



ADMA Biologics Announces Data Presented at IDWeek 2019

October 7, 2019 11:08 AM EDT

RAMSEY, N.J. and BOCA RATON, Fla., Oct. 07, 2019 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (NASDAQ: ADMA) ("ADMA" or the "Company"), a vertically integrated commercial biopharmaceutical and specialty immunoglobulin company that manufactures, markets and develops specialty plasma-derived biologics for the treatment of immune deficiencies and the prevention of certain infectious diseases, announces that a poster presentation was given at IDWeek 2019, the combined annual meeting of IDSA, SHEA, HVMA and PIDS in Washington, D.C. The poster detailed data obtained from the compassionate use of ASCENIV™ (formerly referred to as RI-002) in the treatment of Respiratory Syncytial Virus ("RSV") infection in two immunocompromised children.

The two immunocompromised children admitted to the Mayo Clinic each were diagnosed with T-cell lymphoblastic lymphoma. Both patients were undergoing delayed intensification chemotherapy and each were diagnosed with RSV Lower Respiratory Tract Infection ("LRTI"). Both children were treated with ASCENIV™ under an emergency United States Food and Drug Administration ("FDA") Investigational New Drug protocol.

The treatment and results of patient one are as follows - Patient was admitted with fever, neutropenia, nasal congestion and diagnosed with RSV infection on hospital day five. On hospital day 17, the patient was intubated for respiratory failure. Intravenous Immune Globulin ("IVIG") and palivizumab, and daily oral ribavirin were administered. On hospital day eighteen, the patient required high frequency oscillator ventilation, nitric oxide and paralysis. The patient was then administered ASCENIV™ 1.5g/kg on hospital day twenty and 0.75g/kg on hospital day twenty-two. The patient was placed on veno-venous Extracorporeal Membrane Oxygenation ("ECMO") on hospital day twenty-three. On hospital day thirty-three, a third dose of ASCENIV™ was given at 0.75 g/kg. The patient's pulmonary compliance and chest CTs improved. On day fifty-two, ECMO support was discontinued and the patient was discharged from the hospital on hospital day eighty-eight, and currently requires no respiratory support.

The treatment and results of patient two are as follows - Patient was admitted with fever, neutropenia, nasal congestion, cough and stridor and diagnosed with RSV infection on hospital day one. The patient required nasal cannula oxygen. IVIG and daily oral ribavirin were administered. The patient was administered ASCENIV™ 1.5g/kg on hospital day three and 0.75g/kg on hospital day five. By hospital day five, the patient was afebrile; oxygen was discontinued and the patient was discharged from the hospital on hospital day six.

The data in the poster and abstract concludes that the evaluated product may be useful in the treatment of severe RSV infections and may assist in prevention of progression of RSV lower respiratory tract infection. The data also confirms that further evaluation of ASCENIV™ in this patient population is warranted.

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is a vertically integrated commercial biopharmaceutical company that manufactures and markets three United States Food and Drug Administration ("FDA") approved plasma-derived biologics for the treatment of immune deficiencies and the prevention of certain infectious diseases. ADMA's mission is to manufacture, market and develop plasma-derived, human immune globulins targeted to niche patient populations for the treatment and prevention of certain infectious diseases and management of immune compromised patient populations who suffer from an underlying immune deficiency disease, or who may be immune compromised for other medical reasons. ADMA has received U.S. Patents 9,107,906, 9,714,283, 9,815,886, 9,969,793 and 10,259,865 related to certain aspects of its products and product candidates. For more information, please visit www.admabiologics.com.

About ASCENIV™ (Formerly referred to as RI-002)

ASCENIV™, Immune Globulin Intravenous, Human – slra 10% Liquid, is a plasma-derived, polyclonal, intravenous immune globulin ("IVIG"). ASCENIV™ is protected by U.S. Patents: 9,107,906, 9,714,283 and 9,815,886. ASCENIV™ is manufactured using our unique, patented plasma donor screening methodology and tailored plasma pooling design, which blends normal source plasma and plasma from donors tested using our proprietary microneutralization assay. ASCENIV™ contains naturally occurring polyclonal antibodies. ASCENIV™ is indicated for the treatment of Primary Humoral Immunodeficiency or Primary Immune Deficiency Disease ("PI") in adults and adolescents (12 to 17 years of age). ADMA received FDA approval for ASCENIV™ on April 1, 2019. Polyclonal antibodies are proteins that are used by the body's immune system to neutralize microbes, such as bacteria and viruses and prevent against infection and disease. ASCENIV™ prevented serious bacterial infection among 59 patients treated for twelve months during the pivotal investigation. The most common adverse reactions to ASCENIV™ (>5% of study subjects) were headache, sinusitis, diarrhea, gastroenteritis viral, nasopharyngitis, upper respiratory tract infection, bronchitis, and nausea. ADMA anticipates the commercial launch of ASCENIV™ during the fourth quarter of 2019. Certain data and other information about ASCENIV™ or ADMA Biologics and its products can be found on the Company's website at: www.admabiologics.com.

