



ADMA Biologics Announces Peer-Reviewed Publication Highlighting New Data From Its Optimized, Proprietary IVIG Manufacturing Process

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Optimized Process Demonstrated Effective Removal of Procoagulant Impurities While Maintaining Immunoglobulin Quality and Increasing IgG Yield
No Thromboembolic Events Were Reported for ADMA IVIG Products Manufactured Using the Optimized Process During the Postmarketing Surveillance Period Evaluated

RAMSEY, N.J. and BOCA RATON, Fla., Oct. 15, 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 publication of a peer-reviewed article in *Frontiers in Cardiovascular Medicine* detailing new data from the Company's optimized, proprietary intravenous immune globulin ("IVIG") manufacturing process.

The article, titled "Further Optimization of an ADMA Biologics' Proprietary Manufacturing Process to Ensure Removal of Impurities Associated With Thrombosis Risk in IVIG Products," reports the results of analytical testing performed on three commercial-scale lots of ADMA's IVIG products manufactured using its U.S. Food and Drug Administration (FDA)-licensed further optimized process.

Thromboembolic events ("TEEs") are rare but serious adverse events associated with immune globulin therapy. Patient-specific risk factors and certain product-related impurities can contribute to the potential risk of these events. ADMA further optimized its proprietary manufacturing process to enhance the removal of procoagulant and other impurities while maintaining immunoglobulin purity, quality and structural integrity.

Key findings reported in the publication include:

- All evaluated procoagulant and product-related impurities, including Factor Xla, IgA, IgM, cholesterol and prekallikrein activator, were measured at or below applicable quantification limits across the three lots tested.
- Two of the three evaluated lots had Factor Xla levels below the limit of quantification. Factor Xla has been associated with thrombotic risk in immune globulin products.
- The three lots demonstrated an average non-activated partial thromboplastin time ("NAPTT") exceeding 250 seconds, indicating very low procoagulant activity. NAPTT results greater than 200 seconds have been associated with a reduced incidence of TEEs.
- Chromatographic testing detected no immunoglobulin aggregates or fragments.
- The optimized process increased immunoglobulin yield while maintaining product quality and IgG integrity.
- ADMA's postmarketing pharmacovigilance surveillance and the FDA Adverse Event Reporting System received no reports of TEEs associated with ADMA IVIG products manufactured using the further optimized process from July 1, 2025 through July 31, 2026.

"Patients with primary humoral immunodeficiency may require lifelong immune globulin therapy, making product quality and continued manufacturing innovation critically important," said Adam Grossman, President and Chief Executive Officer of ADMA. "The findings reported in this peer-reviewed publication demonstrate the capabilities of ADMA's proprietary manufacturing platform to remove impurities associated with thrombotic risk while maintaining immunoglobulin quality and increasing IgG recovery. We believe these results further support the differentiated quality profile of our IVIG portfolio and reinforce ADMA's commitment to advancing manufacturing science for the benefit of immune-compromised patients."

"Thromboembolic events are uncommon but clinically important complications of immunoglobulin therapy, making the control of procoagulant impurities an important component of IVIG manufacturing. The very low procoagulant activity observed in this analysis, together with effective removal of Factor Xla and other impurities and the absence of reported thromboembolic events during the post-marketing observation period, provides reassuring evidence regarding the quality and safety profile of IVIG produced using ADMA's further optimized manufacturing process," said Dr. Maeve O'Connor, Chief Medical Officer, Consortium of Independent Immunology Clinics (CIIC) & CEO and Medical Director, Integrative Allergy and Immunology Care, Charlotte, NC.

The results should be considered in the context of the study's limitations, including the evaluation of three manufacturing lots and the relatively limited postmarketing surveillance period. Spontaneous adverse-event reporting systems are also subject to underreporting and cannot establish the

absence of risk or a causal relationship between a manufacturing process and clinical outcomes. Thrombosis remains a labeled risk for all IVIG products, including ASCENIV™ and BIVIGAM®.

