



## New Phase 3 Analyses Show That a Single Dose of REGEN-COV® (casirivimab and imdevimab) Provides Long-term Protection Against COVID-19

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**Single dose of REGEN-COV (1,200 mg subcutaneous) reduced the risk of COVID-19 by 81.6% during the pre-specified follow-up period (months 2-8), maintaining the 81.4% risk reduction previously reported during month 1**

**During the 8-month assessment period there were 0 hospitalizations for COVID-19 in the REGEN-COV group and 6 in the placebo group**

**The fully human antibodies in REGEN-COV were developed to provide long-lasting protective effects without any artificial mutations or sequences**

Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced additional positive results from a Phase 3 trial jointly run with the National Institute of Allergy and Infectious Diseases (NIAID), which assessed use of a single dose of investigational REGEN-COV® (1,200 mg administered via 4 subcutaneous injections) to prevent COVID-19 in uninfected individuals. The new analyses show REGEN-COV reduced the risk of contracting COVID-19 (i.e., laboratory-confirmed symptomatic SARS-CoV-2 infections) by 81.6% during the pre-specified follow-up period (months 2-8), maintaining the 81.4% risk reduction during the first month after administration, which was previously reported in [The New England Journal of Medicine](#).

"Today's new data demonstrate how a single dose of REGEN-COV can help protect people from COVID-19 for many months after administration," said Myron S. Cohen, M.D., who leads the monoclonal antibody efforts for the NIH-sponsored COVID Prevention Network (CoVPN) and is Director of the Institute for Global Health & Infectious Diseases at the University of North Carolina at Chapel Hill. "These results demonstrate that REGEN-COV has the potential to provide long-lasting immunity from SARS-CoV-2 infection, a result particularly important to those who do not respond to COVID-19 vaccines including people who are immunocompromised."

In results previously published, the trial met its primary endpoint, reducing the risk of COVID-19 (i.e., laboratory-confirmed symptomatic SARS-CoV-2 infections) by 81.4% within 1 month of receiving REGEN-COV ( $p < 0.0001$ ). The new results released today describe a pre-specified analysis for the following 7 months, throughout which an additional 45 symptomatic infections occurred. During this time period, REGEN-COV continued to prevent infection, without requiring additional doses. Compared to placebo ( $n=842$ ), people who received a single dose of REGEN-COV ( $n=841$ ) experienced:

- 81.6% reduced risk of developing COVID-19 during the pre-specified follow-up period, between months 2-8 (7 REGEN-COV, 38 placebo; 95% confidence interval [CI]: 59.8%, 91.6%; nominal  $p < 0.0001$ ).
- 81.5% reduced risk of developing COVID-19 at any time during the 8 months after receiving REGEN-COV (20 REGEN-COV, 108 placebo; 95% CI: 70.6%, 88.4%; nominal  $p < 0.0001$ ).
- During the 8-month assessment period, 0 individuals in the REGEN-COV group were hospitalized due to COVID-19, compared to 6 individuals in the placebo group (1 person in the first month; 5 people during months 2-8). There were no deaths due to COVID-19 in any treatment group during the 8-month assessment period, and there were no new safety signals identified for REGEN-COV.

The trial, which was fully enrolled in early 2021, allowed participants to become vaccinated if they wished once the primary efficacy treatment period (month 1) was complete. Vaccination rates during the months 2-8 assessment period were balanced, with 34.5% ( $n=290$ ) of the REGEN-COV group and 35.2% ( $n=296$ ) of the placebo group receiving at least 1 COVID-19 vaccine dose by the end of the 8-month assessment period.

