January 9, 2020

ADMA Biologics Announces Preliminary Fourth Quarter and Full Year 2019 Revenues and Provides 2020 Strategic Outlook

Achieved Fourth Quarter 2019 Preliminary Unaudited Total Revenues of $11.9 Million, a 193% Increase Over Fourth Quarter 2018

Full Year 2019 Preliminary Unaudited Total Revenues of $29.2 Million, a 72% Increase Over Full Year 2018

ADMA to Host Conference Call and Webcast in the First Quarter of 2020 to Report Fourth Quarter and Full Year 2019 Financial Results

RAMSEY, N.J. and BOCA RATON, Fla., Jan. 09, 2020 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (NASDAQ: ADMA), an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics for the treatment of immunodeficient patients at risk for infection and for the prevention of certain infectious diseases, today announced its preliminary unaudited fourth quarter and full year 2019 revenues. The Company also provided updates on the commercial launches of its marketed intravenous immunoglobulin (IVIG) products, BIVIGAM® and ASCENIV™, as well as introduced its 2020 strategic outlook.

Fourth Quarter and Full Year 2019 Highlights

- Achieved fourth quarter 2019 preliminary unaudited total revenues of $11.9 million, compared to $4.1 million during the fourth quarter of 2018, reflecting a 193% increase over fourth quarter 2018
- Full year 2019 preliminary unaudited total revenues of $29.2 million, compared to $17.0 million for the full year 2018, reflecting a 72% increase over full year 2018
- Commercial launches for BIVIGAM and ASCENIV progressing in line with expectations. The Company continues to ramp commercial production of these two products and build inventory to support continued growth and market supply.

“We are extremely pleased with our preliminary fourth quarter and full year 2019 revenue results, which are primarily attributable to the commercial rollouts of BIVIGAM and ASCENIV, as well as our first sale of intermediate fractions related to our IVIG production process, and we look forward to continuing the upward production ramp throughout the coming year,” said Adam Grossman, ADMA’s President and Chief Executive Officer. “ADMA made significant progress and achieved a number of milestones over the past year and we believe we are entering 2020 well positioned to execute on several strategic priorities aimed at growing our overall revenues. These strategic priorities include expanding throughput capacity at our manufacturing facility, enhancing our control over the supply-chain for our commercial products, securing new contract manufacturing (CMO) supply agreements, and building and opening new plasma collection centers. We are actively pursuing potential new pipeline assets targeting specialty plasma products and/or hyperimmune immunoglobulin indications and compositions and we will provide further details when available.”

ADMA executed on its 2019 strategic objectives, including:

- Received FDA approval for BIVIGAM and ASCENIV
- Commenced commercial sales of both BIVIGAM and ASCENIV in the U.S.
- Transfer of BIVIGAM and NABI-HB® licenses to ADMA
- Issuance of new establishment license by the FDA for the Boca Raton, FL manufacturing facility to produce and sell U.S. FDA-approved IVIG products
- Data presented at IDWeek 2019 highlighting clinical results from the compassionate use of ASCENIV for the treatment of respiratory syncytial virus (RSV) in immunocompromised children
- Published a peer-review manuscript in the November 2019 issue of *Immunotherapy* describing the manufacturing process optimization undertaken by the Company
- Received a U.S. patent for a novel hyperimmune globulin for the treatment and prevention of *S. pneumoniae* infections

ADMA is focused on the following key strategic priorities in 2020:

- Continue to expand the commercial traction of BIVIGAM and ASCENIV for the treatment of patients with primary humoral immunodeficiency (PI) and continued ramp-up of production throughput for the first full fiscal year of commercial sales
- Evaluate and implement strategies for potential manufacturing capacity expansion as well as strengthening the supply chain capabilities to potentially unlock efficiencies, improve production yields and provide more control and visibility for timing of commercial product releases
- Execute on fulfilling the newly secured, long-term CMO supply agreement to produce and sell plasma-derived intermediate fractions
- Expand plasma collection center network to bolster long-term raw material supply and prepare for forward-looking production ramp up and growth to capitalize on the global growing IVIG and source plasma markets
- Secure new supply contracts for potential CMO opportunities as well as explore business development opportunities with our multi-faceted revenue generation platform
- Announce potential product development pipeline consisting of additional specialty plasma and/or hyperimmune immunoglobulin products

ADMA plans to discuss these results with investors while attending the 38th Annual J.P. Morgan Healthcare Conference taking place January 13-16, 2020 in San Francisco, CA.

Fourth Quarter and Full Year 2019 Financial Results Conference Call

ADMA plans to host a conference call and webcast to discuss its fourth quarter and full year 2019 financial results during the first quarter of 2020 in conjunction with filing its annual report on Form 10-K, which is expected to be filed with the U.S. Securities and Exchange Commission no later than March 16, 2020.

The financial information included in this press release is preliminary, unaudited and subject to adjustment. It does not present all information necessary for an understanding of the Company's fourth quarter and full year financial results for 2019.

About Primary Humoral Immunodeficiency

Primary humoral immunodeficiency (PI), also known as primary immune deficiency disease (PIDD), 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 are present at birth or in early childhood and 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 are more likely to suffer complications from these infections compared to individuals with a normal functioning immune system. 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. Initially thought to be very rare, it is now estimated that the prevalence of PI in the U.S. is 1 in 1,200, which translates to approximately 250,000 people.

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), including, but not limited to the following group of genetic disorders: X-linked and congenital agammaglobulinemia, common variable immunodeficiency, 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 (IgG) antibodies.

About ASCENIV™ (Formerly RI-002)

ASCENIV (immune globulin intravenous, human – slra 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 (PI), also known as primary immune deficiency disease (PIDD), 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 is protected by U.S. Patents: 9,107,906, 9,714,283 and 9,815,886.

Indication

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 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 pseudohyponatremia may occur in patients receiving IGIV treatment, including ASCENIV. It is critical to clinically distinguish true hyponatremia from a pseudohyponatremia that is associated with or causally related to hyperproteinemia. Treatment aimed at decreasing serum free water in patients with pseudohyponatremia 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 (≥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 ADMA Biologics, Inc. (ADMA)

ADMA Biologics is an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived 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 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 the hepatitis B virus. 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 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 preliminary revenues for the fourth quarter and year-end 2019 and expected revenues in the future; statements about increasing demand for our therapeutic products; statements about ADMA's fractionation plant turnaround; expansion of ADMA's plasma collection center network; statements about ADMA's research and development activities and management's belief regarding implementation of manufacturing strategies and improvements with the ultimate goal of efficiently bringing plasma-derived products to market. 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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