



FDA Approves ASCENIV™, a Novel Intravenous Immune Globulin

April 1, 2019 12:09 PM EDT

- Approved for Use in the Treatment of Primary Humoral Immunodeficiency Disease ("PIDD" or "PI") in Adults and Adolescents (12 to 17 Years of Age)
- FDA Approval Triggers Funding up to \$27.5M from Existing Credit Facility with Perceptive Advisors

RAMSEY, N.J. and BOCA RATON, Fla., April 01, 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 plasma-derived biologics for the treatment of immune deficiencies and the prevention of certain infectious diseases, announces that the U.S. Food and Drug Administration ("FDA") has approved ASCENIV™, Immune Globulin Intravenous, Human – slra 10% Liquid, formerly referred to as RI-002.

ASCENIV™ is an Intravenous Immune Globulin ("IVIG") drug product for the treatment of Primary Humoral Immunodeficiency Disease ("PIDD" or "PI") in adults and adolescents (12 to 17 years of age). The Company anticipates having the product available for commercial launch during the second half of 2019.

The ASCENIV™ pivotal Phase III clinical study followed FDA guidance for treatment of patients with PI. The study enrolled fifty-nine patients with PI at nine sites across the U.S. in which study patients received regular infusions of ASCENIV™ over the course of one year. The trial's primary endpoint evaluated the rate of Serious Bacterial Infections ("SBI") in patients treated with ASCENIV™. Secondary endpoints included time to first SBI and to first serious infection, days on antibiotics, days off school or work due to infections, all confirmed infections of any kind, and hospitalizations due to infection. There were zero SBIs during the 12-month study period. The manuscript and data set describing the results are published by Dr. Richard Wasserman, et al in the Journal of Clinical Immunology (2016) Volume 36: 590-599. The approved labeling will include a boxed warning about potential thrombosis and renal dysfunction or failure, as well as the most common adverse events observed in the pivotal study, which were headache, sinusitis, diarrhea, gastroenteritis viral, nasopharyngitis, upper respiratory tract infection, bronchitis, and nausea.

"We are excited about this significant achievement in receiving FDA approval for ASCENIV™ a novel, patented IVIG product that we feel is a necessary addition to existing available therapies for patients who suffer from PI. We hope availability of ASCENIV™ will help ameliorate a portion of the current shortages facing U.S. IVIG supply," stated Adam Grossman, President and CEO of ADMA Biologics. "There are approximately 250,000 PI patients diagnosed and living in the U.S., and we believe there is an opportunity to treat meaningful segments of this patient population with ASCENIV™. As previously disclosed, 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. Going forward, we believe this FDA approval better positions ADMA to further its mission to evaluate ASCENIV™ in immune-compromised patients infected with or at-risk for Respiratory Syncytial Virus ("RSV") infection. We look forward to working with the FDA and the immunology and infectious disease community on developing a clinical investigation to evaluate use of ASCENIV™ in this patient population in the near future."

Mr. Grossman continued, "We are grateful to the clinical trial subjects, investigators, and health care workers who participated in our Phase III trial and thank them for their extraordinary efforts. We are also thankful to our dedicated and loyal employees who relentlessly contributed to the approval of ASCENIV™ and exemplify our corporate mission of working tirelessly because patients are counting on us."

"With the receipt of ASCENIV's™ FDA approval, ADMA, at its sole option, can elect to access up to an additional \$27.5M of available funding from Perceptive Advisors under ADMA's existing credit facility. This option remains available to the Company through June 2020, and such funds could be used to support the launch of ASCENIV™, procure plasma raw material inventory, and begin construction on potential new plasma centers, as well as for general corporate activities," concluded Mr. Grossman.

Any medical or scientific questions regarding ASCENIV™ or any other product produced by ADMA Biologics should be directed to the Company's medical information department by calling 800-458-4244 or emailing to MA@admabio.com.

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is a vertically integrated commercial biopharmaceutical company that manufactures, markets and develops specialty plasma-based biologics for the treatment of Primary Immune Deficiency Disease ("PIDD" or "PI") and the prevention and treatment of certain infectious diseases. ADMA's mission is to develop and commercialize plasma-derived, human immune globulins targeted to niche patient populations for the treatment and prevention of certain infectious diseases. The target patient populations include immune-compromised individuals 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 and 9,969,793 related to certain aspects of its products. For more information, please visit www.admabio.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 ("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 fifty-nine 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 second half of 2019. Certain data and other information about ASCENIV™ or ADMA Biologics and its products can be found on the Company 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.

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.

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 the words "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 concerning our plans to develop, manufacture, market, launch and expand our own commercial infrastructure and commercialize our current products and future products, the safety, efficacy and expected timing of, and our ability to, obtain and maintain regulatory approvals of our current products, product expansions into new fields of use and product candidates, and the labeling or nature of any such approvals, the success of our work with our third party vendors and the U.S. Food and Drug Administration (the "FDA") in furtherance of and progress towards an approval of our Biologics License Application for specialty plasma-based biologics and the ability of such third parties to respond adequately or in a timely manner to the issues raised by the FDA, our ability to successfully pursue commercialization and prelaunch activities, the timeframe within which we may receive approval from the FDA for specialty plasma-based biologics, if at all, the potential of our specialty plasma-based biologics to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease or other indications, our ability to realize increased prices for plasma growth in the plasma collection industry and our expectations for future capital requirements. 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. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation or warranty by ADMA or any other person that the objectives and plans of ADMA will be achieved in any specified time frame, if at all. 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.

COMPANY CONTACT:

Brian Lenz

Executive Vice President and Chief Financial Officer | 201-478-5552 | www.admabiologics.com

INVESTOR RELATIONS CONTACT:

Jeremy Feffer

Managing Director, LifeSci Advisors, LLC | 212-915-2568 |



Source: ADMA Biologics, Inc.