Merck Discontinues Development of SARS-CoV-2/COVID-19 Vaccine Candidates; Continues Development of Two Investigational Therapeutic Candidates

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KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that the company is discontinuing development of its SARS-CoV-2/COVID-19 vaccine candidates, V590 and V591, and plans to focus its SARS-CoV-2/COVID-19 research strategy and production capabilities on advancing two therapeutic candidates, MK-4482 and MK-7110. This decision follows Merck’s review of findings from Phase 1 clinical studies for the vaccines. In these studies, both V590 and V591 were generally well tolerated, but the immune responses were inferior to those seen following natural infection and those reported for other SARS-CoV-2/COVID-19 vaccines. Merck continues to advance clinical programs and to scale-up manufacturing for two investigational medicines, MK-7110 and MK-4482 (molnupiravir); molnupiravir is being developed in collaboration with Ridgeback Bio.

“We are grateful to our collaborators who worked with us on these vaccine candidates and to the volunteers in the trials,” said Dr. Dean Y. Li, president, Merck Research Laboratories. “We are resolute in our commitment to contribute to the global effort to relieve the burden of this pandemic on patients, health care systems and communities.”

Due to the discontinuation, the company will record a charge in the fourth quarter of 2020. The charge will be included in Merck’s generally accepted accounting principles (GAAP) results, but will not impact non-GAAP results.

Merck and its collaborators plan to submit the results of the Phase 1 studies for V590 and V591 for publication in a
peer-reviewed journal. In addition to advancing the development and production of MK-7110 and MK-4482, Merck will continue to conduct SARS-CoV-2/COVID-19 research. Merck will also continue to evaluate the potential of the measles-virus vector and vesicular stomatitis virus vector-based platforms and pursue broader pandemic-response capabilities. The COVID-19 pandemic underscores the need for our company and our industry to continue to invest in research to address threats to health security.

About Merck's therapeutic candidates

- MK-7110 (formerly CD24Fc) is a potentially first-in-class investigational recombinant fusion protein that modulates the inflammatory response to SARS-CoV-2, principally by targeting a novel immune pathway checkpoint. Interim results from a Phase 3 study showed a greater than 50 percent reduction in the risk of death or respiratory failure in patients hospitalized with moderate to severe COVID-19. Full results from this study are expected in the first quarter of 2021. In December, Merck announced a supply agreement with the U.S. government to advance the manufacturing and initial distribution of MK-7110 (link).
- Molnupiravir (MK-4482) is an oral novel investigational antiviral agent being developed in collaboration with Ridgeback Bio. Molnupiravir is currently being evaluated in Phase 2/3 clinical trials in both the hospital and out-patient settings. The primary completion date for the Phase 2/3 studies is May 2021. The company anticipates initial efficacy data in the first quarter of 2021, which Merck plans to share publicly if clinically meaningful.

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 the global outbreak of novel coronavirus disease (COVID-19); 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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