Regeneron Reports Positive Interim Data with REGEN-COV™ Antibody Cocktail used as Passive Vaccine to Prevent COVID-19

January 26, 2021 at 7:00 AM EST

TARRYTOWN, N.Y., Jan. 26, 2021 /PRNewswire/ --

Reduction in overall infections seen within first week, with 100% prevention of symptomatic infections

Markedly decreased levels and duration of viral shedding in asymptomatic infections that still occurred in REGEN-COV group

Confirmatory Phase 3 results expected early in second quarter

Potential application in people who need immediate protection or respond poorly to vaccination

REGEN-COV 1,200 mg administered by subcutaneous injection, providing greater convenience and efficiency than infusion

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced positive initial results from an ongoing Phase 3 clinical trial evaluating REGEN-COV™ (casirivimab and imdevimab antibody cocktail) used as a passive vaccine for the prevention of COVID-19 in people at high risk of infection (due to household exposure to a COVID-19 patient). The trial is being run jointly with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH).

An exploratory analysis was conducted on the first approximately 400 evaluable individuals enrolled in the trial, who were randomized to receive passive vaccination with REGEN-COV (1,200 mg via subcutaneous injections) or placebo. Results included:

- Passive vaccination with REGEN-COV resulted in 100% prevention of symptomatic infection (8/223 placebo vs. 0/186 REGEN-COV), and approximately 50% lower overall rates of infection (symptomatic and asymptomatic) (23/223 placebo vs. 10/186 REGEN-COV).
- The lower number of infections occurring with REGEN-COV therapy were all asymptomatic, with decreased peak virus levels and short duration of viral shedding.
    - Infections occurring in the placebo group had, on average, more than 100-fold higher peak viral load.
    - Infections in the REGEN-COV group lasted no more than 1 week, while approximately 40% of infections in the placebo group lasted 3-4 weeks.
    - No infected individuals in the REGEN-COV group had high viral loads (>10^4 copies/mL) compared to 62% of the infected placebo group (13/21 placebo vs. 0/9 REGEN-COV).
- REGEN-COV was associated with lower disease burden:
    - Fewer total viral shedding weeks (44 weeks placebo vs. 9 weeks REGEN-COV).
    - Fewer total high viral shedding weeks (>10^4 copies/mL) (22 weeks placebo vs. 0 weeks REGEN-COV).
    - Fewer total symptomatic weeks (18 weeks placebo vs. 0 weeks REGEN-COV).

"These data using REGEN-COV as a passive vaccine suggest that it may both reduce transmission of the virus as well as reduce viral and disease burden in those who still get infected," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer at Regeneron. "Even with the emerging availability of active vaccines, we continue to see hundreds of thousands of people infected daily, actively spreading the virus to their close contacts. The REGEN-COV antibody cocktail may be able to help break this chain by providing immediate passive immunity to those at high risk of infection, in contrast to active vaccines which take weeks to provide protection. There are also many individuals who unfortunately may be immunocompromised and not respond well to an active vaccine or are otherwise unable to be vaccinated, and REGEN-COV has the potential to be an important option for these individuals. Overall, the REGEN-COV development program has demonstrated definitive anti-viral activity and the collective data strongly suggest it can be effective both as a therapeutic and as a passive vaccine."

In the safety assessment, adverse events occurred more frequently in participants on placebo (18% placebo vs. 12% REGEN-COV); this difference was driven by the increased rate of SARS-CoV-2 infections in the placebo group. In the placebo group, there was one death and one COVID-19-related hospitalization; there were no deaths or COVID-19 hospitalizations in the treatment group. Injection site reactions occurred at a rate of approximately 2% in both treatment and placebo groups.

"In this prevention trial, REGEN-COV was given as injections rather than an infusion, which makes administration much more convenient and efficient for patients and overburdened healthcare providers and facilities," said David Weinreich, M.D., Executive

Vice President and Head of Global Clinical Development at Regeneron. "It's notable that the few infections that did occur after receiving REGEN-COV were all asymptomatic, and associated with markedly lower viral load and duration of viral shedding, potentially further reducing transmission. We look forward to seeing the full dataset early next quarter and will discuss the current results with regulatory authorities, including the potential to expand the Emergency Use Authorization."

The development and manufacturing of REGEN-COV has 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 agreements with the U.S. Government, Regeneron is supplying up to approximately 1.5 million doses of REGEN-COV for treatment of COVID-19 under the current Emergency Use Authorization (EUA). In November, REGEN-COV was granted an EUA by the U.S. Food and Drug Administration (FDA) for use in treating people with mild or moderate COVID-19 who are at high risk of developing severe symptoms and requiring hospitalization and are not currently hospitalized. The EUA is temporary and does not take the place of a formal biologics license application (BLA) review and approval process and the use of the antibody cocktail remains investigational. Evaluation of its safety and efficacy is ongoing in multiple clinical trials.

About the REGEN-COV Phase 3 Prevention Trial
This trial evaluated the use of REGEN-COV as a "passive vaccine" to prevent SARS-CoV-2 infection. Passive vaccination provides immediate short-term passive immunity, by delivering protective virus-neutralizing antibodies, either through therapeutic antibody medicines like REGEN-COV or from mother to child through breastmilk. Traditional vaccines work by activating the immune system to develop its own antibodies, a process that typically takes weeks, but provides longer-term active immunity.

