



## Phase 3 Trial Shows REGEN-COV™ (casirivimab with imdevimab) Antibody Cocktail Reduced Hospitalization or Death by 70% in Non-hospitalized COVID-19 Patients

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**REGEN-COV also significantly shortened the duration of symptoms by 4 days**

**All doses (8,000 mg, 2,400 mg and 1,200 mg) had similar efficacy across all endpoints**

**Companion dose-ranging Phase 2 trial showed significant and comparable viral reductions for all REGEN-COV doses tested, including as low as 300 mg**

**FDA recently updated U.S. EUA fact sheets for all authorized monoclonal antibody treatments, indicating that REGEN-COV is the only one to retain potency against key emerging variants**

**Regeneron will share new data with regulatory authorities immediately and request that a lower 1,200 mg dose be added to EUA**

Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced positive topline results from the largest trial to date assessing a COVID-19 treatment in infected non-hospitalized patients (n=4,567). This definitive Phase 3 outcomes trial in high-risk non-hospitalized COVID-19 patients ("outpatients") met its primary endpoint, showing the investigational REGEN-COV™ (casirivimab with imdevimab) significantly reduced the risk of hospitalization or death by 70% (1,200 mg intravenous [IV]) and 71% (2,400 mg IV) compared to placebo.

"This is a landmark moment in the fight against COVID-19 as this large well-controlled trial provides conclusive results demonstrating that REGEN-COV can dramatically reduce the risk of hospitalization and death in the outpatient setting," said Suraj Saggarr, D.O., trial investigator and Chief of Infectious Disease at Holy Name Medical Center in Teaneck, New Jersey. "With so many people still getting infected, as well as recent data showing that REGEN-COV addresses emerging variants, these data underscore the need to rapidly adopt REGEN-COV as standard-of-care to offer high-risk patients their best chance to reduce serious consequences like hospitalization or death."

REGEN-COV also met all secondary endpoints in the Phase 3 outcomes trial, including the ability to reduce symptom duration. In addition, a companion Phase 2 trial showed that even the lowest doses tested (IV: 300 mg; subcutaneous [SC]: 600 mg) had significant viral load reductions over the first 7 study days, comparable to the 2,400 mg and 1,200 mg IV doses.

"With approximately 60,000 newly diagnosed individuals in the U.S. every day and 40,000 still in the hospital because of COVID-19, we are committed to working with the government, healthcare providers and others to support rapid and widespread adoption of REGEN-COV in appropriate patients," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer at Regeneron. "We will discuss the new data with regulatory authorities and request that the 1,200 mg dose be rapidly added to the U.S. Emergency Use Authorization, in order for the anticipated REGEN-COV supply to be available to treat even more patients. These Phase 3 data will also form the basis of a full Biologics License Application."

**TABLE 1: Key Results from Phase 3 Outpatient Trial<sup>1-3</sup>**

	<b>1,200 mg IV</b>	<b>Placebo</b>	<b>2,400 mg IV</b>	<b>Placebo</b>
	n=736	n=748	n=1,355	n=1,341
<b>Patients with <sup>31</sup> COVID-19-related hospitalization or death through day 29</b>				
Risk reduction	70% (p=0.0024)		71% (p<0.0001)	
# of patients with events	7 (1.0%)	24 (3.2%)	18 (1.3%)	62 (4.6%)
<b>Time to COVID-19 symptom resolution</b>				
Median (days)	10	14	10	14
Median reduction (days)	4 (p<0.0001)		4 (p<0.0001)	

1. Based on the modified Full Analysis Set population, which includes all randomized patients with a positive SARS-CoV-2 RT-qPCR test from nasopharyngeal swabs at randomization and <sup>31</sup> risk factor for severe COVID-19.
2. The formal hierarchical analysis first evaluated the 2,400 mg dose vs. concurrent placebo and then evaluated the 1,200 mg dose vs. concurrent placebo.
3. Based on Phase 1/2 analyses showing that the 8,000 mg and 2,400 mg doses were indistinguishable, the Phase 3 protocol was amended to compare the 2,400 mg and 1,200 mg doses vs. placebo, and the 8,000 mg data were converted to a descriptive analysis.

A safety assessment was conducted on all available patient data up to day 169, and identified no new safety signals. Serious adverse events (SAEs) were largely related to COVID-19 and occurred in 1.1% of patients in the 1,200 mg group, 1.3% in the 2,400 mg group and 4.0% in the placebo group. There was 1 death in the 1,200 mg group (n=827), 1 death in the 2,400 mg group (n=1,849) and 5 deaths in the placebo groups (n=1,843).

All patients in this analysis had at least one risk factor, including obesity (58%), age ≥50 years (51%) and cardiovascular disease, including hypertension (36%). Approximately 35% of patients were Latino/Hispanic, 5% were Black/African American and the median age was 50 years (range: 18-96 years).

