



ADMA Biologics Announces FDA Approval to Expand the Label for ASCENIV™ to Include Pediatric Immune Compromised Patients Two Years of Age and Older

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RAMSEY, N.J. and BOCA RATON, Fla., May 04, 2026 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (Nasdaq: ADMA) ("ADMA" or the "Company"), a U.S. based, end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty biologics, today announced the U.S. Food and Drug Administration ("FDA") has approved the Company's supplemental Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for ASCENIV™. The FDA approval represents the final study report for the Pediatric assessment as required in the post marketing commitment.

Additionally, the approval provides for a revision of ASCENIV's prescribing information to expand the primary humoral immunodeficiency ("PI") indication to pediatric patients two years of age and older. Previously, the indication for ASCENIV was restricted to PI patients aged 12 years and older.

"This expanded label for ASCENIV allows ADMA to actively address the treatment needs of younger PI and immune compromised patients earlier in their treatment journey," said Adam Grossman, President and Chief Executive Officer of ADMA. "In the periods ahead, we look forward to continuing to expand the utilization of ASCENIV by offering our differentiated and patented immune globulin as an FDA-approved treatment option for immune compromised pediatric patients in need."

"We proudly recognize the extraordinary collaboration of the PI disease community and dedicated physicians, along with the courage and commitment of the children and families whose participation was essential in driving this clinical program forward," said Kaitlin Kestenberg, Chief Operating Officer and Senior VP of Compliance. "Enrolling in and successfully completing these complex trials is a significant achievement, and this FDA approval reflects the strength of the clinical and operational execution of the devoted ADMA team."

About ASCENIV™

ASCENIV (immune globulin intravenous, human – slra 10% liquid) is a plasma-derived, polyclonal, intravenous immune globulin (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 pediatric patients 2 years of age and older. 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 that safeguard against infection and disease. ASCENIV is protected by numerous issued patents in the United States and internationally and a wide range of patent applications worldwide. 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™

WARNING: THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE

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

Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with the administration of IGIV products in predisposed patients. **Such events require immediate medical intervention, if not recognized or managed appropriately, may result in persistent or significant disability or lead to fatal outcome.**

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™ Contraindications:

History of anaphylactic or severe systemic reactions to human immunoglobulin.

IgA deficient patients with antibodies to IgA and a history of hypersensitivity.

ASCENIV™ Warnings and Precautions:

IgA-deficient patients with antibodies against IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions. Have medications such as epinephrine available to treat any acute severe hypersensitivity reactions. [4, 5.1]

Thrombotic events have occurred in patients receiving IGIV treatments. Monitor patients with known risk factors for thrombotic events; consider baseline assessment of blood viscosity for patients at risk of hyperviscosity. [5.2, 5.4]

In patients at risk of developing acute renal failure, monitor renal function, including blood urea nitrogen (BUN), serum creatinine, and urine output. [5.3, 5.9]

Hyperproteinemia, increased serum viscosity, and hyponatremia or pseudo hyponatremia can occur in patients receiving IGIV treatment.

Aseptic meningitis syndrome (AMS) has been reported with IGIV treatments, especially with high doses or rapid infusion. [5.5]

Hemolytic anemia can develop subsequent to IGIV treatment. Monitor patients for hemolysis and hemolytic anemia. [5.6]

Monitor patients for pulmonary adverse reactions (Transfusion-related acute lung injury [TRALI]). If transfusion related acute lung injury is suspected, test the product and patient for antineutrophil antibodies. [5.7]

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

ASCENIV™ 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.

To report SUSPECTED ADVERSE REACTIONS, contact ADMA Biologics at (800) 458-4244 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is a U.S.-based, end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty 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 – sIra 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. Additionally, ADMA is developing SG-001, a pre-clinical, investigative hyperimmune globulin targeting *S. pneumonia*. ADMA manufactures its immune globulin products and product candidates 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 its blood plasma for the manufacture of its products and product candidates. 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 holds numerous U.S. and foreign patents related to and encompassing various aspects of its products and product candidates. For more information, please visit www.admabiologics.com.

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