



REGEN-COV™ Antibody Cocktail Is Active Against SARS-CoV-2 Variants First Identified in the UK and South Africa

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Columbia University researchers and Regeneron have independently confirmed findings; data included in *bioRxiv* paper and submitted for peer-reviewed publication

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that researchers in Dr. David Ho's Columbia University lab and Regeneron scientists have independently confirmed that REGEN-COV™ (casirivimab and imdevimab antibody cocktail) successfully neutralizes the circulating SARS-CoV-2 variants first identified in the UK (B.1.1.7) and South Africa (B.1.351). Columbia's findings were included in a [paper posted to bioRxiv](#) and submitted for peer-reviewed publication on the changing resistance of SARS-CoV-2 variants to antibody neutralization.

Both teams of researchers assessed *in vitro* neutralization potency of numerous COVID-19 antibodies (including those that have received emergency authorization and those still in development) against various mutated strains of the virus. Although some antibody therapies were no longer effective against some of these variants, the REGEN-COV antibody cocktail continued to neutralize all variants tested. REGEN-COV, which consists of the highly potent neutralizing antibodies imdevimab (REGN10987) and casirivimab (REGN10933), retained its potent neutralizing capability against the B.1.1.7 variant, with both antibodies retaining their potency. REGEN-COV also retained its highly potent neutralizing capacity against the B.1.351 variant; imdevimab retained its potency against this variant, and, while casirivimab potency was reduced, it was still comparable to the potency that other single antibodies in development have against the original virus.

The variant first identified in Brazil (1.1.248) and recently seen in a patient in the United States contains the same receptor binding domain mutations as the B.1.351 variant, therefore REGEN-COV is expected to remain similarly potent. Regeneron is conducting additional preclinical research against this particular strain to confirm this.

"As we expected, the virus continues to mutate, and these data show the continued ability of REGEN-COV to neutralize emerging strains, further validating our multi-antibody cocktail approach to infectious diseases," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer at Regeneron. "With two complementary antibodies in one therapeutic, even if one has reduced potency, the risk of the cocktail losing efficacy is significantly diminished, since the virus would need to mutate in multiple distinct locations to evade both antibodies. Thanks to our proprietary *VelocImmune*® technology, we have hundreds of additional potent, neutralizing antibodies in our labs that could form new combinations that might be useful against future variants. We are evaluating potential next steps with these novel candidates."

"In the face of this daunting pandemic, we appreciate the open exchange of pre-publication data and the opportunity to confirm important findings with one of the world's leading academic laboratories," said Christos A. Kyratsous, Ph.D., Vice President of Research, Infectious Diseases and Viral Vector Technologies at Regeneron.

The development and manufacturing of REGEN-COV has been funded in part with federal funds from the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, under OT number: HHSO100201700020C.

About the REGEN-COV Antibody Cocktail

REGEN-COV (casirivimab and imdevimab) is a cocktail of two monoclonal antibodies (also known as REGN10933 and REGN10987) and was designed specifically to block infectivity of SARS-CoV-2, the virus that causes COVID-19. The two potent, virus-neutralizing antibodies that form the cocktail 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](#).

In [November 2020](#), REGEN-COV received Emergency Use Authorization (EUA) from the FDA for the treatment of mild to moderate COVID-19 in adults, as well as in pediatric patients at least 12 years of age and weighing at least 40 kg, who have received positive results of direct SARS-CoV-2 viral testing and are at high risk for progressing to severe COVID-19 and/or hospitalization. The clinical evidence from Regeneron's outpatient trial suggests that monoclonal antibodies such as casirivimab and imdevimab have the greatest benefit when given early after diagnosis and in patients who are seronegative and/or who have high viral load. The criteria for 'high-risk' patients are described in the [Fact Sheet for Healthcare Providers](#). In the U.S., casirivimab and imdevimab are not authorized for use in patients who are hospitalized due to COVID-19 or require oxygen therapy, or for people currently using chronic oxygen therapy because of an underlying comorbidity who require an increase in baseline oxygen

flow rate due to COVID-19.

Regeneron is [collaborating](#) with Roche to increase global supply of REGEN-COV. Regeneron is responsible for development and distribution of the treatment in the U.S., and Roche is primarily responsible for development and distribution outside the U.S. The companies share a commitment to making the antibody cocktail available to COVID-19 patients around the globe and will support access in low- and lower-middle-income countries through drug donations to be made in partnership with public health organizations.

AUTHORIZED USE AND IMPORTANT SAFETY INFORMATION

Authorized Emergency Use

Casirivimab and imdevimab injection is an investigational combination therapy and has been authorized by FDA for the emergency use described above. Casirivimab and imdevimab injection is not FDA approved for any use. Safety and effectiveness of casirivimab and imdevimab injection have not yet been established for the treatment of COVID-19.