### Dose-ranging Virology Trial

A companion dose-ranging Phase 2 trial of 803 outpatient COVID-19 patients was conducted to evaluate the antiviral effect of several different REGEN-COV doses (IV: 2,400 mg, 1,200 mg, 600 mg and 300 mg; SC: 1,200 mg and 600 mg). All tested doses met the primary endpoint, rapidly and significantly reducing patients' viral load (log<sub>10</sub> copies/mL) compared to placebo (p£0.001). Each dose demonstrated similar efficacy, including the lowest doses tested (IV: 300 mg; SC: 600 mg).

"These encouraging results confirm the rapid and significant antiviral effects of REGEN-COV, even at much lower and subcutaneous doses," said David Weinreich, M.D., Executive Vice President and Head of Global Clinical Development at Regeneron. "We are grateful to all patients and investigators who participated in these and other ongoing REGEN-COV trials. We will share both our Phase 3 outcomes data and our Phase 2 virology data with regulatory authorities to discuss next steps, including the possibility of utilizing lower doses and more convenient subcutaneous administration."

Detailed results from both trials will be shared with regulatory authorities and submitted for peer review as soon as possible. REGEN-COV continues to be evaluated in clinical trials in multiple settings for COVID-19: in non-hospitalized and certain 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. As of March 2021, more than 25,000 people have participated in clinical trials involving REGEN-COV.

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.

### FDA Updates to Fact Sheets

To address SARS-CoV-2 variants, last week the U.S. Food and Drug Administration (FDA) [authorized](#) revisions to the fact sheets for monoclonal antibodies currently under emergency use authorization (EUA). The REGEN-COV [fact sheet](#) (see table below), notes that it retains potency against the main variants of concern known to be circulating within the U.S. In contrast, multiple variant strains had reduced susceptibility to the other two FDA-authorized monoclonal antibodies (fact sheets are available [here](#) and [here](#)).

**TABLE 2: Pseudovirus Neutralization Data for SARS-CoV-2 Variant Substitutions with casirivimab and imdevimab Together**

Lineage with Spike Protein Substitution	Key Substitutions Tested	Fold Reduction in Susceptibility
B.1.1.7 (UK origin)	N501Y <sup>a</sup>	no change <sup>c</sup>
B.1.351 (South Africa origin)	K417N, E484K, N501Y <sup>b</sup>	no change <sup>c</sup>
P.1 (Brazil origin)	K417T + E484K	no change <sup>c</sup>
B.1.427/B.1.429 (California origin)	L452R	no change <sup>c</sup>
B.1.526 (New York origin) <sup>d</sup>	E484K	no change <sup>c</sup>

- Pseudovirus expressing the entire variant spike protein was tested. The following changes from wild-type spike protein are found in the variant: del69-70, del145, N501Y, A570D, D614G, P681H, T716I, S982A, D1118H.
- Pseudovirus expressing the entire variant spike protein was tested. The following changes from wild-type spike protein are found in the variant: D80Y, D215Y, del241-243, K417N, E484K, N501Y, D614G, A701V.
- No change: < 2-fold reduction in susceptibility.
- Not all isolates of the New York lineage harbor the E484K substitution (as of February 2021).

### Supply and Distribution Update

REGEN-COV is available throughout the U.S. without restriction – information on availability in your area is available from the [Department of Health and Human Services](#) and the [National Infusion Center Association](#).

Regeneron anticipates recording approximately \$260 million in REGEN-COV U.S. net product sales to the U.S. government in the first quarter of 2021, representing final deliveries from the [initial agreement](#) with the U.S. government. Sales under the [second U.S. government agreement](#) are now expected to begin in the second quarter of 2021. The company expected to provide approximately 750,000 doses at the 2,400 mg dose level, but now anticipates being able to provide approximately 1.25 million doses if the 1,200 mg dose is added to the EUA. Due to the pandemic, many organizations are currently utilizing the same limited manufacturing resources including external fill and finish capacity, and this may impact the timing of final delivery of doses. The government is obligated to purchase all finished doses supplied by June 30, 2021, up to 1.25 million doses total, and may accept doses after this date at its discretion.

Roche, which is responsible for REGEN-COV outside the U.S., continues to work with the European Medicines Agency, governments and other health authorities across the globe to bring this antibody cocktail to as many patients as possible.

### About the REGEN-COV Antibody Cocktail

REGEN-COV (casirivimab with 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*<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 [Science](#).

Under an EUA [issued](#) by the FDA, REGEN-COV is currently available in the U.S. to treat 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.

REGEN-COV is currently authorized and available in a 2,400 mg IV dose, with infusion times as short as 20 minutes. The criteria for 'high-risk' patients are described in the [Fact Sheet for Healthcare Providers](#). 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 co-Founder, 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 with imdevimab), Dupixent® (dupilumab), Libtayo® (cemiplimab-rwlc), Praluent® (alirocumab), Kevzara® (sarilumab), Evkeeza™ (evinacumab-dgnb) and Inmazed™ (atoltivimab, maftivimab and odesivimab-ebgn).

