FDA Authorizes Lower 1,200 mg Intravenous and Subcutaneous Dose of REGEN-COV™ (casirivimab and imdevimab) Antibody Cocktail to Treat Patients with COVID-19

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EUA supported by pivotal Phase 3 data showing 1,200 mg dose reduced risk of hospitalization or death by 70%

Only antibody therapy currently available in all 50 states, including eight states with high rates of two variants of concern

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced the U.S. Food and Drug Administration (FDA) updated the Emergency Use Authorization (EUA) for REGEN-COV™, lowering the dose to 1,200 mg (600 mg casirivimab and 600 mg imdevimab), which is half the dose originally authorized. As part of the updated EUA, REGEN-COV should be administered by intravenous (IV) infusion; subcutaneous (SC) injections are an alternative when IV infusion is not feasible and would lead to a delay in treatment.

"Despite increased use of vaccines, thousands of patients are still becoming infected in the U.S. every day, with many at high risk of serious complications from COVID-19. Unfortunately, to date only a fraction of patients eligible for antibody treatments have received them, which we hope will change based on this updated FDA authorization. REGEN-COV is readily available and supplied free of charge by the U.S. government," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer at Regeneron. "REGEN-COV has also demonstrated potency against the main variants of concern to date *in vitro* and is the only antibody therapy currently available across the U.S., including in states where variants first identified in Brazil and South Africa are circulating at a higher rate."

REGEN-COV is authorized for use under an EUA to treat mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing ≥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. The Fact Sheet updates remove the previously authorized 2,400 mg IV REGEN-COV dose.

The updated FDA authorization is based on data from several trials, including a recently presented Phase 3 trial which showed REGEN-COV reduced the risk of hospitalization or death by 70% in high-risk non-hospitalized patients, and that the treatment effect was consistent between the 1,200 mg and 2,400 mg doses. The SC administration was authorized based on the totality of scientific evidence, incorporating clinical, viral load reduction and pharmacokinetic data.

In addition, *in vitro* research has shown that REGEN-COV retains potency against the main variants of concern circulating within the U.S., including the P.1 variant (first identified in Brazil, now classified by the World Health Organization [WHO] as Gamma) and the B.1.351 variant (first identified in South Africa, now classified by the WHO as Beta). Consequently, REGEN-COV remains available for use in all 50 states. The combined frequency of the P.1 and B.1.351 variants now exceeds 10% of new COVID-19 diagnoses across eight states (Arizona, California, Florida, Illinois, Indiana, Massachusetts, Oregon and Washington), and the prevalence of these and other variants continues to be closely monitored.

Overall, more than 9,000 people have received IV REGEN-COV in clinical trials in both hospitalized and non-hospitalized settings. In a pooled Phase 1/2/3 analysis of non-hospitalized patients, investigator-assessed infusion-related reactions (≥grade 2) were observed in 0.2% (10/4,026) of those who received REGEN-COV at the authorized dose or a higher dose. Rare anaphylactic reactions have been reported as part of the REGEN-COV clinical program. In trial participants who received study drug via SC injection, injection site reactions were observed in 12% of those treated with REGEN-COV (88/729) and 4% with placebo (10/240).

In May, the REGEN-COV Fact Sheet was updated to expand the definition of eligible patients under the EUA. Patients with certain medical conditions or other factors (for example, race or ethnicity) may be at high risk for progression to severe COVID-19 and are eligible to receive REGEN-COV if they become infected with SARS-CoV-2. Recently, the National Institutes of Health COVID-19 Treatment Guidelines Panel also strongly recommended the use of REGEN-COV in non-hospitalized COVID-19 patients ("outpatients") at high risk of clinical progression.

REGEN-COV has not been approved by FDA but has been authorized for emergency use. This use is authorized 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.

Regeneron expects to submit a full Biologics License Application (BLA) for REGEN-COV in non-hospitalized outpatients with COVID-19 later this summer. In addition to outpatients, REGEN-COV is also being evaluated in prevention and certain hospitalized COVID-19 patient settings. In April 2021, Regeneron announced positive results from a Phase 3 trial evaluating REGEN-COV for the prevention of infection among household contacts of SARS-CoV-2 infected individuals. Regeneron has submitted these data to regulatory authorities to potentially expand the EUA for use in the prevention setting.

The development and manufacturing of REGEN-COV have 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.

REGEN-COV Supply Update
The U.S. government will purchase all REGEN-COV doses delivered by June 30, 2021 and may accept additional doses through September 30, 2021 at its discretion, up to a maximum amount of 1.25 million doses. Regeneron expects to deliver at least 1 million REGEN-COV doses to the U.S. government in the second quarter. The specific quantity of doses delivered will be impacted by the timeliness of manufacturing operations.

