RECOVERY COVID-19 Phase 3 Trial to Evaluate Regeneron's REGN-COV2 Investigational Antibody Cocktail in the UK

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One of the world's largest efforts to find effective COVID-19 treatments will evaluate the impact of REGN-COV2 on mortality, hospital stays, and the need for ventilation

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and the University of Oxford today announced that RECOVERY (Randomised Evaluation of COVid-19 thERapY), one of the world's largest randomized clinical trials of potential COVID-19 treatments, will evaluate Regeneron's investigational anti-viral antibody cocktail, REGN-COV2. The Phase 3 open-label trial in patients hospitalized with COVID-19 will compare the effects of adding REGN-COV2 to the usual standard-of-care versus standard-of-care on its own.

Peter Horby, Professor of Emerging Infectious Diseases and Global Health, Nuffield Department of Medicine, University of Oxford and chief investigator of the trial, said "We have already discovered that one treatment, dexamethasone, benefits COVID-19 patients, but the death rate remains too high so we must keep searching for others. The RECOVERY trial was specifically designed so that when promising investigational drugs such as REGN-COV2 became available they can be tested quickly. We are looking forward to seeing whether REGN-COV2 is safe and effective in the context of a large-scale randomized clinical trial; this is the only way to be certain about whether it works as a treatment for COVID-19."

"The world urgently needs new medicines to combat COVID-19, and well-designed trials to evaluate new treatment options will quickly help us learn which are most effective," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron. "REGN-COV2 was specifically designed by Regeneron scientists to target the virus that causes COVID-19. RECOVERY will be the fourth late-stage randomized clinical trial evaluating REGN-COV2 and will add to our knowledge about how this novel antibody cocktail may help hospitalized patients in need."

REGN-COV2 is the first specifically designed COVID-19 therapy being evaluated by RECOVERY. It was selected in part based on its emerging safety profile in humans, pre-clinical data showing it could protect against viral escape mutations, and prevention and treatment studies in non-human primates showing it reduced the amount of virus and associated damage in the lungs. REGN-COV2 is currently being studied in two Phase 2/3 clinical trials for the treatment of COVID-19 and in a Phase 3 trial for the prevention of COVID-19 in household contacts of infected individuals.

Martin Landray, Professor of Medicine & Epidemiology, Nuffield Department of Population Health, University of Oxford, added, "Throughout the COVID-19 pandemic we have seen the power of randomized trials to provide rigorous assessment of potential treatments. Up to now, we have largely been studying whether existing drugs can be re-purposed to tackle this new disease, but we now have the opportunity to rigorously assess the impact of a drug specifically designed to target this coronavirus. There are good reasons to be excited about this new development – RECOVERY will provide a robust assessment of the effect of this lab-manufactured monoclonal antibody combination treatment in hospitalized patients.

"We are very grateful to the patients who have already taken part in the trial and to those who will participate in this next phase of RECOVERY. We would not be able to find the best treatments without their support and that of the thousands of hospital and research staff who are working with us."

The open-label RECOVERY trial will assess the impact of adding REGN-COV2 to the usual standard-of-care on all-cause mortality 28 days after randomization. Other endpoints include the impact on hospital stay and the need for ventilation. It is anticipated that at least 2,000 patients will be randomly allocated to receive REGN-COV2 plus usual standard-of-care, and results will be compared with at least 2,000 patients who receive standard-of-care on its own. Usual standard-of-care varies by local hospital.

The trial is being coordinated by researchers at the University of Oxford, which acts as the sponsor for the research, working with clinical teams at 176 hospital sites across the UK.

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.

The inclusion of convalescent plasma in the RECOVERY trial was announced in June. The trial will compare adding convalescent plasma (plasma taken from patients who have recovered from COVID-19) to usual standard-of-care versus standard-of-care on its own.

About REGN-COV2
REGN-COV2 comprises two monoclonal antibodies (REGN10933 and REGN10987) and was designed specifically by Regeneron scientists to block infectivity of SARS-CoV-2, the virus that causes COVID-19. They evaluated thousands of fully-human antibodies produced by the company's *VelocImmune*® mice, which have been genetically modified to have a human immune system, as well as antibodies identified from humans who have

recovered from COVID-19. The two potent, virus-neutralizing antibodies that form REGN-COV2 bind non-competitively to the critical receptor binding domain of the virus's spike protein, which diminishes the ability of mutant viruses to escape treatment and protects against spike variants that have arisen in the human population, as detailed in *Science*.

An Independent Data Monitoring Committee is monitoring all Regeneron-led REGN-COV2 Phase 2 and 3 trials, and all trials continue to enroll patients.

REGN-COV2's development and manufacturing has been funded in part by 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 recently partnered with Roche to increase the global supply of REGN-COV2. 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.

About Regeneron

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for over 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to seven FDA-approved treatments and numerous product candidates in development, all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite* technologies, such as *VelocImmune®,* which uses unique genetically-humanized mice to produce optimized fully-human antibodies and bispecific antibodies, and through ambitious research initiatives such as the Regeneron Genetics Center, which is conducting one of the largest genetics sequencing efforts in the world.

For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

Forward-Looking Statements and Use of Digital Media

This press release 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 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 REGN-COV2 (Regeneron's investigational two-antibody cocktail for the treatment and prevention of COVID-19); 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; 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; 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 press release, on any potential regulatory approval 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; 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; 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 discussed in this press release, to be cancelled or terminated without any product success; 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 June 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 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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