Through an innovative trial design, researchers were able to demonstrate the impact of REGEN-COV in high-risk household transmission settings (month 1, both pre- and post-exposure prophylaxis), as well as after the immediate risk of household infection had subsided (months 2-8, pre-exposure prophylaxis), when most infections were presumably acquired in the broader community. During the initial high-risk period related to household transmission, the rate of COVID-19 (in the absence of protection with REGEN-COV) was 13-fold higher than during the subsequent period of ongoing transmission: during month 1, the rate of COVID-19 in the placebo group was 8.3% per month; and during months 2-8 it decreased to 0.6% per month on average.

"In this trial, a single dose of REGEN-COV provided long-term protection against COVID-19, including times of particularly high risk from household exposure, and in the longer-term during ongoing broader exposure," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer at Regeneron. "These data add to the increasing body of evidence supporting use of REGEN-COV to prevent COVID-19 in uninfected individuals, which may be especially useful for the many immunocompromised people who do not respond adequately to vaccines and remain 'prisoners of the pandemic.' With infections still occurring despite widespread vaccination, the immunocompromised face an ongoing risk of encountering the virus during their daily lives. We intend to rapidly share these additional data with regulatory authorities to help those in most need of protection from COVID-19."

REGEN-COV is currently authorized in the U.S. to treat people who are at high risk of serious consequences from COVID-19 infection who are either already infected ([non-hospitalized](#)) or in certain [post-exposure prophylaxis](#) settings. In the U.S., REGEN-COV is not authorized as a substitute for vaccination against COVID-19, or for pre-exposure prophylaxis for prevention of COVID-19, or 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. REGEN-COV has not been approved by the Food and Drug Administration (FDA), but is currently [authorized](#) 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.

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.

Regeneron is [collaborating](#) with Roche to increase global supply of the antibody cocktail, with Roche primarily responsible for development and distribution outside the U.S. Regeneron and Roche 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 the Trial**

The Phase 3 double-blind, placebo-controlled trial enrolled people who lived in the same household as an individual who was diagnosed with SARS-CoV-2 within the prior 4 days. All participants were tested for SARS-CoV-2 at baseline using a RT-qPCR test from nasopharyngeal swabs and for the presence of antibodies using serum antibody testing. Participants were randomized (1:1) to receive either 1 dose of REGEN-COV (1,200 mg) or placebo, administered via 4 subcutaneous injections.

During the trial, participants were tested weekly for SARS-CoV-2 during the initial month (4 weeks), as part of the primary analyses. Following this, from months 2-8 (week 5 to week 32), participants were to be tested if they developed any COVID-19 symptoms.

The new analyses include results from 1,683 people who were not infected with SARS-CoV-2 and did not have antibodies for SARS-CoV-2 (seronegative) at baseline. Across both groups approximately 95% completed the trial. In total, 42% identified as Hispanic/Latino and 9% identified as Black/African American. In addition, 34% were obese and 37% were aged ≥50 years (median age: 43 years; range: 12-92 years).

#### **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*<sup>®</sup> and *VelociSuite*<sup>®</sup> 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 [Cell](#) and [Science](#).

REGEN-COV has not been approved by the FDA, but is currently [authorized](#) in the U.S. for the treatment and post-exposure prophylaxis in certain high risk individuals. 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 (authorized uses and important safety information).

In October, the U.S. FDA [accepted](#) for priority review the first of two Biologics License Applications (BLAs) for REGEN-COV to treat COVID-19 in non-hospitalized patients and as prophylaxis in certain individuals. The second BLA submission will focus on those hospitalized because of COVID-19, and is expected to be completed later this year.

Emergency or temporary pandemic use authorizations are currently in place in more than 40 countries, including the U.S., several European Union countries, India, Switzerland and Canada, and the antibody cocktail is fully approved in Japan and conditionally approved in the UK.

#### **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<sup>®</sup> (dupilumab), Libtayo<sup>®</sup> (cemiplimab-rwlc), Praluent<sup>®</sup> (alirocumab), Kevzara<sup>®</sup> (sarilumab), Evkeeza<sup>®</sup> (evinacumab-dgnb) and Imzabz<sup>™</sup> (atoltivimab, maftivimab and odesivimab-ebgn).

