



ATS 2021 Breaking News Session to Feature Pivotal Data on REGEN-COV™ (casirivimab with imdevimab) and Dupixent® (dupilumab)

May 3, 2021 at 8:00 AM EDT

**Positive Phase 3 results from REGEN-COV trial in high-risk non-hospitalized patients with COVID-19 to be presented
Session to also include presentation of positive Phase 3 results from Dupixent trial in children with moderate-to-severe asthma**

TARRYTOWN, N.Y., May 3, 2021 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced that positive Phase 3 data from trials evaluating two Regeneron medicines will be featured at the 2021 American Thoracic Society International Conference (ATS 2021) in the *Breaking News: Clinical Trial Results in Pulmonary Medicine* Scientific Symposium on May 17, 2021. The data selected for presentation in this session represent late-breaking information on leading clinical trials in pulmonary and critical care medicine. It includes positive results from two Regeneron pivotal Phase 3 trials, the first evaluating REGEN-COV™ (casirivimab with imdevimab) in high-risk non-hospitalized patients (outpatients) with mild-to-moderate COVID-19, and the second evaluating Dupixent® (dupilumab) in children as young as 6 years with uncontrolled moderate-to-severe asthma. These uses for both medicines are investigational.

"We work every day to push the boundaries of science to improve patient lives, and are pleased to see two of our medicines recognized at ATS as leading data that could potentially impact the COVID-19 and asthma landscape," said David Weinreich, M.D., Executive Vice President and Head of Global Clinical Development at Regeneron. "We pride ourselves on quickly and consistently translating science to medicine, and as part of this process, it is particularly important to present our data in peer-reviewed settings. We are moving rapidly to publish these significant results in peer-reviewed journals."

REGEN-COV is an investigational antibody cocktail authorized for emergency use in the U.S. for patients with mild-to-moderate COVID-19 who are at high-risk of severe disease or hospitalization, and is [strongly recommended](#) by the National Institute of Health COVID-19 Treatments Guidelines for these patients. REGEN-COV continues to be studied in the outpatient ([symptomatic](#) and [asymptomatic](#) infections), [prevention](#) and [certain hospitalized](#) COVID-19 patient settings.

In addition to the pivotal Phase 3 results in children as young as 6 years, Dupixent data being presented at ATS 2021 also include results from a two-year open-label extension trial on the ability of Dupixent to reduce and eliminate long-term oral corticosteroid use in adults and simultaneously improve patient-reported, health-related quality of life outcomes in adults and adolescents with asthma. Regeneron will also present data from the largest clinical trial to date demonstrating rapid and significant symptom improvement in patients with chronic rhinosinusitis with nasal polyps (CRSwNP). This includes results across several key measures including sense of smell, and in adults with or without coexisting respiratory diseases such as asthma, allergic rhinitis and aspirin-exacerbated respiratory disease. Safety results from these trials were generally consistent with the known safety profile of Dupixent in its approved indications.

Presentations at ATS 2021 (May 14-19)

B007: Breaking News: Clinical Trial Results in Pulmonary Medicine Scientific Symposium
May 17, 2021 | 10:00 am-11:30 am EDT

- Casirivimab with Imdevimab, a Cocktail of Two Antibodies Against SARS-CoV-2, in the Outpatient Setting: Phase 3 Efficacy and Safety Results, Julie Philley
- Efficacy and Safety of Dupilumab in Children With Uncontrolled Moderate-to-Severe Asthma, Leonard Bacharier

Dupixent Data Presentations

Data evaluating Dupixent efficacy, safety, and long-term clinical and health-related quality of life outcomes will be also presented:

