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ADMA Biologics Announces Positive Top-Line Phase III Data for Primary Immune Deficiency Disease (PIDD) Patients

RI-002 Phase III Study Achieves Primary Endpoint

RAMSEY, N.J., Dec. 3, 2014 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (Nasdaq:ADMA), a late-stage biopharmaceutical company that develops, manufactures, and intends to market specialty plasma-based biologics for the treatment and prevention of certain infectious diseases, today announced its lead product candidate RI-002 has demonstrated positive Phase III results and successfully achieved its primary endpoint.

"This is a tremendous milestone for our Company and for immune compromised patients," stated Adam Grossman, President & CEO of ADMA Biologics. Mr. Grossman continued, "We are proud and encouraged that based upon the initial review, RI-002 has met its primary endpoint of preventing serious bacterial infections such as bacterial pneumonia, osteomyelitis and bacterial sepsis in immune compromised PIDD patients."

The Phase III US based clinical study enrolled 59 patients with diagnosed primary immune deficiency disease (PIDD) who received the investigational product, RI-002 for 12 months.

While final data from the study will be reported during the first quarter of 2015, preliminary analysis indicates that treatment with RI-002 resulted in no serious bacterial infections (SBI) observed in study subjects during the trial. This is well under the Food and Drug Administration (FDA) requirement of ≤1 SBI per patient-year and therefore the trial successfully achieved its primary endpoint.

Secondary endpoints include incidence of all infections (serious & non-serious), lost days of work or school, hospitalizations, emergency room visits and antibiotic use among others. Data on these secondary endpoints is expected to be provided during the first quarter of 2015.

"ADMA Biologics IVIG (RI-002) is formulated to meet FDA requirements. It is noteworthy that the Company will, in addition, ensure that each lot of ADMA Biologics IVIG (RI-002) contains standardized, high-levels of neutralizing antibodies to RSV," stated Richard Wasserman, MD, Clinical Professor of Pediatrics, University of Texas Southwestern Medical School, Director of Pediatric Allergy and Immunology, Medical City Children's Hospital and one of the lead investigators for the ADMA-003 Phase III clinical trial evaluating RI-002.

Dr. Wasserman continued, "The preliminary data analysis demonstrated that the trial met its primary endpoint and there were no reported acute serious bacterial infections during the 59 patient-years of primary immunodeficiency patient treatments during this study. This IVIG product will be a very welcome addition for a segment of the primary immunodeficiency population because of its unique antibody profile."

Dr. Jordan Orange, Chief of Immunology, Allergy, and Rheumatology, Professor of Pediatrics at Baylor College of Medicine, and the Director of the Center for Human Immunobiology at Texas Children's Hospital stated, "It is encouraging to see that ADMA Biologics is moving the peg for immune globulin research and advancing our understanding of polyclonal antibodies and IVIG products for the PIDD population. As a member of ADMA Biologics' Scientific Advisory Board, I look forward to examining future results from the various secondary endpoints."

Dr. James Mond, Chief Medical & Scientific Officer for ADMA Biologics stated, "Over 750 infusions of RI-002 into 59 patients were well tolerated with no reported serious adverse events attributable by investigators to the study drug. The safety profile of RI-002 is similar to that of other immune globulin products and is well characterized in this study. We are grateful to all the investigators and patients for their time, effort and collaboration with our clinical trial. We believe that this positive data will enable ADMA to file for FDA BLA approval for RI-002 as a treatment for patients with Primary Humoral Immune Deficiency."

In this Phase III trial, measurements of key secondary endpoints including trough levels of IgG were made. The pharmacokinetic profile of total IgG was measured and met required criteria. This pharmacokinetic component of Study ADMA-003 was consistent with the requirements for the pharmacokinetic characterization of IVIG as specified in FDA's 2008 Guidance for Industry: Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency. The Company plans to report on additional secondary endpoints when the data is available.

ADMA is currently assembling its BLA for planned submission to FDA during the first half of 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 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. For more information, please visit 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 (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 IGIV product for treatment of patients diagnosed with primary immune deficiency diseases, or 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. Preliminary review indicate that the polyclonal antibodies that are present in RI-002 support the ability of this product to prevent infections in immune-compromised patients. Preliminary analysis demonstrated that the Phase III trial has met the primary endpoint with no serious bacterial infections (SBI) reported. These results are well below the requirement specified by FDA guidance of ≤ 1 SBI per patient-year.

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," "target," "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 timing of availability of final data, possible characteristics of RI-002, acceptability of RI-002 for any purpose, results relating to secondary endpoints, final data relating to RI-002, likelihood and timing of FDA action with respect to any further filings by the Company, results of the clinical development, the availability of data, the reporting of data, 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, the risks listed under the heading "Risk Factors" in our Annual Report on Form 10-K for the

year ended December 31, 2013, as filed with the U.S. Securities and Exchange Commission on March 28, 2014 and our other filings with the U.S. Securities and Exchange Commission including, among other things, risks as to whether any final or secondary data will, if and when available, be 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, permit us to submit a BLA, grant a license, or approve RI-002 for marketing, whether we will meet any of our clinical or regulatory milestones, develop any new products or expand existing ones, receive FDA approval of our new facility, changes in regional and worldwide supply and demand for source plasma, whether we will be able to attract sufficient donors and operate the 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 and whether we will meet any timing targets expressed by the Company. 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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Source: ADMA Biologics, Inc.