#### **AUTHORIZED USES AND IMPORTANT SAFETY INFORMATION**

##### **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 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)

#### **Limitations of Authorized Use (Post-Exposure Prophylaxis)**

- Post-exposure prophylaxis with REGEN-COV is not a substitute for vaccination against COVID-19
- REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19

REGEN-COV has not been approved, but has been authorized for emergency use by FDA

These uses are 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 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](#)

#### **Criteria for Identifying High Risk Individuals**

Please refer to the Fact Sheet for Healthcare Providers for criteria for identifying high risk individuals

#### **SARS-CoV-2 Viral Variants**

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

- **Contraindication:**  
REGEN-COV is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to REGEN-COV
- **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, arrhythmia (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, arrhythmia (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:** 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:**

- **COV-2067 (Treatment):** Infusion-related reactions (adverse event assessed as causally related by the investigator) of grade 2 or higher severity have been observed in 10/4,206 (0.2%) of those who received REGEN-COV at the authorized dose or a higher dose. 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, pruritus, 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
- **COV-2069 (Post-exposure prophylaxis):** In subjects who were SARS-CoV-2 negative at baseline (Cohort A), injection site reactions (all grade 1 and 2) occurred in 55 subjects (4%) in the REGEN-COV group and 19 subjects (2%) in the placebo group. The most common signs and symptoms of injection site reactions which occurred in at least 1% of subjects in the REGEN-COV group were erythema and pruritus. Hypersensitivity reactions occurred in 2 subjects (0.2%) in the REGEN-COV group and all hypersensitivity reactions were grade 1 in severity. In subjects who were SARS-CoV-2 positive at baseline (Cohort B), injection site reactions, all of which were grade 1 or 2, occurred in 6 subjects (4%) in the REGEN-COV group and 1 subject (1%) in the placebo group. The most common signs and symptoms of injection site reactions which occurred in at least 1% of subjects in the REGEN-COV group were ecchymosis and erythema
- **COV-2093 (Subcutaneous Dosing):** Injection site reactions occurred in 12% and 4% of subjects following single dose administration in the REGEN-COV and placebo groups, respectively. Remaining safety finding following subcutaneous administration in the REGEN-COV group were similar to the safety findings observed with intravenous administration in COV-2067. With repeat dosing, injection site reactions occurred in 252 subjects (35%) in the REGEN-COV group and 38 subjects (16%) in the placebo group; all injection site reactions were grade 1 or 2 in severity. Hypersensitivity reactions occurred in 8 subjects (1%) in the REGEN-COV group; and all hypersensitivity reactions were grade 1 or 2 in severity. There were no cases of anaphylaxis

- **Patient Monitoring Recommendations:** Clinically monitor patients during dose administration 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](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, 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 program relating to the REGEN-COV<sup>®</sup> (casirivimab and imdevimab) antibody cocktail (including any potential approval of REGEN-COV for pre-exposure prophylaxis and/or the treatment for hospitalized patients); 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), such as the study discussed in this press release, on any of the foregoing or any potential regulatory approval of Regeneron's Products and Regeneron's Product Candidates; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates (such as REGEN-COV, including based on the Biologics License Applications filed or planned to be filed with the U.S. Food and Drug Administration (the "FDA") referenced in this press release) and new indications for Regeneron's Products; how long the Emergency Use Authorization ("EUA") granted by the FDA for REGEN-COV will remain in effect, whether the EUA will be updated to include pre-exposure prophylaxis and/or the treatment for hospitalized patients, 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; 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 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 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; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees 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 (known as REGEN-COV in the United States and Ronapreve<sup>®</sup> in other countries) and its REGEN-COV supply agreement with the U.S. government, 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<sup>®</sup> (afibercept) Injection, Dupixent<sup>®</sup> (dupilumab), Praluent<sup>®</sup> (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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