Adult and adolescent asthma, including long-term outcomes

- **Abstract #A1204:** Dupilumab Efficacy and Safety in Children With Uncontrolled Moderate-to-Severe Asthma: The Phase 3 VOYAGE Study, Leonard Bacharier
 - Oral Presentation Session: D007 Advances in Asthma Therapies, Wednesday, May 19, 10:00 am-11:30 am EDT
- **Abstract #A1201:** Long-Term Dupilumab Treatment in Moderate-to-Severe Asthma With Type 2 Inflammation: Open Label LIBERTY ASTHMA TRAVERSE Study, Michael Wechsler
 - Oral Presentation Session: D007 Advances in Asthma Therapies, Wednesday, May 19, 10:00 am-11:30 am EDT
- **Abstract #A1441:** Assessment of Long-Term Maintenance of OCS Reduction and Efficacy in the Dupilumab LIBERTY ASTHMA TRAVERSE Extension Study, Lawrence Sher
- **Abstract #A1452:** Dupilumab Shows Sustained Efficacy and Improvements in Asthma Control and Health-Related Quality of Life in Patients With Moderate-to-Severe Asthma: LIBERTY ASTHMA TRAVERSE, Michael Wechsler

- **Abstract #A1446:** Dupilumab Efficacy in Patients With Moderate-to-Severe Type 2 Asthma With and Without Elevated Blood Neutrophils, Eugene Bleecker
- **Abstract #A1460:** Long-Term 3-Year Efficacy of Dupilumab in QUEST Patients Enrolled in LIBERTY ASTHMA TRAVERSE, Albert Papi
- **Abstract #A1443:** Long-term Exacerbations and Lung Function Assessment in LIBERTY ASTHMA TRAVERSE Stratified by Lung Function Improvements at the End of Parent Study, Nicola Hanania
- **Abstract #A1444:** Dupilumab Provides Rapid and Sustained Exacerbation Protection in Patients With Uncontrolled, Moderate-to-Severe Type 2 Inflammatory Asthma Enrolled in the LIBERTY ASTHMA QUEST Study, Jonathan Corren

Adult CRSwNP efficacy and safety

- **Abstract #A1340:** Efficacy of Dupilumab in Patients With Chronic Rhinosinusitis With Nasal Polyps and Allergic Rhinitis, Anju T. Peters
- **Abstract #A1345:** Rapid and Sustained Effects of Dupilumab in Patients with Severe Chronic Rhinosinusitis with Nasal Polyps: Analysis of the SINUS-24 and SINUS-52 Phase 3 Trials, Peter W. Hellings
- **Abstract #A1343:** Association between Dupilumab Effect on Nasal Polyp Score and Biomarkers of Type 2 Inflammation in Patients With Chronic Rhinosinusitis With Nasal Polyps in the Phase 3 SINUS-24 and SINUS-52 Trials, Claus Bachert
- **Abstract #A1341:** Dupilumab Provides Early and Durable Alleviation of Symptoms in Patients with Chronic Rhinosinusitis with Nasal Polyps: Results from the SINUS-24 and SINUS-52 Phase 3 Trials, Philippe Gevaert

Real-world data in asthma

- **Abstract #A1449:** The RAPID Registry: A Global Real-World Cohort of Patients Receiving Dupilumab for the Treatment of Moderate-to-Severe Asthma, Neal Jain

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*[®] 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](#).

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.

Under an Emergency Use Authorization (EUA) [issued](#) by the U.S. Food and Drug Administration (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 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.

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.

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](#).

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 Dupixent

Dupixent is a fully human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) pathways and is not an immunosuppressant. It was invented using Regeneron's proprietary *VelocImmune* technology. IL-4 and IL-13 are key and central drivers of the type 2 inflammation that plays a major role in asthma, CRSwNP, atopic dermatitis, and eosinophilic esophagitis.

Dupixent is approved in the U.S. to treat patients aged 6 years and older with moderate-to-severe atopic dermatitis that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies; for use with other asthma medicines for the maintenance treatment of moderate-to-severe eosinophilic or oral steroid dependent asthma in patients aged 12

years and older whose asthma is not controlled with their current asthma medicines; and for use with other medicines for the maintenance treatment of CRSwNP in adults whose disease is not controlled.