This authorized use is only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use under section 564 (b)(1) of the Act, 21 U.S.C. § 360bbb-3(b) (1), unless the authorization is terminated or revoked sooner.

Limitations of Authorized Use

- Casirivimab and imdevimab injection is not authorized for use in patients:
 - who are hospitalized due to COVID-19, OR
 - who require oxygen therapy due to COVID-19, OR
 - who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.
- Benefit of treatment with casirivimab and imdevimab injection has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as casirivimab and imdevimab, may be associated with worse clinical outcomes when administered to hospitalized patients requiring high flow oxygen or mechanical ventilation with COVID-19.

Definition of High-Risk Patients

High-risk is defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) ≥ 35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥ 65 years of age
- Are ≥ 55 years of age AND have
 - cardiovascular disease, OR
 - hypertension, OR
 - chronic obstructive pulmonary disease/other chronic respiratory disease.
- Are 12 – 17 years of age AND have
 - BMI ≥ 85 th percentile for their age and gender based on CDC growth charts, OR
 - sickle cell disease, OR
 - congenital or acquired heart disease, OR
 - neurodevelopmental disorders, for example, cerebral palsy, OR
 - a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
 - asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

Warnings and Precautions:

- **Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions:** There is a potential for serious hypersensitivity reaction, including anaphylaxis, with administration of casirivimab and imdevimab injection. If signs or symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy. Infusion-related reactions have been observed with administration of casirivimab and imdevimab injection. Signs and symptoms of infusion related reactions may include fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, and/or dizziness. If an infusion-related reaction occurs, consider slowing or stopping the infusion and administer appropriate medications and/or supportive care.
- **Limitations of Benefit and Potential for Risk in Patients with Severe COVID-19:** Benefit of treatment with casirivimab and imdevimab injection has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as casirivimab and imdevimab, may be associated with worse clinical outcomes when administered to hospitalized patients requiring high flow oxygen or mechanical ventilation with COVID-19. Therefore, casirivimab and imdevimab injection is not authorized for use in who are hospitalized due to COVID-19, OR who require oxygen therapy due to COVID-19, OR who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.

Adverse Reactions:

- Serious adverse events (SAEs) were reported in 4 (1.6%) patients in the casirivimab and imdevimab injection 2,400 mg group, 2 (0.8%) patients in casirivimab and imdevimab injection 8,000 mg group and 6 (2.3%) patients in the placebo group. None of the SAEs were considered to be related to study drug. SAEs that were reported as Grade 3 or 4 adverse events were pneumonia, hyperglycemia, nausea and vomiting (2,400 mg casirivimab and imdevimab injection), intestinal obstruction and dyspnea (8,000 mg casirivimab and imdevimab injection) and COVID-19, pneumonia and hypoxia (placebo). Casirivimab and imdevimab injection are not authorized at the 8,000 mg dose (4,000 mg casirivimab and 4,000 mg imdevimab).

Patient Monitoring Recommendations: Clinically monitor patients during infusion and observe patients for at least 1 hour after infusion is complete.

Use in Specific Populations:

- **Pregnancy:** There is currently limited clinical experience in the use of casirivimab and imdevimab injection in COVID-19 patients who are pregnant. Casirivimab and imdevimab injection therapy should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus.
- **Nursing Mothers:** There is currently no clinical experience in use of casirivimab and imdevimab injection in COVID-19 patients who are breastfeeding. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for casirivimab and imdevimab injection and any potential adverse effects on the breastfed child from casirivimab and imdevimab injection or from the underlying maternal condition.

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 eight FDA-approved treatments and numerous product candidates in development, almost 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, 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 REGEN-COV™ (casirivimab and imdevimab antibody cocktail); how long the Emergency Use Authorization ("EUA") granted by the U.S. Food and Drug Administration (the "FDA") for REGEN-COV will remain in effect and whether the EUA is revoked by the FDA based on its determination that the underlying health emergency no longer exists or warrants such authorization or other reasons; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's product candidates (such as REGEN-COV) and new indications for Regeneron's Products; 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 (including REGEN-COV) and the impact of the foregoing on Regeneron's ability to supply its Products and product candidates (including REGEN-COV); the ability of Regeneron to manage supply chains for multiple products and product candidates; safety issues resulting from the administration of Regeneron's Products and product candidates (such as REGEN-COV) 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) on any potential regulatory approval (including with respect to REGEN-COV) 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 REGEN-COV; 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, collaboration, or supply 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 REGEN-COV, 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[®] (afibercept) 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>).

Contacts:

Media Relations

Alexandra Bowie

Tel: +1 (914) 847-3407

Alexandra.bowie@regeneron.com

Investor Relations

Mark Hudson

Tel: +1 (914) 847-3482

mark.hudson@regeneron.com

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