REGENERON®

January 24, 2022

U.S. Food and Drug Administration Revises Emergency Use Authorization for REGEN-COV® (casirivimab and imdevimab) Antibody Cocktail due to Omicron Variant

Regeneron continues to progress next generation antibodies that retain potency against Omicron, Delta and other variants of concern

The U.S. Food and Drug Administration (FDA) today amended the Emergency Use Authorization (EUA) for Regeneron's REGEN-COV® (casirivimab and imdevimab) to exclude its use in geographic regions where, based on available information including variant susceptibility and regional variant frequency, infection or exposure is likely due to a variant such as Omicron (B.1.1.529) that is not susceptible to the treatment. With this EUA revision, REGEN-COV is not currently authorized for use in any U.S. states, territories or jurisdictions, since Omicron is currently the dominant variant across the United States. REGEN-COV remains an investigational drug and is not approved for any indication.

The FDA stated that if, in the future, patients in certain geographic regions are likely to be infected or exposed to a variant that is susceptible to REGEN-COV, then the limitation on use may be revised in these areas.

Regeneron continues to progress next generation antibodies that are active against Omicron, Delta (B.1.617.2) and other variants of concern. The company is working urgently and collaboratively with the FDA to determine how to bring additional safe and effective monoclonal antibody treatments to patients as quickly as possible. Pending regulatory discussions, new therapeutic candidates could enter the clinic in coming months.

About the REGEN-COV Antibody Cocktail
REGEN-COV (casirivimab and imdevimab) is a cocktail of two monoclonal antibodies that was designed specifically to block infectivity of SARS-CoV-2, the virus that causes COVID-19, using Regeneron's proprietary *VelocImmune*® and *VelociSuite*® technologies. Since its first EUA in November 2020, it has been used to treat millions of people with COVID-19 around the globe.

REGEN-COV remains an investigational drug and has not been approved by the FDA, but is authorized for emergency use, subject to the limitations set forth in the FDA's Letter of Authorization. This authorization is for the duration of the declaration that circumstances exist justifying the authorization of the emergency uses under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. Additional information about REGEN-COV in the U.S. is below.

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

AUTHORIZED USES AND LIMITATIONS OF AUTHORIZED USE

Treatment:

REGEN-COV is authorized for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death

Limitations of Authorized Use (Treatment)

- REGEN-COV is not authorized for treatment of mild to moderate COVID-19 in geographic regions where infection is likely to have been caused by a non-susceptible SARS-CoV-2 variant based on available information such as variant susceptibility to this drug and regional variant frequency.
    - FDA's determination and any updates will be available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs.[1]

- REGEN-COV (casirivimab and imdevimab) 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.

- Monoclonal antibodies, such as REGEN-COV, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

Post-Exposure Prophylaxis:

REGEN-COV is authorized in adult and pediatric individuals (12 years of age and older weighing at least 40 kg) for post-exposure prophylaxis of COVID-19 in individuals who are at high risk for progression to severe COVID-19, including hospitalization or death, and are:

- not fully vaccinated **or** who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) **and**
    - have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Centers for Disease Control and Prevention (CDC) **or**
    - who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons)

[1] FDA will monitor conditions to determine whether use in a geographic region is consistent with this scope of authorization, referring to available information, including information on variant susceptibility *[see Microbiology/Resistance Information (15)]*, and CDC regional variant frequency data available at: https://covid.cdc.gov/covid-data-tracker/#variant-proportions.

Limitations of Authorized Use (Post-Exposure Prophylaxis)

- REGEN-COV is not authorized for post-exposure prophylaxis of COVID-19 in geographic regions where exposure is likely to have been to a non-susceptible SARS-CoV-2 variant, based on available information including variant susceptibility to this drug and regional variant frequency.
  - FDA's determination and any updates will be available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs.[1]

- Post-exposure prophylaxis with REGEN-COV (casirivimab and imdevimab) is not a substitute for vaccination against COVID-19.

- REGEN-COV (casirivimab and imdevimab) is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

Healthcare providers should review the **Fact Sheet for Healthcare Providers** for information on the authorized uses of REGEN-COV and mandatory requirements of the EUA and must comply with the requirements of the EUA. The **FDA Letter of Authorization** is available for reference**,** as well as the **Dear Healthcare Provider Letter** and **Patient Fact Sheet**

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 nine 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, hematologic conditions, 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 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, Regeneron's ability to manage its supply chain, net product sales of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation the development programs relating to the REGEN-COV® (casirivimab and imdevimab) antibody cocktail and other "next generation" fully human monoclonal antibodies targeting SARS-CoV-2 being developed by Regeneron and discussed in this statement; whether and to what extent REGEN-COV or any such other "next generation" antibody will retain potency against the Omicron (B.1.1.529) variant, the Delta (B.1.617.2) variant, or other existing or potential variants of SARS-CoV-2 (as applicable); the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees (such as those relating to the "next generation" fully human monoclonal antibodies targeting SARS-CoV-2 discussed in this statement) may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; how long the Emergency Use Authorization ("EUA") granted by the FDA for REGEN-COV will remain in effect and whether the EUA is revoked or further limited by the FDA based on its determination that the underlying health emergency no longer exists or warrants such authorization or other reasons; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates (including any such competing drugs and product candidates that may provide more efficacious, more easily administered, more cost-effective, or otherwise superior treatment or prophylaxis for COVID-19); the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products (including those discussed in this statement); uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates (such as REGEN-COV), including the impact of recommendations, guidelines, or studies (whether conducted by Regeneron or others and whether mandated or voluntary), on any of the foregoing or any potential regulatory approval of Regeneron's Products and Regeneron's Product Candidates; the ability of Regeneron's collaborators, licensees, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates (including those discussed in this statement) and the impact of the foregoing on Regeneron's ability to supply Regeneron's Products and Regeneron's Product Candidates (including those discussed in this statement); 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 Regeneron's Product Candidates (such as those discussed in this statement) in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in clinical trials; 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 Regeneron's Product Candidates, including without limitation those discussed in

this statement; 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; 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® (aflibercept) Injection, Dupixent® (dupilumab), Praluent® (alirocumab), and REGEN-COV), 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, 2020 and its Form 10-Q for the quarterly period ended September 30, 2021. 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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