Outside of the U.S., Dupixent is approved for specific patients with moderate-to-severe atopic dermatitis and certain patients with asthma in a number of other countries around the world, including those in the European Union (EU) and Japan. Dupixent is also approved in the EU and Japan to treat certain adults with severe CRSwNP. Across all approved indications globally, more than 260,000 patients have been treated with Dupixent.

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 Inmazole™ (atoltivimab, maftivimab and odesivimab-ebgn)

Dupilumab Development Program

To date, dupilumab has been studied in more than 10,000 patients across 50 clinical trials in various chronic diseases driven by type 2 inflammation.

In addition to the currently approved indications, Regeneron and Sanofi are studying dupilumab in a broad range of diseases driven by type 2 inflammation or other allergic processes, including pediatric asthma (6 to 11 years of age, Phase 3), chronic obstructive pulmonary disease with evidence of type 2 inflammation (Phase 3), pediatric atopic dermatitis (6 months to 5 years of age, Phase 3), eosinophilic esophagitis (Phase 3), bullous pemphigoid (Phase 3), prurigo nodularis (Phase 3), chronic spontaneous urticaria (Phase 3), chronic inducible urticaria-cold (Phase 3), chronic rhinosinusitis without nasal polyposis (Phase 3), allergic fungal rhinosinusitis (Phase 3), allergic bronchopulmonary aspergillosis (Phase 3) and food allergies (Phase 2). These potential uses are under clinical investigation, and the safety and efficacy of dupilumab in these conditions have not been fully evaluated by any regulatory authority. Dupilumab is being jointly developed by Regeneron and Sanofi under a global collaboration agreement.

U.S. INDICATIONS

DUPIXENT is a prescription medicine used:

- to treat people aged 6 years and older with moderate-to-severe atopic dermatitis (eczema) that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies. DUPIXENT can be used with or without topical corticosteroids. It is not known if DUPIXENT is safe and effective in children with atopic dermatitis under 6 years of age.
- with other asthma medicines for the maintenance treatment of moderate-to-severe eosinophilic or oral steroid dependent asthma in people aged 12 years and older whose asthma is not controlled with their current asthma medicines. DUPIXENT helps prevent severe asthma attacks (exacerbations) and can improve your breathing. DUPIXENT may also help reduce the amount of oral corticosteroids you need while preventing severe asthma attacks and improving your breathing. DUPIXENT is not used to treat sudden breathing problems. It is not known if DUPIXENT is safe and effective in children with asthma under 12 years of age.
- with other medicines for the maintenance treatment of chronic rhinosinusitis with nasal polyposis (CRSwNP) in adults whose disease is not controlled. It is not known if DUPIXENT is safe and effective in children with chronic rhinosinusitis with nasal polyposis under 18 years of age.

IMPORTANT SAFETY INFORMATION FOR U.S. PATIENTS

Do not use if you are allergic to dupilumab or to any of the ingredients in DUPIXENT®.

Before using DUPIXENT, tell your healthcare provider about all your medical conditions, including if you:

- have eye problems
- have a parasitic (helminth) infection
- are scheduled to receive any vaccinations. You should not receive a "live vaccine" if you are treated with DUPIXENT.
- are pregnant or plan to become pregnant. It is not known whether DUPIXENT will harm your unborn baby.
 - There is a pregnancy exposure registry for women who take DUPIXENT during pregnancy to collect information about the health of you and your baby. Your healthcare provider can enroll you or you may enroll yourself. To get more information about the registry call 1-877-311-8972 or go to <https://mothertobaby.org/ongoing-study/dupixent/>.
- are breastfeeding or plan to breastfeed. It is not known whether DUPIXENT passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

Especially tell your healthcare provider if you are taking oral, topical, or inhaled corticosteroid medicines; have asthma and use an asthma medicine; or have atopic dermatitis or CRSwNP, and also have asthma. **Do not** change or stop your corticosteroid medicine or other asthma medicine without talking to your healthcare provider. This may cause other symptoms that were controlled by the corticosteroid medicine or other asthma medicine to come back.

