



ADMA Biologics Announces Submission of RI-002 Biologics License Application (BLA) to FDA

July 31, 2015 1:28 PM EDT

Submission Reinforces Commitment to Commercialize Novel Therapies for Immune Compromised Patients

RAMSEY, N.J., July 31, 2015 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (Nasdaq:ADMA), a late-stage biopharmaceutical company that develops, manufactures and intends to commercialize specialty plasma-based biologics for the primary immunodeficiency (PI) population and the treatment and prevention of certain infectious diseases, announced that it has submitted its Biologics License Application (BLA) to the United States Food and Drug Administration (FDA), seeking marketing authorization for RI-002.

RI-002 demonstrated positive results in a Phase III study in patients with PI, meeting its primary endpoint of no serious bacterial infections (SBI). These results, included in the submission, more than meet the requirement specified by the FDA guidance of ≤ 1 SBI per patient-year.

"The BLA submission for RI-002 is a significant milestone for our growing company," stated Adam Grossman, President and CEO of ADMA Biologics. "This submission, combined with our recent announcement of obtaining patent protection for RI-002, places ADMA in a rare position as a company poised to transition from development to commercial stage. We believe that RI-002, if approved by the FDA, has great potential to provide meaningful clinical improvement for patients living with PI, as well as offers clinicians a much needed option for their immune compromised patients. Under PDUFA V, the BLA filing fee is \$2.3 million. The FDA reviewed ADMA's small business waiver application and it was approved."

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 FDA has a 60-day review period to determine whether ADMA's BLA submission for RI-002 is complete and acceptable for filing.

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). On June 30, 2015, ADMA announced that it had received a notice of allowance for a U.S. patent pertaining to RI-002 entitled "*Compositions and Methods for the Treatment of Immunodeficiency*." ADMA is pursuing an indication for the use of this specialty IGIV product for treatment of patients diagnosed with primary immune deficiency disease (PIDD). Polyclonal antibodies are the primary active component of IGIV/immunoglobulin 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 submitted to the FDA on July 31, 2015.

About ADMA Biologics, Inc.

ADMA is a late-stage biopharmaceutical company that develops, manufactures and intends to market specialty plasma-based biologics for the treatment and prevention of PI 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, for which a notice of allowance for a U.S. patent was granted pertaining to RI-002 entitled "*Compositions and Methods for the Treatment of Immunodeficiency*," has completed a Phase III clinical trial in patients with primary immune deficiency disease (PIDD) and has met the primary endpoint. A BLA for RI-002 was submitted to the FDA on July 31, 2015. For more information, please visit the company's website at www.admabiologics.com.

About Primary Immune Deficiency Disease (PI)

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 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 acceptability by the FDA of the BLA, 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 PI, as well as to offer clinicians with an option for their

immune compromised patients, market data and incidence of infection, regulatory processes, 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 the BLA, continue to recognize its previously reported guidance, grant a license, or approve RI-002 for marketing, whether we will meet any of our clinical or regulatory milestones, whether we will develop any new products or expand existing ones, whether we will receive FDA approval of our new facility, 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 to 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



Source: ADMA Biologics, Inc.