The initial descriptive analysis included 409 evaluable participants enrolled early in the trial who did not have COVID-19 at baseline and were "seronegative," meaning they did not have existing antibodies in their blood to SARS-CoV-2. Individuals were eligible for the trial if they had a household member with COVID-19. Participants were tested weekly by nasopharyngeal swab. The confirmatory results will evaluate the ability of REGEN-COV to prevent asymptomatic and symptomatic COVID-19 infections as the primary endpoint. The trial has enrolled over 2,000 participants.

Among the first 409 participants, approximately 49% were Hispanic and 13% were African American. On average, participants were 43 years of age, approximately 46% were male and 54% were female.

In addition to the Phase 3 trial for the prevention of COVID-19, REGEN-COV is being studied in two late-stage hospitalized patient trials and a Phase 3 trial for the treatment of non-hospitalized patients.

About REGEN-COV Antibody Cocktail
REGEN-COV (casirivimab and imdevimab) is a cocktail of two monoclonal antibodies (also known as REGN10933 and REGN10987) and was designed specifically to block infectivity of SARS-CoV-2, the virus that causes COVID-19. 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*.

In November 2020, REGEN-COV received an EUA from the FDA for the treatment of 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. The clinical evidence from Regeneron's outpatient trial suggests that monoclonal antibodies such as casirivimab and imdevimab have the greatest benefit when given early after diagnosis and in patients who are seronegative and/or who have high viral load. The criteria for 'high-risk' patients are described in the Fact Sheet for Healthcare Providers. In the U.S., casirivimab and imdevimab are 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.

AUTHORIZED USE AND IMPORTANT SAFETY INFORMATION
Authorized Emergency Use

Casirivimab and imdevimab injection is an investigational combination therapy and has been authorized by FDA for the emergency use described above. Casirivimab and imdevimab injection is not FDA approved for any use. Safety and effectiveness of casirivimab and imdevimab injection have not yet been established for the treatment of COVID-19.

This authorized use is 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.

Limitations of Authorized Use

- Casirivimab and imdevimab injection 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 casirivimab and imdevimab injection has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as casirivimab and imdevimab, may be associated with worse clinical outcomes when administered to hospitalized patients requiring high flow oxygen or mechanical ventilation with COVID-19.

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 ≥85th percentile for their age and gender based on CDC growth charts, OR
    - sickle cell disease, OR
    - congenital or acquired heart disease, OR
    - neurodevelopmental disorders, for example, 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.

Warnings and Precautions:

- **Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions:** There is a potential for serious hypersensitivity reaction, including anaphylaxis, with administration of casirivimab and imdevimab injection. 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 casirivimab and imdevimab injection. Signs and symptoms of infusion related reactions may include fever, chills, nausea, headache, bronchospasm, hypotension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, and/or dizziness. If an infusion-related reaction occurs, consider slowing or stopping the infusion and administer appropriate medications and/or supportive care.
- **Limitations of Benefit and Potential for Risk in Patients with Severe COVID-19:** Benefit of treatment with casirivimab and imdevimab injection has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as casirivimab and imdevimab, may be associated with worse clinical outcomes when administered to hospitalized patients requiring high flow oxygen or mechanical ventilation with COVID-19. Therefore, casirivimab and imdevimab injection is not authorized for use in 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 the casirivimab and imdevimab injection 2,400 mg group, 2 (0.8%) patients in casirivimab and imdevimab injection 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 casirivimab and imdevimab injection), intestinal obstruction and dyspnea (8,000 mg casirivimab and imdevimab injection) and COVID-19, pneumonia and hypoxia (placebo). Casirivimab and imdevimab injection are not authorized at the 8,000 mg dose (4,000 mg casirivimab and 4,000 mg imdevimab).

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 casirivimab and imdevimab injection in COVID-19 patients who are pregnant. Casirivimab and imdevimab injection therapy should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus.

- **Nursing Mothers:** There is currently no clinical experience in use of casirivimab and imdevimab injection 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 casirivimab and imdevimab injection and any potential adverse effects on the breastfed child from casirivimab and imdevimab injection 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 eight 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 (including those discussed or referenced in this press release), 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 and imdevimab antibody cocktail); how long the Emergency Use Authorization ("EUA") granted by the U.S. Food and Drug Administration (the "FDA") for REGEN-COV will remain in effect, whether and to what extent the EUA may be expanded (including based on the data from the ongoing Phase 3 clinical trial discussed in this press release), 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; 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 its ability to supply doses of REGEN-COV under the terms of the agreements with the U.S. government referenced in this press release (collectively, the "Manufacturing and Supply Agreement"); whether and to what extent Regeneron will be able to supply doses of REGEN-COV under the Manufacturing and Supply Agreement; whether the Manufacturing and Supply Agreement is terminated by the U.S. government or otherwise prior to completion; 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 (including those discussed or referenced in this press release); 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 trials discussed or referenced 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® (aflibercept) Injection, Dupixent® (dupilumab), and Praluent® (alirocumab)), 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, 2019 and its Form 10-Q for the quarterly period ended September 30, 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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