#### **AUTHORIZED USE AND IMPORTANT SAFETY INFORMATION**

##### **Authorized Emergency Use**

REGEN-COV, (casirivimab with imdevimab 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 progressing to severe COVID-19 and/or hospitalization. [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 with 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**

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, [https://www.cdc.gov/growthcharts/clinical\\_charts.htm](https://www.cdc.gov/growthcharts/clinical_charts.htm), OR
  - sickle cell disease, OR
  - congenital or acquired heart disease, OR

- neurodevelopmental disorders (e.g., 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.

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 with 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:** There is a potential for serious hypersensitivity reaction, including anaphylaxis, 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. Infusion-related reactions have been observed with administration of REGEN-COV.
  - **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, dizziness, fatigue and diaphoresis. If an infusion-related reaction occurs, consider slowing or stopping the infusion and administer appropriate medications and/or supportive care.
- **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:** 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:**

- Serious adverse events (SAEs) were reported in 4 (1.6%) patients in REGEN-COV 2,400 mg group, 2 (0.8%) patients in REGEN-COV 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 REGEN-COV), intestinal obstruction and dyspnea (8,000 mg REGEN-COV) and COVID-19, pneumonia and hypoxia (placebo). **REGEN-COV is not authorized at the 8,000 mg dose (4,000 mg casirivimab and 4,000 mg imdevimab).**
- One anaphylactic reaction was reported in the clinical program. The event began within 1 hour of completion of the infusion, and required treatment including epinephrine. The event resolved. Infusion-related reactions, of Grade 2 or higher severity, were reported in 4 subjects (1.5%) in the 8,000 mg (4,000 mg casirivimab and 4,000 mg imdevimab) arm. These infusion-related reactions events were moderate in severity; and include pyrexia, chills, urticaria, pruritus, abdominal pain, and flushing. One infusion-related reaction (nausea) was reported in the placebo arm and none were reported in the 2,400 mg (1,200 mg casirivimab and 1,200 mg imdevimab) arm. In two subjects receiving the 8,000 mg dose of REGEN-COV, the infusion-related reactions (urticaria, pruritus, flushing, pyrexia, shortness of breath, chest tightness, nausea, vomiting) resulted in permanent discontinuation of the infusion. All events resolved.

**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 REGEN-COV in COVID-19 patients who are pregnant. REGEN-COV therapy should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus.
- **Lactation:** There is currently no clinical experience in use of REGEN-COV 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



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, all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite* technologies, such as *VelocImmune*, which uses unique genetically-humanized mice to produce optimized fully-human antibodies and bispecific antibodies, and through ambitious research initiatives such as the Regeneron Genetics Center, which is conducting one of the largest genetics sequencing efforts in the world. For additional information about the company, please visit [www.regeneron.com](http://www.regeneron.com) or follow @Regeneron on Twitter.

#### **Regeneron Forward-Looking Statements and Use of Digital Media**

*This press release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron's business and its employees, collaborators, and suppliers and other third parties on which Regeneron relies, Regeneron's and its collaborators' ability to continue to conduct research and clinical programs, Regeneron's ability to manage its supply chain, net product sales of products marketed or otherwise commercialized by Regeneron and/or its collaborators (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and product candidates and research and clinical programs now underway or planned, including without limitation the development program relating to REGEN-COV™ (casirivimab with 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; whether the 1,200 mg dose of REGEN-COV will be added the EUA for REGEN-COV based on the data discussed in this press release or otherwise; the amount of net product sales of REGEN-COV under Regeneron's agreements with the U.S. government and timing of recognition of any such sales; the ability of Regeneron's collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and product candidates (including REGEN-COV) and the impact of the foregoing on Regeneron's ability to supply its Products and product candidates (including REGEN-COV); the ability of Regeneron to manage supply chains for multiple products and product candidates; safety issues resulting from the administration of Regeneron's Products and product candidates (such as REGEN-COV) in patients, including serious complications or side effects in connection with the use of Regeneron's Products and product candidates in clinical trials; uncertainty of market acceptance and commercial success of Regeneron's Products and product candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) (including the study discussed in this press release) on any potential regulatory approval (including with respect to REGEN-COV) and/or the commercial success of Regeneron's Products and product candidates; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's Products and product candidates, including without limitation REGEN-COV; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; the availability and extent of reimbursement of Regeneron's Products from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payers and new policies and procedures adopted by such payers; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and product candidates; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license, collaboration, or supply agreement, including Regeneron's agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), as well as Regeneron's collaboration with Roche relating to REGEN-COV, to be cancelled or terminated; and risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to EYLEA® (afibercept) Injection, Dupixent® (dupilumab), 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. 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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