Regeneron Donates Ebola Treatment for Use in Countries Most at Risk of Outbreaks

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***Inmazeb® (atoltivimab, maftivimab, and odesivimab-ebgn) was the first treatment approved by the U.S. Food and Drug Administration (FDA) for* Orthoebolavirus zairense*, also known as* Zaire ebolavirus**

Supply is being rushed to Democratic Republic of Congo (DRC) to help with the current outbreak

TARRYTOWN, N.Y., Sept. 19, 2025 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced that it will donate up to 500 doses of Inmazeb® (atoltivimab, maftivimab, and odesivimab-ebgn), an Ebola treatment for the infection caused by *Orthoebolavirus zairense*, to the World Health Organization (WHO) for exclusive use by governments of low- and lower-middle income countries.[1] The donation ensures this life-saving treatment continues to be available and free for people living in countries most at risk for Ebola outbreaks, and follows Regeneron's delivery of an Inmazeb stockpile to the U.S. Government as part of the U.S. Department of Health and Human Services (HHS) efforts to enhance national preparedness for public health emergencies.

"Ebola is a notoriously dangerous and highly contagious disease, with a fatality rate of up to 90 percent when untreated," said Leonard S. Schleifer, M.D., Ph.D., Board co-Chair, President and Chief Executive Officer of Regeneron. "During the 2018 outbreak, Regeneron changed the world's approach to Ebola by applying our innovative *VelociSuite*® technology and rapid response protocols to develop Inmazeb, the first FDA-approved treatment for this deadly disease. Our donation advances our corporate responsibility goal of breaking down barriers to patient access and will benefit the most vulnerable people. We thank the world-class scientists, government and public health leaders, and courageous healthcare providers whose collaboration made this possible."

Alongside the WHO supply agreement announced today, Regeneron is rushing Inmazeb treatments to the Democratic Republic of the Congo (DRC) for use in the current outbreak. Since 2018, Regeneron has worked with public health agencies and non-governmental organizations to rapidly offer Inmazeb at no cost under a compassionate use protocol to any country experiencing an *Orthoebolavirus zairense* outbreak, including the DRC and Guinea. Through June 2025, 266 patients have received treatment.

About Inmazeb
Inmazeb is approved by the U.S. FDA for the treatment of infection caused by *Orthoebolavirus zairense* (also known as *Zaire ebolavirus*) in adult and pediatric patients, including neonates born to a mother who is RT-PCR positive for *Orthoebolavirus zairense* infection.

Inmazeb was created using Regeneron's *VelocImmune*® platform and associated *VelociSuite*® technologies. The treatment consists of three monoclonal antibodies that help neutralize the Ebola virus by blocking its ability to invade a patient's cells and/or enlisting other immune cells to target infected cells and remove them from the body.

The safety and efficacy of Inmazeb was established through the 681-patient PALM Trial, which was independently conducted by the WHO, the National Institutes of Health (NIH) and the Institut National de Recherche Biomédicale (INRB) during the 2018 DRC outbreak. In 2019, as reported in the *New England Journal of Medicine*, the PALM Trial was stopped early following a pre-specified interim analysis that showed the superiority of Inmazeb in preventing death versus two other investigational treatments.

Inmazeb was approved by the FDA in 2020, and in 2022, WHO published its first guidelines for Ebola virus therapeutics, which strongly recommends the use of Inmazeb and calls on the global community to engage all possible mechanisms to improve access to life-saving Ebola medicines. In 2023, Inmazeb was added to the WHO Essential Medicines List and became the first and only Ebola treatment to be prequalified by the WHO, certifying that the medicine meets the organization's standards for quality, safety and efficacy. In addition to the supply channels established in the U.S. and low- and lower-middle income countries, Regeneron has also worked with governments in higher- and middle-income countries to establish Inmazeb stockpiles.

Inmazeb was developed in collaboration and with federal funds from the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response within HHS, under ongoing USG Contract Nos. HHSO100201700016C and HHSO100201500013C.

