Regeneron's Antibody Cocktail REGN-EB3 (Inmazeb®) is First FDA-Approved Treatment for Ebola (Zaire Ebolavirus)

October 14, 2020

In a large clinical trial, Inmazeb showed superiority compared to other investigational agents (ZMapp and remdesivir) with respect to mortality; treatment was most effective when given early in the course of disease[1]

Inmazeb (atoltivimab, maftivimab and odesivimab-ebgn) is a novel anti-viral antibody medicine developed using the same 'rapid response' technologies as Regeneron's investigational COVID-19 antibody combination

TARRYTOWN, N.Y., October 14, 2020 – Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) announced today that the U.S. Food and Drug Administration (FDA) approved Inmazeb® (atoltivimab, maftivimab and odesivimab-ebgn) for the treatment of infection caused by *Zaire ebolavirus* in adult and pediatric patients, including newborns of mothers who have tested positive for the infection.

"We are incredibly proud that the FDA has approved Inmazeb, which is also known as REGN-EB3. This is the first time the FDA has approved a treatment specifically for Ebola, which has caused a number of deadly outbreaks," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron. "Decades of investment in our *VelociSuite*® rapid response technologies, the dedication of world-class scientists, and the courageous contributions of healthcare providers and patients, together with remarkable cooperation between leading international health organizations and governments, have led to this important moment. As we apply the same sophisticated technologies and manufacturing capabilities against COVID-19, we hope this will be one of many demonstrations of how the power of science can be successfully deployed against dangerous infectious diseases."

As part of an agreement announced in July 2020, Regeneron will deliver an established number of Inmazeb treatment doses over the course of six years to the Biomedical Advanced Research and Development Authority (BARDA), as part of the U.S. Department of Health and Human Services' (HHS) goal of building national preparedness for public health emergencies.

In keeping with our mission and values, Regeneron is committed to making this important medicine available to the people who need it. In response to the 2018 Ebola outbreak in the Democratic Republic of the Congo (DRC), we worked with the World Health Organization (WHO), U.S. FDA and other global organizations to offer Inmazeb under a compassionate use protocol and include it in the four-arm PALM (PAmoja TuLinde Maisha) Trial. With BARDA support, we continue to provide Inmazeb for free in response to outbreaks in the DRC through the MEURI protocol for compassionate use. Regeneron is actively working with non-governmental organizations and public health agencies to ensure continued access to Inmazeb in low- and middle-income countries.

"Since 2015, BARDA has partnered with Regeneron to develop a life-saving treatment for Ebola Zaire. The Food and Drug Administration's approval of Inmazeb shows the power of public private partnerships to bring forward these critical treatments and improve global public health," said Gary Disbrow, the Acting Director of BARDA. "BARDA is continuing our collaboration with Regeneron on other life-threatening diseases such as MERS and COVID-19, and we look forward to continued success."

The safety and efficacy of Inmazeb was established through the 681-patient PALM Trial, a randomized, multicenter, controlled trial initiated in 2018 in the DRC. The WHO, the National Institutes of Health (NIH) and the Institut National de Recherche Biomédicale (INRB) in the DRC jointly sponsored and served as co-principal investigators of the trial. 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 superiority of Inmazeb to ZMapp and remdesivir with respect to mortality. Adverse events that occurred in at least 10% of Inmazeb patients were chills, elevation in fever (pyrexia), rapid heartbeat (tachycardia), rapid breathing (tachypnea), vomiting, low blood pressure (hypotension), diarrhea and inadequate oxygen supply to the tissue (hypoxia); of these, only chills occurred more frequently with Inmazeb than ZMapp. The evaluation of AEs in Inmazeb patients may have been confounded by the signs and symptoms of the underlying *Zaire ebolavirus* infection.

About Inmazeb

Inmazeb, previously called REGN-EB3, was created using Regeneron's *VelocImmune*® platform and associated *VelociSuite*® technologies. The treatment consists of three monoclonal antibodies of similar structure, atoltivimab, maftivimab and odesivimab, that bind to different, non-overlapping epitopes on *Zaire ebolavirus* glycoprotein. The three antibodies help neutralize the Ebola virus by blocking its ability to invade patients' and/or enlisting other immune cells to target infected cells and remove them from the body.

Inmazeb is administered as a single, weight-based intravenous infusion (50 mg atoltivimab, 50 mg maftivimab and 50 mg odesivimab per kg). Inmazeb was developed in collaboration and with federal funds from BARDA, part of the Office of the Assistant Secretary for Preparedness and Response at the 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 10% of subjects who received INMAZEB were pyrexia (or elevation in fever), chills, tachycardia, tachypnea, vomiting, hypotension, diarrhea and hypoxia. The evaluation of adverse events in subjects who received INMAZEB may have been confounded by the signs and symptoms of the underlying *Zaire ebolavirus*
- Selected grade 3 and 4 laboratory abnormalities for INMAZEB included high sodium (≥ 154 mmol/L), low sodium (<125 mmol/L), high potassium (≥ 6.5 mmol/L), low potassium (< 2.5 mmol/L), creatinine ((mg/dL) ≥ 1.8 x ULN), high alanine aminotransferase ((U/L) ≥ 5 x ULN) and high aspartate aminotransferase ((U/L) ≥ 5 x ULN).

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 *Zaire ebolavirus* in adult and pediatric patients, including neonates born to a mother who is RT-PCR positive for *Zaire ebolavirus* infection.

Limitations of Use: The efficacy of INMAZEB has not been established for other species of the *Ebolavirus* and *Marburgvirus* genera. *Zaire ebolavirus* 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 *Zaire ebolavirus* strains when deciding to use INMAZEB.

Please see accompanying full Prescribing Information

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, 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 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 Regeneron's product candidates and research and clinical programs now underway or planned, including without limitation Inmazeb® (atoltivimab, maftivimab and odesivimab-ebgn); 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) on the commercial success of Regeneron's Products (such as Inmazeb) and product candidates; safety issues resulting from the administration of Regeneron's Products (such as Inmazeb) and product candidates in patients, including serious complications or

side effects in connection with the use of Regeneron's Products and product candidates in clinical trials; whether Regeneron will be able to deliver the anticipated number of treatment doses under its agreement with the Biomedical Advanced Research and Development Authority, part of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services (HHS), discussed in this press release (the "BARDA Supply Agreement") and the impact of the BARDA Supply Agreement on Regeneron's financial condition and results of operations; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's product candidates (including without limitation REGN-COV2 (Regeneron's investigational two-antibody cocktail for the treatment and prevention of COVID-19)) and new indications for Regeneron's Products ; 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; 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; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; 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; 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 or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), as well as the BARDA Supply Agreement, 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 June 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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