NEWS RELEASE

# Merck Announces Supply Agreement with U.S. Government for Initial Doses of Investigational Biological Therapy for the Treatment of Patients with Severe and Critical COVID-19

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KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced it has entered into an agreement with the United States Government to support the development, manufacture and initial distribution of an investigational biological therapeutic (CD24Fc, to be named MK-7110) upon approval or Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA). Merck acquired MK-7110 through the acquisition of OncoImmune, a privately held, clinical-stage biopharmaceutical company.

“Building upon the promising clinical findings to date for MK-7110, Merck is pleased to be collaborating with the U.S. Government to advance the manufacture and distribution of this candidate for patients with serious COVID-19 disease,” said Dr. Roger M. Perlmutter, president, Merck Research Laboratories.

Under the agreement, Merck will receive up to approximately $356 million for manufacturing and supply of approximately 60,000-100,000 doses of MK-7110 to the U.S. Government through June 30, 2021 to meet the government’s Operation Warp Speed goals. This approach is intended to expedite delivery of MK-7110 to the American people as quickly as possible, following potential EUA or FDA approval. Merck is also investing to expand its manufacturing capacity to increase supply of MK-7110.

In September 2020, OncoImmune reported topline findings from an interim efficacy analysis of a Phase 3 study evaluating MK-7110 for the treatment of patients with severe and critical COVID-19. An interim analysis of data

from 203 participants (75% of the planned enrollment) indicated that hospitalized patients with COVID-19 treated with a single dose of MK-7110 showed a 60% higher probability of improvement in clinical status compared to placebo, as defined by the protocol. The risk of death or respiratory failure was reduced by more than 50%. The study is ongoing.

## About SAC-COVID Phase 3 Trial

The SAC-COVID Phase 3 clinical trial (**NCT04317040**) is a randomized, double blind, placebo-controlled trial designed to evaluate the safety and efficacy of CD24Fc/MK-7110 in hospitalized patients with COVID-19 requiring oxygen support, including those requiring supplemental oxygen, high flow oxygen, and mechanical ventilation. Participants were randomly assigned into two arms receiving either standard of care plus a single dose of MK-7110 via an intravenous infusion on Day 1 or standard of care plus placebo on Day 1. The multi-center trial was initiated in April 2020 and had enrolled 243 patients when the trial was closed due to full enrollment in September 2020.

## About Operation Warp Speed

OWS is a partnership among components of the Department of Health and Human Services and the Department of Defense, engaging with private firms and other federal agencies, and coordinating among existing HHS-wide efforts to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics.

## About MK-7110 (CD24Fc)

MK-7110 is a potentially first-in-class recombinant fusion protein that targets the innate immune system. In addition to the Phase 3 clinical trial for COVID-19 patients, MK-7110 has been studied for safety in healthy volunteers and in Phase 2 clinical trials for the prevention of graft versus host disease (GVHD) following hematopoietic stem cell transplantation in patients with leukemia. A pivotal Phase 3 clinical trial (NCT04095858) for prophylaxis of GVHD has been initiated nationwide.

## About Merck’s Ongoing Commitment to COVID-19

Merck has been committed to developing an effective response to COVID-19 since the early stage of the pandemic and is exploring multiple paths to advance the understanding of SARS-CoV-2 infection. In addition to the development of MK-7110, in collaboration with Ridgeback Biotherapeutics Merck is evaluating molnupiravir, an investigational orally available anti-viral agent being evaluated in two Phase 2/3 trials for the treatment of patients with COVID-19 in both the outpatient and hospital settings. The company is also conducting clinical trials to evaluate two SARS-CoV-2/COVID-19 vaccine candidates: V590, being developed through a collaboration with IAVI,

which utilizes a recombinant vesicular stomatitis vector, and V591 which uses a measles virus vector-based platform.

## 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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