66 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 EMD Serono in healthcare, MilliporeSigma in life science, and EMD Performance Materials. 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.