



NEWS RELEASE

# Merck to Acquire Oncolmmune

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Acquisition adds to Merck's suite of clinical programs in response to SARS-CoV-2/COVID-19

Merck will accelerate development of CD24Fc, a candidate for the treatment of patients with severe and critical COVID-19

KENILWORTH, N.J., & ROCKVILLE, Md.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, and Oncolmmune, a privately-held, clinical-stage biopharmaceutical company, today announced that the companies have entered into a definitive agreement pursuant to which Merck, through a subsidiary, will acquire all outstanding shares of Oncolmmune for an upfront payment of \$425 million in cash. In addition, Oncolmmune shareholders will be eligible to receive sales-based payments and payments contingent on the successful achievement of certain regulatory milestones. Oncolmmune recently announced positive top-line findings from an interim efficacy analysis of a Phase 3 study evaluating its lead therapeutic candidate CD24Fc for the treatment of patients with severe and critical COVID-19.

This press release features multimedia. View the full release here:

<https://www.businesswire.com/news/home/20201123005593/en/>

"Meaningful new therapeutic options are desperately needed for possibly millions of people around the world who will develop severe or critical COVID-19 disease," said Dr. Roger M. Perlmutter, President Merck Research Laboratories. "Recent clinical investigations support the view that CD24Fc may provide benefit beyond standard of care therapy for COVID-19 patients requiring oxygen support, and hence will represent an important addition to the Merck pipeline of investigational medicines and vaccines designed to address the COVID-19 pandemic."

Interim analysis of data from 203 participants (75% of the planned enrollment) reported by Oncolmmune indicated that patients with severe or critical COVID-19 treated with a single dose of CD24Fc showed a 60% higher probability of improvement in clinical status, as defined by the protocol, compared to placebo. The risk of death or respiratory failure was reduced by more than 50%. Detailed results will be submitted for publication in a peer-reviewed medical journal.

“Outstanding work by the Oncolmmune team has provided compelling evidence regarding the use of CD24Fc in patients with severe and critical COVID-19 in our Phase 3 Trial,” said Yang Liu, PhD, Co-founder and Chief Executive Officer of Oncolmmune. “We look forward to working with the scientists and manufacturing engineers at Merck as well as regulators as we seek to accelerate the global development of this potentially important therapy.”

Under the agreement, prior to the completion of the acquisition, Oncolmmune will spin-out certain rights and assets unrelated to the CD24Fc program to a new entity to be owned by the existing shareholders of Oncolmmune. In connection with the closing of the acquisition, Merck will invest \$50 million, and become a minority shareholder, in the new entity.

The closing of the acquisition, which is subject to approval under the Hart-Scott-Rodino Antitrust Improvements Act and other customary conditions, is expected before the end of 2020.

Oncolmmune was represented by Goodwin Procter LLP as legal advisor and Guggenheim Securities as financial advisor.

## 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 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 CD24Fc 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 to enrollment in September 2020.

## About CD24Fc

Oncolmmune’s lead product is CD24Fc, a first-in-class recombinant fusion protein that targets the innate immune system. Prior to the Phase 3 clinical trial for COVID-19 patients, CD24Fc 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 collaboration with Ridgeback Biotherapeutics, Merck is evaluating molnupiravir, an investigational orally available anti-viral candidate, in two Phase 2/3 trials, for the treatment of patients with COVID-19 in both the outpatient and inpatient 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 Oncolmmune

Oncolmmune is a privately-held, clinical-stage biopharmaceutical company that is actively engaged in the discovery and development of novel biopharmaceuticals for the treatment of cancer and autoimmune disease.

The company's lead therapeutic candidate CD24Fc has a novel mechanism of action that has potential applications to a number of inflammatory diseases and has shown good safety and tolerability in a Phase 1 clinical trial in healthy volunteers. Clinical activity has been observed in two Phase 2 trials in GVHD and the Phase 3 trial in COVID-19. In addition to CD24Fc, Oncolmmune has a rich pipeline of immuno-oncology candidates that will be the focus of the new spinout. Oncolmmune has initiated a Phase 1 clinical trial evaluating a novel CTLA-4 antibody candidate that selectively eliminates immune suppressive regulatory T cells in the tumor microenvironment while preserving their physiological function to protect host against autoimmune diseases (NCT04140526). Visit [www.oncoimmune.com](http://www.oncoimmune.com).

## 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](http://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 recent 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](http://www.sec.gov)).

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