Additionally, Regeneron expects its second quarter 2021 GAAP and non-GAAP effective tax rates to be similar and approximately 17% and the company's full year effective tax rate guidance remains unchanged.

About the REGEN-COV Antibody Cocktail
REGEN-COV (casirivimab and imdevimab) is a cocktail of two monoclonal antibodies (also known as REGN10933 and REGN10987) 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. 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*.

Under this EUA, REGEN-COV is available throughout the U.S. – information on availability in your area is available from the Department of Health and Human Services and the National Infusion Center Association. REGEN-COV can be administered by IV infusion (as short as 20 minutes) or by SC injection (four injections), which is an alternative when IV infusion is not feasible and would lead to a delay in treatment. It is now authorized as a co-formulated single vial, or in individual vials to be administered together.

In the U.S., REGEN-COV is 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.

About Regeneron's *VelocImmune* Technology
Regeneron's *VelocImmune* technology utilizes a proprietary genetically engineered mouse platform endowed with a genetically humanized immune system to produce optimized fully human antibodies. When Regeneron's President and Chief Scientific Officer George D. Yancopoulos was a graduate student with his mentor Frederick W. Alt in 1985, they were the first to envision making such a genetically humanized mouse, and Regeneron has spent decades inventing and developing *VelocImmune* and related *VelociSuite* technologies. Dr. Yancopoulos and his team have used *VelocImmune* technology to create approximately a quarter of all original, FDA-approved fully human monoclonal antibodies currently available. This includes REGEN–COV (casirivimab and imdevimab), Dupixent® (dupilumab), Libtayo® (cemiplimab-rwlc), Praluent® (alirocumab), Kevzara® (sarilumab), Evkeeza® (evinacumab-dgnb) and Inmazeb™ (atoltivimab, maftivimab and odesivimab-ebgn).

AUTHORIZED USE AND IMPORTANT SAFETY INFORMATION

REGEN-COV, (casirivimab and imdevimab) co-formulated product and REGEN-COV (casirivimab and imdevimab) supplied as individual vials to be administered together, 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. [see Limitations of Authorized Use]

- REGEN-COV has not been approved, but has been authorized for emergency use by FDA
- This use is authorized 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
- Healthcare providers should review the **Fact Sheet for Healthcare Providers** for information on the authorized use 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**

Limitations of Authorized Use

- 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
- Benefit of treatment with REGEN-COV has not been observed in patients hospitalized due to COVID-19. 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

Definition of High Risk Patients

The following medical conditions or other factors may place adults and pediatric patients (age 12-17 years and weighing at least 40 kg) at higher risk for progression to severe COVID-19:

- Older age (for example, age ≥65 years of age)
- Obesity or being overweight (for example, BMI >25 kg/m^2, or if age 12-17, have BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm)
- Pregnancy
- Chronic kidney disease

- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID 19))

Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of REGEN-COV under the EUA is not limited to the medical conditions or factors listed above.

For additional information on medical conditions and factors associated with increased risk for progression to severe COVID, see the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html. Healthcare providers should consider the benefit-risk for an individual patient.

Circulating SARS-CoV-2 viral variants may be associated with resistance to monoclonal antibodies. Healthcare providers should review the Antiviral Resistance information in Section 15 of the Fact Sheet for details regarding specific variants and resistance, and refer to the CDC website (https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html) as well as information from state and local health authorities regarding reports of viral variants of importance in their region to guide treatment decisions.

Important Safety Information

REGEN-COV (casirivimab and imdevimab) is an unapproved investigational therapy, and there are limited clinical data available. Serious and unexpected adverse events may occur that have not been previously reported with REGEN-COV use