Additional Important Safety Information about ASCENIV™

ASCENIV™ (immune globulin intravenous, human – slra) is a 10% immune globulin liquid for intravenous injection, indicated for the treatment of primary humoral immunodeficiency (PI) in adults and adolescents (12 to 17 years of age). PI includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies (SCID).

WARNING: THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE

Thrombosis may occur with immune globulin (IGIV) products, including ASCENIV™. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.

Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with the administration of IGIV products in predisposed patients.

Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. ASCENIV™ does not contain sucrose.

For patients at risk of thrombosis, renal dysfunction or renal failure, administer ASCENIV™ at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

ASCENIV™ is contraindicated in:

- Patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin.
- IgA-deficiency patients with antibodies to IgA and a history of hypersensitivity.

Warnings and Precautions

Severe hypersensitivity reactions may occur with IGIV products, including ASCENIV™. In case of hypersensitivity, discontinue ASCENIV™ infusion immediately and institute appropriate treatment. Medications such as epinephrine should be available for treatment of acute hypersensitivity reactions.

Thrombosis may occur following treatment with immunoglobulin products, including ASCENIV™. Thrombosis may occur in the absence of known risk factors.

Acute renal dysfunction/failure, osmotic nephrosis, and death may occur upon use of human IGIV products. Ensure that patients are not volume depleted before administering ASCENIV™. Periodic monitoring of renal function and urine output is particularly important in patients judged to be at increased risk of developing acute renal failure.

Hyperproteinemia, increased serum viscosity, and hyponatremia may occur in patients receiving IGIV treatment, including ASCENIV™.

Aseptic meningitis syndrome (AMS) may occur with IGIV treatments, including ASCENIV™. AMS may occur more frequently in association with high doses (2 g/kg) and/or rapid infusion of IGIV.

IGIV products, including ASCENIV™, may contain blood group antibodies that can act as hemolysins and induce in vivo coating of red blood cells (RBCs) with immunoglobulin, causing a positive direct antiglobulin reaction and hemolysis.

Monitor patients for pulmonary adverse reactions. If TRALI is suspected, perform appropriate tests for the presence of anti-neutrophil antibodies in both the product and the patient's serum.

Because ASCENIV™ is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Periodic monitoring of renal function and urine output is particularly important in patients at increased risk of developing acute renal failure. Assess renal function, including measurement of blood urea nitrogen (BUN) and serum creatinine, before the initial infusion of ASCENIV™ and at appropriate intervals thereafter.

After infusion of immunoglobulin, the transitory rise of the various passively transferred antibodies in the patient's blood may yield positive serological testing results, with the potential for misleading interpretation. Passive transmission of antibodies to erythrocyte antigens (e.g., A, B, and D) may cause a positive direct or indirect antiglobulin (Coombs') test.

Adverse Reactions

The most common adverse reactions to ASCENIV™ (≥5% of study subjects) were headache, sinusitis, diarrhea, gastroenteritis viral, nasopharyngitis, upper respiratory tract infection, bronchitis, and nausea.

You are encouraged to report side effects of prescription drugs to ADMA Biologics @ 1-800-458-4244 or the FDA. Visit www.fda.gov/MedWatch or call 1-800-FDA-1088.

Cautionary Note Regarding 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, about ADMA Biologics, Inc. ("we", "our" or the "Company"). Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance or achievements, and may contain such words as "estimate," "project," "intend," "plan," "planning," "expect," "believe," "will," "is likely," "will likely," "should," "could," "would," "may," or, in each case, their negative, or words or expressions of similar meaning. These forward-looking statements also include, but are not limited to, statements concerning our ability to operate in accordance with FDA quality and compliance, regulations and expectations; our ability to successfully pursue commercialization and prelaunch activities for our products; and the potential of our specialty plasma-based biologics products and product candidates to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease or other indications. Actual events or results may differ materially from those described in this document due to a number of important factors. 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. Forward-looking statements are subject to many risks, uncertainties and other factors 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 and uncertainties described in our filings with the U.S. Securities and Exchange Commission, including our most recent reports on Form 10-K, 10-Q and 8-K, and any amendments thereto.

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Source: ADMA Biologics, Inc.