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# ADMA Biologics Announces the Presentation of Real-World Experience in the Management of Respiratory Syncytial Virus (RSV) Presented at IDWeek 2021

RAMSEY, N.J. and BOCA RATON, Fla., Oct. 04, 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 on-demand access to an exclusive educational event at IDWeek 2021 on respiratory viral infections, presented by nationally recognized clinical experts Dr. Michael Ison from Northwestern University and Dr. Jolan Walter from the University of South Florida and Johns Hopkins All Children’s Hospital. During the live presentation and question and answer session, Dr. Walter discussed real-world experiences in patients that were successfully treated with ADMA’s ASCENIV™, a novel intravenous immunoglobulin (IVIG) product with a unique composition. The two cases presented detailed scenarios in which ASCENIV administration demonstrated notable benefits in the clinical course of two children diagnosed with primary immunodeficiency (PI) and documented RSV infection.

**Educational Event Presentation Title:** *Key Insights on RSV and Other Respiratory Viruses Beyond COVID-19 in the Immunocompromised: An Expert Discussion*

- **Michael G. Ison, MD, MS**, Professor of Medicine (Infectious Diseases) and Surgery (Organ Transplantation) at the Feinberg School of Medicine at Northwestern University, discussed respiratory viruses in the immunocompromised, its clinical impact and management strategies.
- **Jolan Walter, MD, PhD**, Division Chief of the University of South Florida (USF) and Johns Hopkins All Children’s Pediatric Allergy & Immunology Programs, discussed management modalities and introduced ASCENIV, a novel IVIG, and presented two challenging patient cases:
  - ASCENIV use in a 15-month-old immunocompromised male with chronic RSV bronchiolitis
  - ASCENIV use in a 12-month-old immunocompromised male with severe RSV bronchiolitis

**To view the on-demand presentation please visit the IDWeek 2021 conference website.**

## **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 (PID), 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](http://www.asceniv.com). Information about ADMA Biologics and its products can be found on the Company's website at [www.admabiologics.com](http://www.admabiologics.com).

### **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](http://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](http://www.fda.gov/MedWatch) or call 1-800-FDA-1088.**

### **COMPANY CONTACT:**

Skyler Bloom

Director, Investor Relations and Corporate Strategy | 201-478-5552 | [sbloom@admabio.com](mailto:sbloom@admabio.com)

### **INVESTOR RELATIONS CONTACT:**

Michelle Pappanastos

Senior Managing Director, Argot Partners | 212-600-1902 | [michelle@argotpartners.com](mailto:michelle@argotpartners.com)



Source: ADMA Biologics, Inc.