IMPORTANT SAFETY INFORMATION AND INDICATION
WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions Including Infusion-Associated Events: Hypersensitivity reactions including infusion-associated events have been reported during and post-infusion with INMAZEB. These may include acute, life-threatening reactions during and after the infusion. Monitor all patients for signs and symptoms including, but not limited to, hypotension, chills and elevation of fever, during and following INMAZEB infusion. In the case of severe or life-threatening hypersensitivity reactions, discontinue the administration of INMAZEB immediately and administer appropriate emergency care.

Infusion could not be completed in 1% of subjects who received INMAZEB due to infusion-associated adverse events. The rate of infusion of INMAZEB may be slowed or interrupted if the patient develops any signs of infusion-associated events or other adverse events.

ADVERSE REACTIONS:
The most common adverse events reported in at least 20% of subjects who received INMAZEB were pyrexia (or elevation in fever), chills, tachycardia, tachypnea and vomiting. The evaluation of adverse events in subjects who received INMAZEB may have been confounded by the signs and symptoms of the underlying *Orthoebolavirus zairense* infection.

DRUG INTERACTIONS: INMAZEB may reduce the efficacy of live vaccine therefore, avoid the concurrent administration of a live vaccine during treatment with INMAZEB. The interval between live vaccination following initiation of INMAZEB therapy should be in accordance with current vaccination guidelines. The efficacy of INMAZEB among subjects who reported receipt of a recombinant live vaccine prior to their enrollment in the PALM clinical trial was similar to subjects who did not receive a vaccine.

INDICATION
INMAZEB is indicated for the treatment of infection caused by *Orthoebolavirus zairense* in adult and pediatric patients, including neonates born to a mother who is RT-PCR positive for *Orthoebolavirus zairense* infection.

Limitations of Use: The efficacy of INMAZEB has not been established for other species of the *Orthoebolavirus* and *Orthomarburgvirus* genera. *Orthoebolavirus zairense* can change over time, and factors such as emergence of resistance, or changes in viral virulence could diminish the clinical benefit of antiviral drugs. Consider available information on drug susceptibility patterns for circulating *Orthoebolavirus zairense* strains when deciding whether to use INMAZEB.

Please see accompanying full Prescribing Information

About Regeneron
Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents, develops and commercializes life-transforming medicines for people with serious diseases. Founded and led by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous approved treatments and product candidates in development, most 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, neurological diseases, hematologic conditions, infectious diseases, and rare diseases.

Regeneron pushes the boundaries of scientific discovery and accelerates drug development using our proprietary technologies, such as *VelociSuite*®, which produces optimized fully human antibodies and new classes of bispecific antibodies. We are shaping the next frontier of medicine with data-powered insights from the Regeneron Genetics Center® and pioneering genetic medicine platforms, enabling us to identify innovative targets and complementary approaches to potentially treat or cure diseases.

For more information, please visit www.Regeneron.com or follow Regeneron on LinkedIn, Instagram, Facebook or X.

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 nature, timing, and possible success and therapeutic applications of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "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 Inmazeb® (atoltivimab, maftivimab, and odesivimab-ebgn) for the treatment of infection caused by Orthoebolavirus zairense (also known as Zaire ebolavirus); uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products (such as Inmazeb) and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), including the studies discussed or referenced in this press release, on any of the foregoing; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products; 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; the ability of Regeneron to manage supply chains for multiple products and product candidates and risks associated with tariffs and other trade restrictions; safety issues resulting from the administration of Regeneron's Products (such as Inmazeb) and Regeneron's Product Candidates 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; 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 or copay assistance for Regeneron's Products from third-party payors and other third parties, including private payor 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 payors and other third parties and new policies and procedures adopted by such payors and other third parties; changes in laws, regulations, and policies affecting the healthcare industry; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates (including biosimilar versions of Regeneron's Products); 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 and Bayer (or their respective affiliated companies, as applicable), to be cancelled or terminated; the impact of public health outbreaks, epidemics, or pandemics on Regeneron's business; and risks associated with litigation and other proceedings and government investigations relating to the Company and/or its operations (including the pending civil proceedings initiated or joined by the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts), 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), 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, 2024 and its Form 10-Q for the quarterly period ended June 30, 2025. 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 (https://investor.regeneron.com) and its LinkedIn page (https://www.linkedin.com/company/regeneron-pharmaceuticals).

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[1] As defined by the World Bank based on gross national income per capita.

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Source: Regeneron Pharmaceuticals, Inc.