The peer-reviewed article is available through *Frontiers in Cardiovascular Medicine* at: <https://www.frontiersin.org/journals/cardiovascular-medicine/articles/10.3389/fcvm.2026.1874074/full>.

About ASCENIV™

ASCENIV (immune globulin intravenous, human – sIra 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 (PIDD), 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.

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 pseudohyponatremia can occur in patients receiving IGIV treatment. [5.4]

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. [5.8]

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 BIVIGAM®

BIVIGAM (immune globulin intravenous, human – 10% liquid) is a plasma-derived, polyclonal, intravenous immune globulin (IVIG). BIVIGAM was approved by the FDA in May 2019 and is indicated for the treatment of primary humoral immunodeficiency (PI) in adults and pediatric patients (2 years of age and older), including, but not limited to the following group of genetic disorders: X-linked and congenital agammaglobulinemia, common variable immunodeficiency (CVID), Wiskott-Aldrich syndrome, and severe combined immunodeficiency. BIVIGAM contains a broad range of antibodies similar to those found in normal human plasma. These antibodies are directed against bacteria and viruses and help to protect PI patients against serious infections. BIVIGAM is a purified, sterile, ready-to-use preparation of concentrated human Immunoglobulin antibodies. Certain data and other information about BIVIGAM® or ADMA Biologics and its products can be found on the Company's website at www.admabiologics.com.

Important Safety Information About BIVIGAM®

WARNING: THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE

Thrombosis may occur with immune globulin intravenous (IGIV) products, including BIVIGAM. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, a 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 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. BIVIGAM does not contain sucrose.

For patients at risk of thrombosis, renal dysfunction or renal failure, administer BIVIGAM 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.

BIVIGAM® Contraindications:

History of anaphylactic or severe systemic reactions to human immunoglobulin.

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

BIVIGAM® Warnings and Precautions:

Thrombotic events have occurred in patients receiving IGIV therapy. Monitor patients with known risk factors for thrombotic events; consider baseline assessment of blood viscosity for those at risk of hyperviscosity. [5.1, 5.4]

IgA deficient patients with antibodies against IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions. Have medications such as epinephrine available immediately to treat any acute severe hypersensitivity reactions. [4, 5.2]

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

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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. [5.8]

BIVIGAM® Adverse Reactions:

The most common adverse reactions to BIVIGAM (reported in ≥5% of clinical study subjects) were headache, fatigue, infusion site reaction, nausea, sinusitis, blood pressure increased, diarrhea, dizziness, and lethargy.

To report SUSPECTED ADVERSE REACTIONS, contact ADMA Biologics at (800) 458-4244 or 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 FDA-approved plasma-derived biologics: 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 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 a portion of 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 encompassing various aspects of its products, manufacturing processes 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. ("ADMA" 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 "confident," "estimate," "project," "intend," "forecast," "target," "anticipate," "plan," "planning," "expect," "believe," "will," "is likely," "will likely," "position us," "positioned," "support," "should," "could," "would," "may," "potential," "view," "opportunity" or, in each case, their negative, or words or expressions of similar meaning. These forward-looking statements include, without limitation, statements concerning the potential implications of the published analytical and postmarketing findings; the capabilities and potential benefits of ADMA's manufacturing process; the quality and differentiation of ADMA's IVIG portfolio; and the Company's

continued manufacturing, development and commercialization activities.

Actual events or results may differ materially from those described in this press release due to a number of important factors. Current and prospective security holders are cautioned that there can be no assurance that the forward-looking statements included in this press release will prove accurate. Except as required by applicable laws or regulations, ADMA undertakes no obligation to update any forward-looking statement or announce revisions to any forward-looking statement. Forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of events to differ materially from any future results expressed or implied by the forward-looking statements, including the risks and uncertainties described in ADMA's filings with the U.S. Securities and Exchange Commission, including its most recent reports on Forms 10-K, 10-Q and 8-K and any amendments thereto.

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