



## Regeneron Announces U.S. Government Agreement to Purchase Additional COVID-19 Antibody Cocktail Doses

January 12, 2021 at 5:45 PM EST

TARRYTOWN, N.Y., Jan. 12, 2021 /PRNewswire/ --

**New agreement covers 1.25 million additional doses of the casirivimab and imdevimab antibody cocktail, bringing total potential U.S. supply to over 1.5 million doses**

**Doses are being supplied for use pursuant to the FDA Emergency Use Authorization for high-risk patients with mild to moderate COVID-19 in order to reduce the risk of progression to severe COVID-19 and/or hospitalization**

Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced that the U.S. Department of Health and Human Services (HHS) and the Department of Defense (DOD) will purchase additional supply of the casirivimab and imdevimab antibody cocktail for use in non-hospitalized COVID-19 patients to meet the federal government's Operation Warp Speed goals. The government has said it will provide these doses at no cost to patients, though healthcare facilities may charge fees related to administration.

Under the new agreement, the government will purchase all finished doses of the casirivimab and imdevimab antibody cocktail delivered by June 30, 2021, up to 1.25 million doses. Under a [previous agreement](#), Regeneron is already supplying doses to treat approximately 300,000 people, bringing the total potential purchase to over 1.5 million doses.

"COVID-19 continues to sicken hundreds of thousands of Americans every day and the people of Regeneron are committed to help," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "Tackling the COVID-19 pandemic will require a combination of public health measures, vaccines and therapeutics. We are pleased to work with the U.S. government to supply our antibody cocktail as an important weapon in this fight."

The U.S. government has said it will continue to coordinate allocation of the antibody cocktail to state and territorial health departments. Patients, caregivers and healthcare providers can find sites with COVID-19 antibody treatments through these links to the [HHS](#) or [National Infusion Center Association](#) locator tools.

"Patients in our antibody cocktail outpatient clinical trial experienced significant reductions in virus levels and required fewer medical visits for COVID-19, suggesting the therapy can help reduce the current burden on hospitals and healthcare systems," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron. "Additionally, as expected, the virus continues to mutate, with the possibility of developing resistance to any one antibody. The Regeneron cocktail of two antibodies, each targeting a different site on the virus, reduces the possibility of the virus becoming resistant."

The casirivimab and imdevimab antibody cocktail continues to be evaluated in clinical trials for the treatment of COVID-19 in certain hospitalized and non-hospitalized patients, including the open-label RECOVERY trial of hospitalized patients in the UK, and a trial for the prevention of COVID-19 in household contacts of infected individuals. To date, nearly 15,000 people have participated in casirivimab and imdevimab clinical trials.

The development and manufacturing of the antibody cocktail has been funded in part with federal funds from the Biomedical Advanced Research and Development Authority (BARDA), part of HHS, Office of the Assistant Secretary for Preparedness and Response, under OT number: HHSO100201700020C.

### Details of the New Agreement

The current authorized dose for emergency use in non-hospitalized patients is 2,400 mg (1,200 mg casirivimab and 1,200 mg imdevimab) administered as a one-time infusion. Regeneron is evaluating the safety and efficacy of a lower 1,200 mg dose (600 mg casirivimab and 600 mg imdevimab) of the antibody cocktail in this 'outpatient' setting.

Under the agreement, the government will acquire doses at the lowest authorized dose. The government is obligated to purchase all finished doses supplied by June 30, up to 1.25 million doses total (an agreement value of up to \$2.625 billion), and may accept doses after this date at its discretion. A number of factors may impact available finished supply by June 30, including manufacturing considerations and authorized dose levels. Regeneron expects to supply approximately 750,000 finished doses by the end of June based on the 2,400 mg dose level, with the vast majority supplied in the second quarter. Regeneron expects to fulfill the entire 1.25 million targeted doses if the 1,200 mg dose is authorized.

### About the Regeneron Antibody Cocktail for COVID-19

Casirivimab and imdevimab is a cocktail of two monoclonal antibodies (also known as REGN10933 and REGN10987, respectively) 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](#), the casirivimab and imdevimab antibody combination 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 casirivimab and imdevimab. 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)  $\geq 35$
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are  $\geq 65$  years of age
- Are  $\geq 55$  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  $\geq 85$ 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, 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*<sup>®</sup> 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](http://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 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 the casirivimab and imdevimab antibody*

*cocktail (Regeneron's investigational dual-antibody therapy for COVID-19); how long the Emergency Use Authorization ("EUA") granted by the U.S. Food and Drug Administration (the "FDA") for the casirivimab and imdevimab antibody cocktail 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 the casirivimab and imdevimab antibody cocktail) 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 the casirivimab and imdevimab antibody cocktail) and the impact of the foregoing on Regeneron's ability to supply its Products and product candidates, including its ability to supply doses of the casirivimab and imdevimab antibody cocktail under the terms of the agreement with the U.S. Department of Health and Human Services and the Department of Defense (collectively, the "U.S. Government") discussed in this press release (the "Manufacturing and Supply Agreement"); whether and to what extent Regeneron will be able to supply doses of the casirivimab and imdevimab antibody cocktail under the Manufacturing and Supply Agreement; what the lowest authorized dose of the casirivimab and imdevimab antibody cocktail will be at the time of delivery to the U.S. Government under the Manufacturing and Supply Agreement; the amount of payments (if any) Regeneron may receive pursuant to the Manufacturing and Supply Agreement; whether the Manufacturing and Supply Agreement is terminated by the U.S. Government or otherwise prior to completion; 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 the casirivimab and imdevimab antibody cocktail) in patients, including serious complications or side effects in connection with the use of Regeneron's Products and product candidates in clinical trials (including those discussed in this press release); 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 trials discussed in this press release, on any potential regulatory approval (including with respect to the casirivimab and imdevimab antibody cocktail) 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 the casirivimab and imdevimab antibody cocktail; 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 the casirivimab and imdevimab antibody cocktail, 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>).*

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