NEWS RELEASE

Merck Announces Top-Line Results from Phase 3 Trials Evaluating Gefapixant, an Investigational Treatment for Refractory or Unexplained Chronic Cough

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KENILWORTH, N.J.--(**BUSINESS WIRE**)--Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced top-line efficacy results from two ongoing pivotal Phase 3 trials (COUGH-1 and COUGH-2) evaluating the efficacy and safety of gefapixant (MK-7264), an investigational, orally administered, selective P2X3 receptor antagonist, for the treatment of refractory or unexplained chronic cough. In these studies, the primary efficacy endpoints were met for the gefapixant 45 mg twice daily treatment arms – demonstrating a statistically significant decrease in 24-hour coughs per hour (average hourly cough frequency based on 24-hour sound recordings) versus placebo at 12 (COUGH-1) and 24 weeks (COUGH-2). The gefapixant 15 mg twice daily treatment arms did not meet the primary efficacy endpoint in either Phase 3 study. The safety and tolerability profile of gefapixant during the trials to date is consistent with the previously reported Phase 2 study. The trials will continue for long-term follow-up to collect additional safety data.

“The burden for patients faced with this disease underscores the need for effective therapeutic options for refractory and unexplained chronic cough,” said Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories. “We are pleased gefapixant at the 45 mg dose met the primary efficacy endpoints in both Phase 3 studies and we look forward to sharing the detailed findings at an upcoming medical meeting.”

About COUGH-1 and COUGH-2

COUGH-1 (NCT03449134) and COUGH-2 (NCT03449147) are international Phase 3, randomized, double-blind, placebo-controlled, studies to evaluate the efficacy and safety of gefapixant in reducing cough frequency in adult participants with refractory or unexplained chronic cough. COUGH-1 enrolled 732 participants and COUGH-2 enrolled 1,317 participants, with refractory or unexplained chronic cough for at least one year, as defined by guidelines from the American College of Chest Physicians (ACCP). In both studies, patients were randomized to one of three groups: gefapixant 45 mg twice daily, gefapixant 15 mg twice daily, or placebo. Participants remained on their assigned treatment at randomization throughout both studies. The primary efficacy outcomes measure for COUGH-1 and COUGH-2 were 24-hour coughs per hour at Week 12, and 24-hour coughs per hour at week 24, respectively, measured using an ambulatory digital audio recording device. Secondary endpoints in both trials included awake coughs per hour, percentage of participants with a greater than 1.3-point increase from baseline in the Leicester Questionnaire (LCQ) total score, and percentage of participants with a greater than 30% reduction from baseline in 24-hour coughs per hour. COUGH-1 had a 12-week treatment period and a 40-week extension period, while COUGH-2 had a 24-week treatment period and a 28-week extension period. Primary safety outcomes include the percentage of patients experiencing greater than one adverse event during treatment and follow up, and the percentage of patients discontinuing treatment because of adverse events.

About Gefapixant

Gefapixant is an investigational, orally administered, selective P2X3 receptor antagonist, for the treatment of refractory or unexplained chronic cough. It is believed that excessive activation of P2X3 receptors is associated with hyper-sensitization of sensory neurons. Neuronal hyper-sensitization in the airways and lungs, triggered by injury or infection, can cause an exaggerated, persistent and frequent urge to cough, otherwise known as chronic cough.

About Chronic Cough

The prevalence of chronic cough (a cough lasting more than 8 weeks) is estimated at 10% of the general adult population globally, and in up to 46% of these cases, no treatable cause can be identified despite a thorough diagnostic investigation. There are currently no approved therapies for the treatment of chronic cough.

About Merck

For more than 125 years, Merck, known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases – as we aspire to be the premier

research-intensive biopharmaceutical company in the world. For more information, visit **www.merck.com** and connect with us on **Twitter**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2019 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (**www.sec.gov**).

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