- **Warnings and Precautions:**
  - **Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions:** Serious hypersensitivity reactions, including anaphylaxis, have been observed with administration of REGEN-COV.If signs or symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy. Hypersensitivity reactions occurring more than 24 hours after the infusion have also been reported with the use of REGEN-COV under EUA. Infusion-related reactions, occurring during the infusion and up to 24 hours after the infusion, have been observed with administration of REGEN-COV. These reactions may be severe or life threatening
    - **Signs and symptoms of infusion-related reactions may include**: fever, difficulty breathing, reduced oxygen saturation, chills, nausea, arrythmia (e.g., atrial fibrillation, tachycardia, bradycardia), chest pain or discomfort, weakness, altered mental status, headache, bronchospasm, hypotension, hypertension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, vasovagal reactions (e.g., pre-syncope, syncope), dizziness, fatigue and diaphoresis. Consider slowing or stopping the infusion and administer appropriate medications and/or supportive care if an infusion-related reaction occurs
  - **Clinical Worsening After REGEN-COV Administration:** Clinical worsening of COVID-19 after administration of REGEN-COV has been reported and may include signs or symptoms of fever, hypoxia or increased respiratory difficulty, arrythmia (e.g., atrial fibrillation, tachycardia, bradycardia), fatigue, and altered mental status. Some of these events required hospitalization. It is not known if these events were related to REGEN-COV use or were due to progression of COVID-19
  - **Limitations of Benefit and Potential for Risk in Patients with Severe COVID-19:** Benefit of treatment with REGEN-COV has not been observed in patients hospitalized due to COVID-19. 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. Therefore, REGEN-COV 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
- **Adverse Reactions:**
  - In a pooled phase 1/2/3 analysis of COV-2067, infusion-related reactions (adverse event assessed as causally related by the investigator) of grade 2 or higher severity have been observed in 10/4206 (0.2%) of those who received REGEN-COV at the authorized dose or a higher dose
  - Overall, in Phase 1/2/3, three subjects receiving the 8,000 mg dose of REGEN-COV, and one subject receiving the 1,200 mg casirivimab and 1,200 mg imdevimab, had infusion-related reactions (urticaria, pruritis, flushing, pyrexia, shortness of breath, chest tightness, nausea, vomiting, rash) which resulted in permanent discontinuation of the infusion. All events resolved
  - Anaphylactic reactions have been reported in the clinical program in subjects receiving REGEN-COV. The events began within 1 hour of completion of the infusion, and in at least one case required treatment including epinephrine.

The events resolved
    - The safety with subcutaneous administration is based on analysis from HV-2093, a randomized double-blind, placebo-controlled trial evaluating the safety and pharmacokinetic profile in healthy volunteer adult subjects. Subjects were randomized 3:1 to REGEN-COV (n=729) or placebo (n=240). Injection site reactions were observed in 12% and 4% of subjects following single dose administration in the casirivimab and imdevimab, and placebo arms respectively; the remaining safety findings with subcutaneous administration in the casirivimab and imdevimab arm were similar to the safety findings observed with intravenous administration in COV-2067
- **Patient Monitoring Recommendations**: Clinically monitor patients during infusion and observe patients for at least 1 hour after intravenous infusion or subcutaneous dosing is complete
- **Use in Specific Populations:**
    - **Pregnancy:** There are insufficient data to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. REGEN-COV should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus
    - **Lactation:** There are no available data on the presence of casirivimab and/or imdevimab in human milk or animal milk, the effects on the breastfed infant, or the effects of the drug on milk production. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for REGEN-COV and any potential adverse effects on the breastfed child from REGEN-COV 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 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 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 being developed by Regeneron and/or its collaborators (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation the development program relating to the 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; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates, including the impact of recommendations, guidelines, or studies (whether conducted by Regeneron or others and whether mandated or voluntary), such as the Phase 3 pivotal trial and the National Institutes of Health COVID-19 Treatment Guidelines referenced in this press release, on any of the foregoing or any potential regulatory approval of Regeneron's Products and Regeneron's Product Candidates (such as REGEN-COV); whether the EUA for REGEN-COV will be expanded for use in the prevention setting; 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 Regeneron's Product Candidates (including REGEN-COV) and the impact of the foregoing on Regeneron's ability to supply Regeneron's Products and Regeneron's 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 Regeneron's Product Candidates (such as REGEN-COV) 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 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 Regeneron's 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, including financial guidance relating to GAAP and non-GAAP effective tax rate; 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 (known as REGEN-COV in the United States), 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 March 31, 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).

Non-GAAP Financial Measures

This press release uses non-GAAP effective tax rate, which is a financial measure that is not calculated in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). This and other non-GAAP financial measures are computed by excluding certain non-cash and other items from the related GAAP financial measure. Non-GAAP adjustments also include the income tax effect of reconciling items. The Company makes such adjustments for items the Company does not view as useful in evaluating its operating performance. For example, adjustments may be made for items that fluctuate from period to period based on factors that are not within the Company's control, such as the Company's stock price on the dates share-based grants are issued. Management uses non-GAAP measures for planning, budgeting, forecasting, assessing historical performance, and making financial and operational decisions, and also provides forecasts to investors on this basis. Additionally, non-GAAP measures provide investors with an enhanced understanding of the financial performance of the Company's core business operations. However, there are limitations in the use of non-GAAP financial measures as they exclude certain expenses that are recurring in nature. Furthermore, the Company's non-GAAP financial measures may not be comparable with non-GAAP information provided by other companies. Any non-GAAP financial measure presented by Regeneron should be considered supplemental to, and not a substitute for, measures of financial performance prepared in accordance with GAAP. Please refer to Exhibit 99.1 to the Company's Current Report on Form 8-K filed with the U.S. Securities and Exchange Commission on May 6, 2021 for a reconciliation of the Company's full year 2021 GAAP to non-GAAP effective tax rate financial guidance.

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