



FDA Accepts ADMA Biologics License Application for RI-002

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RAMSEY, N.J., Sept. 21, 2015 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (Nasdaq:ADMA), a late-stage biopharmaceutical company that develops, manufactures, and intends to commercialize specialty plasma-based biologics, announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Company's Biologics License Application (BLA) for RI-002 intended for the primary immunodeficiency (PI) population. PI is a class of inherited genetic disorders that causes an individual to have a deficient or absent immune system due to either a lack of necessary antibodies or a failure of these antibodies to function properly, affecting approximately 250,000 people in the United States.

The PDUFA date for the FDA to complete the review is scheduled for the second half of 2016.

RI-002 demonstrated positive results in a Phase III study in patients with PI, meeting its primary endpoint, of no serious bacterial infections (SBI) reported. These results, included in the submission, more than meet the requirement specified by the FDA guidance of ≤ 1 SBI per patient-year, which were presented at the 2015 American Academy of Allergy Asthma and Immunology Annual Meeting.

About ADMA Biologics, Inc.

ADMA is a late-stage biopharmaceutical company that develops, manufactures and intends to commercialize specialty plasma-based biologics for the treatment and prevention of Primary Immune Deficiency Disease (PIDD) and certain infectious diseases. ADMA's mission is to develop and commercialize plasma-derived, human immune globulins targeted to niche patient populations for the treatment and prevention of certain infectious diseases. The target patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disease, or who may be immune-compromised for medical reasons. ADMA's lead product candidate, RI-002, has completed a Phase III clinical trial in patients with PIDD and has met the primary endpoint. A BLA for RI-002 was accepted by the FDA on September 18, 2015. The company has received U.S. Patent 9,107,906. For more information, please visit the company's website at www.admabiologics.com.

About RI-002

ADMA's lead product candidate, RI-002, is a specialty plasma-derived, polyclonal, intravenous immune globulin (IGIV) derived from human plasma containing naturally occurring polyclonal antibodies (e.g., *Streptococcus pneumoniae*, *H. influenza* type B, cytomegalovirus (CMV), measles, tetanus, etc.) as well as standardized, high levels of antibodies to respiratory syncytial virus (RSV). ADMA is pursuing an indication for the use of this specialty intravenous immune globulin (IGIV) product for treatment of patients diagnosed with PIDD. Polyclonal antibodies are the primary active component of IGIV products. Polyclonal antibodies are proteins that are used by the body's immune system to neutralize microbes, such as bacteria and viruses. Data review indicates that the polyclonal antibodies present in RI-002 support its ability to prevent infections in immune-compromised patients. ADMA's analysis demonstrated that the Phase III trial met the primary endpoint with no serious bacterial infections (SBI) reported. These results more than meet the requirement specified by the FDA guidance of ≤ 1 SBI per patient-year. A BLA was accepted by FDA on September 18, 2015.

About Primary Immune Deficiency Disease (PIDD)

PIDD is a class of inherited genetic disorders that causes an individual to have a deficient or absent immune system due to either a lack of necessary antibodies or a failure of these antibodies to function properly. PIDD patients are more vulnerable to infections and more likely to suffer complications from these infections. According to the World Health Organization, there are over 150 different presentations of PIDD. As patients suffering from PIDD lack a properly functioning immune system, they typically receive monthly, outpatient infusions of IGIV therapy. Without this exogenous antibody immune support, these patients would be susceptible to a wide variety of infectious diseases. PIDD has an estimated prevalence of 1:1,200 in the United States, or approximately 250,000 people.

Forward-Looking Statements

This press release contains "forward-looking statements" pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance or achievements, and may contain the words "estimate," "project," "intend," "forecast," "target," "anticipate," "plan," "planning," "expect," "believe," "will," "will likely," "is likely," "should," "could," "would," "may" or, in each case, their negative, or words or expressions of similar meaning. These forward-looking statements include, but are not limited to, statements concerning our plans and timing to develop, market and commercialize RI-002 and the success of such efforts, the expected timing of and our ability to obtain and maintain regulatory approvals for our product candidates, the timeframe within which we may receive approval from the FDA, if at all, of our BLA for RI-002, our ability to generate revenue, if any, from the potential commercialization of RI-002, if approved by the FDA, the timing, progress and results of the clinical development, our plans to increase our supplies of plasma, regulatory processes, interpretations of final data, possible characteristics of RI-002, acceptability of RI-002 for any purpose by physicians patients or payers, concurrence by FDA with our conclusions and the satisfaction by us of its guidance, the likelihood and timing of FDA action with respect to any further filings by the Company, results of the clinical development, continuing demonstrations of safety, comparability of results of RI-002 to other comparably run IVIG trials, improvements in clinical outcomes, potential of RI-002 to provide meaningful clinical improvement for patients living with PIDD, as well as to offer clinicians with an option for their immune compromised patients, market data and incidence of infection, potential clinical trial initiations, potential investigational new product applications, biologics license applications, expansion plans, the achievement of clinical and regulatory milestones, commercialization efforts of the Company's product candidate(s) and trends relating to demand for source plasma. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results and the timing of certain events to differ materially from any future results expressed or implied by the forward-looking statements, including, but not limited to, risks as to whether final and secondary data will be accepted as encouraging, positive or will otherwise lead to an effective or approved product, whether we will be able to demonstrate efficacy or gain necessary approvals to market and commercialize any product, whether the FDA will accept our data, accept our submission of BLAs, continue to recognize its previously reported guidance, grant a license, or approve RI-002 for marketing, whether we will meet or achieve any of our clinical, regulatory or other milestones, whether we will develop any new products or expand existing ones, whether there may be changes in regional and worldwide supply and demand for source plasma, whether we will be able to attract sufficient donors and operate our new

facility effectively or profitably, whether we can sell our plasma in the marketplace at prices that will lead to adequate amounts of revenue, whether we will be able to sustain the listing of our common stock on the NASDAQ Capital Market, whether we will meet any timing targets expressed by the Company, and other risks and uncertainties described in our filings with the U.S. Securities and Exchange Commission, including our most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto. Therefore, current and prospective security holders are cautioned that there also can be no assurance that the forward-looking statements included in this press release will prove to be accurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation or warranty by ADMA or any other person that the objectives and plans of ADMA will be achieved in any specified time frame, if at all. Except to the extent required by applicable laws or rules, ADMA does not undertake any obligation to update any forward-looking statements or to announce revisions to any of the forward-looking statements.

CONTACT: Brian Lenz

Vice President and Chief Financial Officer |201-478-5552 |
www.admabiologics.com



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