



ADMA Biologics Commences Pivotal Phase III Clinical Study of RI-002 in PIDD Patients

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HACKENSACK, N.J.--(BUSINESS WIRE)--ADMA Biologics, Inc. (ADMA), a specialty immune globulin company that develops, manufactures and intends to market plasma-based biologics for the treatment and prevention of certain infectious diseases, announced that the first patient enrolled in the pivotal Phase III clinical study of its RI-002 has been dosed. This study is designed to evaluate the efficacy and safety of RI-002 as a novel immune globulin for the treatment of patients who suffer from Primary Immune Deficiency Diseases (PIDD).

The trial is being conducted in accordance with the U.S. Food and Drug Administration (FDA) published guidance for the industry (June 2008) and intends to evaluate RI-002 in an aggregate of between 60 and 70 patients diagnosed with PIDD, for a 12-month treatment period followed by up to 90 days of safety monitoring and follow-up. ADMA anticipates enrolling patients at investigative centers across the United States.

"We are excited to be working with leaders in the PIDD community to evaluate the safety and efficacy of RI-002," said Adam S. Grossman, President and Chief Executive Officer of ADMA. "RI-002 will offer PIDD patients additional treatment options, while providing clinicians who see all types of immune deficient patients with greater flexibility."

"It is encouraging to see a company like ADMA Biologics championing a specialty immune globulin product for the PIDD patient community. Having access to a specialty, high titer immune globulin product such as RI-002, indicated for use in the PIDD population would be a welcome addition to currently available therapies," said Dr. Richard L. Wasserman, Clinical Professor of Pediatrics, University of Texas Southwestern Medical School and Lead Principal Investigator of ADMA's Phase III trial.

Further information about ADMA Biologics can be found by visiting the Securities and Exchange Commission website www.sec.gov and can also be viewed on the company's website at: www.admabiologics.com.

About ADMA's lead product candidate RI-002

ADMA's lead product candidate, RI-002 is a specialty plasma-derived, polyclonal, Intravenous Immune Globulin, or IGIV, derived from human plasma containing naturally occurring polyclonal antibodies (eg. streptococcus pneumoniae, H. influenza type B, CMV, measles, tetanus etc.) as well as high levels of antibodies targeted to respiratory syncytial virus, or RSV. ADMA is pursuing an indication for the use of this specialty IGIV product for treatment of patients diagnosed with primary immune deficiency diseases, or PIDD. Polyclonal antibodies are the primary component of IGIV products. Polyclonal antibodies are proteins produced by B-cells that are used by the body's immune system to neutralize microbes such as bacteria and viruses. The polyclonal antibodies that are present in RI-002 are expected to prevent infections in immune-compromised patients.

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.

About ADMA Biologics, Inc.

ADMA is a specialty immune globulin company that develops, manufactures and intends to market plasma-based biologics for the treatment and prevention of 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 also operates ADMA Bio Centers, which is an FDA-licensed source plasma collection facility located in Norcross, Georgia, which provides us with a portion of our blood plasma for the manufacture of RI-002. www.admabiologics.com

Cautionary Statement Regarding Forward-Looking Information

This press release contains "forward looking statements." 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," "anticipate," "plan," "planning," "expect," "believe," "will," "will 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 the timing, progress and results of the clinical development, regulatory processes, potential clinical trial initiations, potential investigational new product applications, biologics license applications, and commercialization efforts of the Company's product candidate(s). Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements, including, but not limited to, the risks listed under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2012. 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.

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