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ADMA Biologics Announces First Commercial Sales of ASCENIV™

RAMSEY, N.J. and BOCA RATON, Fla., Oct. 21, 2019 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (NASDAQ: ADMA) (“ADMA” or the “Company”), a commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics for the treatment of immunodeficient patients at risk for infection and the prevention of certain infectious diseases, today announced the first commercial sales of ASCENIV (formerly known as RI-002). ASCENIV received approval from the U.S. Food and Drug Administration (“FDA”) on April 1, 2019.

“The first commercial sales of ASCENIV, our third FDA-approved product, marks another major milestone in ADMA’s history,” said Adam Grossman, President and Chief Executive Officer of ADMA. “ASCENIV is a novel Intravenous Immune Globulin (“IVIG”), which 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. This proprietary biologic product is now commercially available for ordering in the U.S. and we are actively working with our distribution partner, BioCare SD, and the physician community, to drive adoption of ASCENIV for appropriate patients in the U.S. who could derive benefit.”

ASCENIV is a plasma-derived, polyclonal human immune globulin product. 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). ASCENIV is protected by U.S. Patents: 9,107,906, 9,714,283 and 9,815,886.

ASCENIV is now available and can be ordered through BioCare SD, ADMA’s authorized distributor. Prescribers and healthcare professionals interested in purchasing ASCENIV for use with their PI patients should contact BioCare SD directly at 800-304-3064 or by visiting their website at www.BioCareSD.com.

Information about ASCENIV for healthcare professionals, patients with primary immune deficiency disease and their healthcare partners can be found at: www.asceniv.com. Through the ASCENIV website, physicians can access the prescription request form and request a meeting with a sales professional. Any medical or scientific questions regarding ASCENIV, or any other products produced by ADMA, should be directed to the Medical Affairs Department at medicalaffairs@admabio.com or 800-458-4244, prompt 2.

About Primary Immune Deficiency Disease (“PI”)

PI is a class of inherited genetic disorders that causes an individual to have a deficient or absent immune system. According to the World Health Organization, there are approximately 350 different genetic mutations encompassing PI. Some disorders present at birth or in early childhood, the disorders can affect anyone regardless of age or gender.

Some affect a single part of the immune system, others may affect one or more components of the system. PI patients are vulnerable to infections and more likely to suffer complications from these infections as compared to individuals with a normal functioning immune system. The infections may occur in any part of the body. Because patients suffering from PI lack a properly functioning immune system, they typically receive monthly treatment with polyclonal immune globulin products. Without this exogenous antibody replacement, these patients would remain vulnerable to persistent and chronic infections. PI has an estimated prevalence of 1:1,200 in the United States, or approximately 250,000 people in the U.S.

About ASCENIV™ (Formerly RI-002)

ASCENIV, immune globulin intravenous, human – sIra 10% liquid, is a plasma-derived, polyclonal, intravenous immune globulin (“IVIG”). ASCENIV was approved by the FDA on April 1, 2019 and 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). ASCENIV is manufactured using ADMA’s unique, patented plasma donor screening methodology and tailored plasma pooling design, which blends normal source plasma and plasma 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 prevented serious bacterial infection among 59 patients treated for twelve months during the pivotal investigation. ASCENIV is protected by U.S. Patents: 9,107,906, 9,714,283 and 9,815,886.

Indication

ASCENIV (immune globulin intravenous, human – sIra) 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 Immune Globulin Intravenous (Human) (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.

For additional safety information about ASCENIV, please see [full Prescribing Information](#).

Contraindications

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. Patients with known antibodies to IgA may have a greater risk of developing potentially severe hypersensitivity and anaphylactic reactions.

Thrombosis may occur following treatment with immunoglobulin products and in the absence of known risk factors. Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity and ensure adequate hydration before administration. For patients at risk of thrombosis, administer ASCENIV at the minimum dose and infusion rate practicable. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

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. Assess renal function, including measurement of blood urea nitrogen (BUN) and serum creatinine, before the initial infusion of ASCENIV and at appropriate intervals thereafter. Discontinue ASCENIV if renal function deteriorates. In at risk patients, administer ASCENIV at the minimum infusion rate practicable.

Hyperproteinemia, increased serum viscosity, and hyponatremia or pseudo hyponatremia may occur in patients receiving IGIV treatment, including ASCENIV. It is critical to clinically distinguish true hyponatremia from a pseudo hyponatremia that is associated with or causally related to hyperproteinemia. Treatment aimed at decreasing serum free water in patients with pseudo hyponatremia may lead to volume depletion, a further increase in serum viscosity, and a possible predisposition to thrombotic events.

Aseptic meningitis syndrome (AMS) may occur with IGIV treatments, including ASCENIV. AMS usually begins within several hours to 2 days following IGIV treatment. AMS may occur more frequently in association with high doses (2 g/kg) and/or rapid infusion of IGIV. Conduct a thorough neurological examination on patients exhibiting signs and symptoms of AMS, including cerebrospinal fluid (CSF) studies, to rule out other causes of meningitis.

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 clinical signs and symptoms of hemolysis, including appropriate confirmatory laboratory testing.

Non-cardiogenic pulmonary edema may occur with IV administered IG. Monitor patients for pulmonary adverse reactions. If suspected, perform appropriate tests for presence of anti-neutrophil in both product and patient serum. May be managed using oxygen therapy with adequate ventilatory support.

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. All infections suspected by a physician to possibly have been transmitted by this product should be reported to ADMA Biologics at **(1-800-458-4244)**.

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 ($\geq 5\%$ 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.

About BioCare SD

Based in Phoenix, Arizona, BioCare SD has been devoted to delivering specialty and therapeutic biological products to its customers since 1982. BioCare SD is committed to being the industry's most trusted specialty distributor by providing customer-oriented solutions, unmatched service levels, and a unique distribution network to ensure the highest quality in patient care. The BioCare SD customer support team and local, field-based account management teams are available 24 hours a day, 7 days a week, 365 days a year by calling 800-304-3064. For more information, please visit www.BioCareSD.com.

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is a commercial biopharmaceutical company dedicated to manufacturing, marketing and developing plasma-derived, biologics for the treatment of immunodeficient patients at risk for infection. 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 hepatitis B. 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 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.

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," "forecast," "target," "anticipate," "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 about our ability and the ability of our distributor to provide a continuous supply of ASCENIV™ to PI patients; our ability to work with our distribution partner, BioCare SD, and the physician community, to drive adoption of ASCENIV for appropriate patients in the U.S.; our ability to operate in accordance with FDA quality and compliance, regulations and expectations; our ability to successfully pursue commercialization 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. 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. 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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