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# ADMA Biologics Receives Patent Issuance Pertaining to the Treatment of Immunodeficiency

## Patent Coverage for RI-002 Immune Globulin (IG) in Immune Compromised PIDD Patients

RAMSEY, N.J., Aug. 31, 2015 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (Nasdaq:ADMA), a late-stage biopharmaceutical company, announced that the U.S. Patent and Trademark Office (USPTO) has issued United States Patent 9,107,906. The patent titled, '*Compositions And Methods For The Treatment of Immunodeficiency*' relates to the use of human plasma immunoglobulin compositions containing select antibody titers specific for a plurality of respiratory pathogens; methods of identifying human donors and donor samples for use in the compositions; methods of manufacturing the compositions; and methods of utilizing the compositions by prophylactic and or therapeutic treatments (e.g. passive immunization). The term of the newly issued patent extends to January 2035.

"The issuance of ADMA's patent validates the differentiated, unique and novel way ADMA approaches immune globulin products. ADMA's goal is to ensure adherence to all FDA standards and produce an IG product with consistent lot to lot potency of polyclonal anti pathogen antibodies," stated Adam Grossman, President and CEO of ADMA Biologics. "This is a major milestone for our company as it provides us the ability to protect our lead product candidate and at the same time supports development of a wide range of other therapeutic IG products for patients with immunodeficiency and related diseases. The company will continue to aggressively pursue additional proprietary rights encompassing this technology."

**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 primary immune deficiency 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 its Phase III clinical trial and has met the primary endpoint. The company has received U.S. Patent 9,107,906. For more information, please visit the Company's website at [www.admabiologics.com](http://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 more than meet the requirement specified by the U.S. Food and Drug Administration, or FDA, guidance of  $\leq 1$  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.

## **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 Patent 9,107,906; the potential value to ADMA of such patent and its effect on ADMA's competitive position, interpretations of final data, possible characteristics of RI-002, acceptability of RI-002 for any purpose by physicians, patients or payers, the timeframe within which we may receive approval from the FDA, if at all, of our Biologics License Application, or 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, the success of commercialization efforts of the Company's product candidate(s) and its ability to produce consistent lot to lot potency 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 to Patent Application 9,107,906; whether such issued patent will adequately protect ADMA's drug product candidate against competition; whether the patent if issued will not be successfully challenged by competitors; 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, 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.*

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