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ADMA Biologics Announces Positive Data on Primary and Secondary Endpoints from its Pivotal Phase III Clinical Trial for RI-002 at the AAAAI Medical Conference

RAMSEY, N.J., Feb. 23, 2015 (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, announced positive results on the primary and secondary endpoint evaluations from its pivotal Phase III trial for RI-002 in Primary Immune Deficiency Disease (PIDD) in a poster presentation yesterday at the American Academy of Allergy, Asthma and Immunology Annual Meeting (http://annualmeeting.aaaai.org). In December 2014, the company announced that the trial met its primary endpoint with zero serious bacterial infections (SBI).

In this multi-site study of 59 patients diagnosed with PIDD, investigators reported on the secondary endpoints that included: a total of 93 days, or 1.66 days per patient per year lost from work or school due to infection; one hospitalization due to an infection of only five days duration in the entire study and IgG trough levels above those required by the FDA for IVIG products. Additionally, there was a marked increase in all of the measured specific anti-pathogen antibodies in PK subjects (n=31), with the greatest increase, 5.3 fold, seen in the level of neutralizing antibody titers to RSV. The safety profile of RI-002 was comparable to that of other immunoglobulins. These encouraging secondary end point results follow the prior announcement that the trial achieved its primary endpoint with zero reported acute serious bacterial infections (SBI) in the course of the trial.

"The secondary endpoint analyses in this Phase III pivotal trial suggests that RI-002 is safe and effective and will be an important new addition for the treatment of PIDD patients," 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.

"In addition to meeting the primary endpoint, this pivotal trial achieved secondary endpoints that compare favorably to historical clinical trial results of other comparably run IVIG trials," stated James Mond, MD-Ph.D, ADMA Biologics Chief Medical and Scientific Officer. "These Phase III results suggest that RI-002 and its unique antibody profile containing standardized high-levels of anti-RSV neutralizing antibodies may demonstrate an improvement in certain clinical outcomes. We believe that the data from the primary and secondary outcomes analyses will enable ADMA to differentiate RI-002 from other IVIG products and offer clinicians and patients a promising alternative to current therapies for the immune deficient population."

"RI-002 will be a welcome addition to the current armamentarium of IVIG products," said Jordan Orange, MD, 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. "The recently completed clinical trial for RI-002 suggests that its unique antibody profile may provide certain improved outcomes for a subset of the Primary Immunodeficiency patient population."

"The results of the pre-specified and ad-hoc secondary endpoint analyses reflect the safety and clinical efficacy of RI-002, which we believe will be meaningful to patients, physicians, and payers. We are very pleased with these outcomes," stated Adam Grossman, President and CEO of ADMA Biologics. Mr. Grossman continued, "In meeting our primary endpoint of preventing acute serious bacterial infections like bacterial pneumonia in this pivotal Phase III trial and with the positive data obtained from the secondary endpoint analyses, we have determined that RI-002 has demonstrated appropriate safety and efficacy in patients diagnosed with PIDD to warrant applying for FDA BLA approval."

Key trial data points:

- Number of study subjects enrolled in the trial | n=59
- Number of study subjects completing all scheduled infusions | n=54
- mITT Patient years for evaluation | 55.9 years
- Total number of RI-002 infusions | 793

Number of days lost from work/school/day care due to infection:

A total of 93 days of work/school/daycare were lost due to infection
1.66 days lost per patient/year due to infection

Incidence of all infections:

Primary endpoint – Zero (0) Serious Bacterial Infections (SBI) – 0.00 SBI per patient/year
Other infections – 3.44 infections per patient/year

Number of unscheduled visits to the physician or ER:

A total of 54 unscheduled visits were reported
0.967 visits per patient/year

Time to resolution of an infection:

The median time (days) to resolution of an infection was 9 days

Number of hospitalizations and days of hospitalization due to infection:

Total number of hospitalizations due to infection was 1; total duration was 5 days
An average of 0.0179 hospitalization days due to infection per patient/year

Number of days of antibiotic therapy for treatment of infection:

1839 days (9% of total study days)
Average was 32.9 days on antibiotics per patient/year

Relationship of trough levels of RI-002 and incidence of serious and non serious infections:

No linear correlation was seen between trough IgG at each infusion and the following parameters from each infusion cycle

1. Number of infections of any kind/seriousness
2. Number of days lost due to infections
3. Number of days on antibiotic therapy

Fold increase of specific antibodies levels:

Specific antibody levels were measured for H. influenza, CMV, measles, S. pneumonia (12 serotypes), RSV and tetanus. The mean of maximum fold increases in specific antibody levels after infusion of RI-002 ranged from 1.9 fold (S. pneumonia type 19A) to 5.3 fold (RSV), which were statistically significant fold increases from the pathogen's specific measured baselines. Further details about the specific antibodies will be presented at various medical conferences throughout this year**.**

The Phase III trial was designed in accordance with the FDA Guidance for industry Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency. This guidance does not require the use of a comparator arm for means of obtaining primary and secondary data outcomes. The average doses of RI-002 in the 3 and 4 weeks groups were 527.3mg/kg and 491.1mg/kg respectively. These doses are on the lower-range for patients with PIDD when compared to other published IVIG trials.

RI-002 was generally well tolerated during the study, 21 (35.6%) subjects had at least 1 study drug related event within 72 hours after completion of infusion. There were only 4

symptoms judged related to the study drug within this period which were reported by 3 or more (>5%) of the subjects. The four symptoms reported as drug related events (number of subjects) included headache (8), myalgia (3), pruritus (3) and adverse drug reaction (3) (without further specification).

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. Data review indicates that the polyclonal antibodies that are present in RI-002 support the ability of this product to prevent infections in immune-compromised patients. ADMA's analysis demonstrated that the Phase III trial has met the primary endpoint with no serious bacterial infections (SBI) reported. These results are below the requirement specified by FDA guidance of ≤ 1 SBI per patient-year.

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.

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 interpretations of final data, possible characteristics of RI-002, acceptability of RI-002 for any purpose by physicians patients or payers, timing and ability of a filing with the FDA of a BLA, 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, 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, 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 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, 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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