



ADMA Biologics Announces Data Presented at the 2021 ISIRV-WHO Conference

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RAMSEY, N.J. and BOCA RATON, Fla., Oct. 22, 2021 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (Nasdaq: ADMA) ("ADMA" or the "Company"), an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics, today announced that a poster presentation was made at the virtual 2021 International Society for Influenza and other Respiratory Virus Diseases - World Health Organization (ISIRV-WHO) Conference. The abstract and poster presentation detailed the use of ASCENIV™, a novel intravenous immune globulin (IGIV) human-slra, as concomitant therapy in a 70-year-old African American male with a history of bronchiectasis who presented with severe respiratory viral disease and confirmed COVID-19 infection.

In the abstract and poster presentation, ADMA described the use of ASCENIV as concomitant therapy in an adult hospitalized with COVID-19 infection and rapidly progressive acute respiratory distress syndrome (ARDS). A 70-year-old African American male with history of bronchiectasis presented to the emergency department with a one-week history of increasing dyspnea, dry cough, sudden onset of high-grade fevers, and body chills. The patient was initiated on broad-spectrum anti-infectives and steroids. Initial blood chemistries were unremarkable, pan cultures were negative but a COVID-19 diagnostic was confirmed positive. The patient's respiratory status deteriorated over the next week with continued progression of pneumonia requiring mechanical ventilation. On Day 11, the patient was initiated on ASCENIV at 1500 mg/kg. In the days following, the patient developed high-grade fevers, prompting modification of anti-infectives and a second dose of ASCENIV at 750 mg/kg. Over the next several days, respiratory function improved, prompting extubation, but complications with a bout of severe tachypnea and declined respiratory function led to temporary re-intubation. With continued clinical management, the patient's respiratory status steadily improved, warranting extubation and transition to rehabilitation with a confirmed negative COVID-19 test result, no documented co-infections, reduced inflammatory markers, and recovery of lung function.

This case documents the clinical outcome of a multi-modality therapeutic approach with broad-spectrum anti-infectives and concomitant ASCENIV (IVIG human-slra) utilization for the management of severe respiratory infection. Further investigation is warranted to evaluate the use of ASCENIV as adjunctive therapy in vulnerable and immune compromised patients with severe respiratory disease.

Abstract Title: *Clinical Impact of Concomitant Use of a Novel High-Titer Immune Globulin in an Adult with COVID-19 and Severe Acute Respiratory Distress Syndrome (ARDS)*

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About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics for the treatment of immunodeficient patients at risk for infection and others at risk for certain infectious diseases. ADMA currently 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: ASCENIV™ (immune globulin intravenous, human – slra 10% liquid) for the treatment of primary humoral immunodeficiency (PI); BIVIGAM® (immune globulin intravenous, human) for the treatment of PI; and NABI-HB® (hepatitis B immune globulin, human) to provide enhanced immunity against the hepatitis B virus. ADMA manufactures its immune globulin products at its FDA-licensed plasma fractionation and purification facility located in Boca Raton, Florida. Through its ADMA BioCenters subsidiary, ADMA also operates as an FDA-approved source plasma collector in the U.S., which provides a portion of its blood plasma for the manufacture of its products. ADMA's mission is to manufacture, market and develop specialty 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, 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™

ASCENIV (immune globulin intravenous, human – slra 10% liquid) is a plasma-derived, polyclonal, intravenous IVIG. ASCENIV was approved by the United States Food and Drug Administration (FDA) in April 2019 and is indicated for the treatment of primary humoral immunodeficiency (PI), also known as primary immune deficiency disease (PIDD), in adults and adolescents (12 to 17 years of age). ASCENIV is manufactured using ADMA's unique, patented plasma donor screening methodology and tailored plasma pooling design, which blends normal source plasma and respiratory syncytial virus (RSV) plasma obtained from donors tested using the Company's proprietary microneutralization assay. ASCENIV contains naturally occurring polyclonal antibodies, which 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 is protected by U.S. Patents: 9,107,906, 9,714,283 and 9,815,886. Certain data and other information about ASCENIV can be found by visiting www.asceniv.com. Information about ADMA 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.

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Source: ADMA Biologics, Inc.