



RECOVERY Trial Data Monitoring Committee Recommends Continuing Evaluation of REGN-COV2 in All Hospitalized Patients

November 5, 2020 at 3:20 PM EST

Regeneron announced today an update from the independent data monitoring committee (DMC) for the United Kingdom-based RECOVERY trial evaluating REGN-COV2 in hospitalized patients with COVID-19. The DMC reviewed available safety and efficacy data for the 15,545 total patients randomized, including the 325 patients who were in the arm randomized to receive either REGN-COV2 or control. The DMC advised that, in the light of these data and the available external information, they saw no cogent reason to modify the protocol or intake to the study and recommended continuing recruitment of eligible patients to all study arms.

The DMC letter is available here: <https://www.recoverytrial.net/for-site-staff/site-set-up-1/data-monitoring-committee-correspondence>.

About the Trial

The RECOVERY trial is conducted by the registered clinical trials units in the Nuffield Department of Population Health in partnership with the Nuffield Department of Medicine. The trial is supported by a grant to the University of Oxford from [UK Research and Innovation/National Institute for Health Research \(NIHR\)](#) and by core funding provided by [NIHR Oxford Biomedical Research Centre](#), [Wellcome](#), the [Bill and Melinda Gates Foundation](#), the [Department for International Development](#), [Health Data Research UK](#), the [Medical Research Council Population Health Research Unit](#) and [NIHR Clinical Trials Unit Support Funding](#).

The trial involves many thousands of doctors, nurses, pharmacists, and research administrators at 176 hospitals across the whole of the UK, supported by staff at the NIHR Clinical Research Network, NHS DigiTrials, Public Health England, Department of Health & Social Care, the Intensive Care National Audit & Research Centre, Public Health Scotland, the Secure Anonymised Information Linkage at University of Swansea, and the NHS in England, Scotland, Wales and Northern Ireland.

REGN-COV2's development and manufacturing has been funded in part with federal funds from the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services under OT number: HHSO100201700020C. Regeneron has partnered with Roche to increase the global supply of REGN-COV2 beginning in 2021. If REGN-COV2 proves safe and effective in clinical trials and regulatory approvals are granted, Regeneron will manufacture and distribute it in the U.S. and Roche will develop, manufacture and distribute it outside the U.S.

Forward-Looking Statements and Use of Digital Media

This statement includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron's business and its employees, collaborators, and suppliers and other third parties on which Regeneron relies, Regeneron's and its collaborators' ability to continue to conduct research and clinical programs (including those discussed in this press release), Regeneron's ability to manage its supply chain, net product sales of products marketed or otherwise commercialized by Regeneron and/or its collaborators (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and product candidates and research and clinical programs now underway or planned, including without limitation the development program relating to REGN-COV2 (Regeneron's investigational dual antibody for the treatment and prevention of COVID-19); safety issues resulting from the administration of Regeneron's Products and product candidates (such as REGN-COV2) in patients, including serious complications or side effects in connection with the use of Regeneron's Products and product candidates in clinical trials (including the RECOVERY trial discussed in this statement); whether the U.S. Food and Drug Administration ("FDA") will grant an Emergency Use Authorization ("EUA") for REGN-COV2 and, if an EUA is granted, the scope and terms of such EUA and how long such EUA would remain in effect for REGN-COV2; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's product candidates (such as REGN-COV2) and new indications for Regeneron's Products; the ability of Regeneron to manufacture in anticipated quantities Regeneron's Products and product candidates, including REGN-COV2; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; the ability of Regeneron's collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's Products and product candidates and the impact of studies (whether conducted by Regeneron or others and

whether mandated or voluntary), including the RECOVERY trial discussed in this statement, on any potential regulatory approval (including with respect to REGN-COV2) and/or the commercial success of Regeneron's Products and product candidates; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's Products and product candidates, including without limitation REGN-COV2; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; the availability and extent of reimbursement of Regeneron's Products from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payers and new policies and procedures adopted by such payers; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and product candidates; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), as well as Regeneron's collaboration with Roche relating to REGN-COV2, to be cancelled or terminated; and risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to EYLEA® (aflibercept) Injection, Dupixent® (dupilumab), and Praluent® (alirocumab)), other litigation and other proceedings and government investigations relating to the Company and/or its operations, the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2019 and its Form 10-Q for the quarterly period ended September 30, 2020. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (<http://newsroom.regeneron.com>) and its Twitter feed (<http://twitter.com/regeneron>).

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