DUPIXENT can cause serious side effects, including:

- **Allergic reactions (hypersensitivity), including a severe reaction known as anaphylaxis.** Stop using DUPIXENT and tell your healthcare provider or get emergency help right away if you get any of the following symptoms: breathing problems, fever, general ill feeling, swollen lymph nodes, swelling of the face, mouth and tongue, hives, itching, fainting, dizziness, feeling lightheaded (low blood pressure), joint pain, or skin rash.
- **Eye problems.** Tell your healthcare provider if you have any new or worsening eye problems, including eye pain or changes in vision.
- **Inflammation of your blood vessels.** Rarely, this can happen in people with asthma who receive DUPIXENT. This may happen in people who also take a steroid medicine by mouth that is being stopped or the dose is being lowered. It is not known whether this is caused by DUPIXENT. Tell your healthcare provider right away if you have: rash, shortness of breath, persistent fever, chest pain, or a feeling of pins and needles or numbness of your arms or legs.

The most common side effects by indication are as follows:

- **Atopic dermatitis:** injection site reactions, eye and eyelid inflammation, including redness, swelling, and itching, and cold sores in your mouth or on your lips.
- **Asthma:** injection site reactions, pain in the throat (oropharyngeal pain), and high count of a certain white blood cell (eosinophilia).
- **Chronic rhinosinusitis with nasal polyposis:** injection site reactions, eye and eyelid inflammation, including redness, swelling, and itching, high count of a certain white blood cell (eosinophilia), trouble sleeping (insomnia), toothache, gastritis, and joint pain (arthralgia).

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of DUPIXENT. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Use DUPIXENT exactly as prescribed. Your healthcare provider will tell you how much DUPIXENT to inject and how often to inject it. DUPIXENT is an injection given under the skin (subcutaneous injection). If your healthcare provider decides that you or a caregiver can give DUPIXENT injections, you or your caregiver should receive training on the right way to prepare and inject DUPIXENT. **Do not** try to inject DUPIXENT until you have been shown the right way by your healthcare provider. In children 12 years of age and older, it is recommended that DUPIXENT be administered by or under supervision of an adult. In children younger than 12 years of age, DUPIXENT should be given by a caregiver.

Please see accompanying full [Prescribing Information](#) including Patient Information.

REGEN-COV 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) ≥ 35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are ≥ 65 years of age
- Are ≥ 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 ≥ 85 th percentile for their age and gender based on CDC growth charts, 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, 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, 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 and research and clinical programs now underway or planned, including without limitation the development programs relating to REGEN-COV™ (casirivimab with imdevimab) antibody cocktail and Dupixent® (dupilumab); 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, such as Dupixent for the treatment of pediatric asthma, chronic obstructive pulmonary disease with evidence of type 2 inflammation, pediatric atopic dermatitis, eosinophilic esophagitis, bullous pemphigoid, prurigo nodularis, chronic spontaneous urticaria, chronic inducible urticaria-cold, chronic rhinosinusitis without nasal polyposis, allergic fungal rhinosinusitis, food allergies, and other potential indications; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and product candidates, including the impact of recommendations, guidelines (including the National Institutes of Health COVID-19 Treatment Guidelines referenced in this press release), 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 product candidates (such as REGEN-COV); whether the 1,200 mg subcutaneous dose of REGEN-COV will be included in the EUA for REGEN-COV based on the data referenced in this press release or otherwise; 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 and Dupixent) in patients, including serious complications or side effects in connection with the use of Regeneron's Products and 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 product candidates, including without limitation REGEN-COV and Dupixent; 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, 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>).

Regeneron Contacts:

Media Relations

Hannah Kwagh

Tel: +1 914-847-6314


Hannah.Kwagh@regeneron.com

Investor Relations

Mark Hudson

Tel: +1 914-847-3482

Mark.Hudson@regeneron.com

 View original content: <http://www.prnewswire.com/news-releases/ats-2021-breaking-news-session-to-feature-pivotal-data-on-regencov-casirivimab-with-imdevimab-and-dupixent-dupilumab-301281713.html>

SOURCE Regeneron Pharmaceuticals, Inc.