

Asceniv[™] (immune globulin intravenous, human – slra) – New drug approval

- On April 1, 2019, <u>ADMA Biologics announced</u> the <u>FDA approval</u> of <u>Asceniv (immune globulin intravenous, human slra)</u>, 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, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
- The efficacy of Asceniv was evaluated in an open-label, single-arm study in 59 adult and pediatric
 patients with PI. Patients received an Asceniv infusion administered every 3 or 4 weeks for 12
 months. The study assessed efficacy in preventing serious bacterial infections, defined as a rate of <
 1.0 cases of bacterial pneumonia, bacteremia/septicemia, osteomyelitis/septic arthritis, visceral
 abscess, and bacterial meningitis per person-year.
 - During the 12-month study period, zero serious acute bacterial infections occurred.
- Asceniv carries a boxed warning for thrombosis, renal dysfunction, and acute renal failure.
- Asceniv is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin and IgA-deficiency patients with antibodies to IgA and a history of hypersensitivity.
- Additional warnings and precautions of Asceniv include hypersensitivity; hyperproteinemia, increased serum viscosity, and hyponatremia; aseptic meningitis syndrome; hemolysis; transfusionrelated acute lung injury; transmissible infectious agents; monitoring laboratory tests; and interference with laboratory tests.
- The most common adverse reactions (≥ 5%) with Asceniv use were headache, sinusitis, diarrhea, viral gastroenteritis, nasopharyngitis, upper respiratory tract infection, bronchitis, and nausea.
- The recommended dose of Asceniv for replacement therapy in PI is 300 to 800 mg/kg body weight
 administered intravenously every 3 to 4 weeks. The dose may be adjusted over time to achieve the
 desired trough levels and clinical response.
 - For additional dosing and administration recommendations, refer to the Asceniv drug label.
- ADMA Biologics plans to launch Asceniv during the second half of 2019. Asceniv will be available as a liquid solution containing 10% IgG (100 mg/mL) for intravenous infusion.



optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum[®] trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2019 Optum, Inc. All rights reserved.