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ASIA EDITION

FDA approves ASCENIV for the treatment of primary humoral immunodeficiency disease

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FDA approval triggers funding up to $27.5M from existing credit facility with perceptive advisors

ADMA Biologics, 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 has approved ASCENIV, Immune Globulin Intravenous, Human – slra 10% Liquid, formerly referred to as RI-002. ASCENIV is an Intravenous Immune Globulin drug product for the treatment of Primary Humoral Immunodeficiency Disease 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 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 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.

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 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.