



ADMA Biologics Resubmits Biologics License Application for RI-002

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RAMSEY, N.J. and BOCA RATON, Fla., Oct. 01, 2018 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (NASDAQ: ADMA) ("ADMA" or the "Company"), a vertically integrated commercial biopharmaceutical company that develops, manufactures and markets specialty plasma-based biologics for the treatment of Primary Immune Deficiency Disease ("PIDD") and the prevention and treatment of certain infectious diseases, announces that the Company has responded to the July 2016 Complete Response Letter ("CRL") and resubmitted its Biologics License Application ("BLA") for RI-002 its product candidate to the U.S. Food and Drug Administration ("FDA") on September 28, 2018.

The Company was able to resubmit RI-002's BLA as a direct result of the recent improvement in compliance status for the Company's Boca Raton, FL manufacturing facility to Voluntary Action Indicated ("VAI"), as previously announced in September 2018.

"We are pleased that our remediation efforts have been successful and we are now operating our biologics production facility in accordance with the FDA's quality and compliance expectations. Because of the hard work of our dedicated and talented staff, ADMA is now in a position to submit applications to FDA for substantive review and approval including our BLA for RI-002, our lead pipeline-product candidate. We have been informed by FDA that the Company should no longer receive CRL's solely for compliance reasons," stated Adam Grossman, President and Chief Executive Officer. "This is an exciting time for the Company and for immune compromised patients with PIDD. RI-002 was developed to provide a polyclonal immune globulin alternative for clinicians when making a determination on how to care for these chronically ill patients and tailor treatment regimens that specific patients deserve and require. RI-002's pivotal Phase III clinical trial successfully met its primary and secondary endpoints. We believe RI-002, if approved, will have the ability to provide meaningful outcomes for patients."

The FDA typically provides companies with a notification of BLA acceptance within sixty ("60") days of submission, and ADMA anticipates that the agency will set a Prescription Drug User Fee Act ("PDUFA") target action date for RI-002 at that time.

About RI-002

ADMA's lead portfolio product candidate, RI-002, which has demonstrated positive Phase III pivotal clinical trial data, is a specialty plasma-derived, polyclonal, intravenous immune globulin ("IVIG") derived from human plasma containing naturally occurring polyclonal antibodies (e.g., Streptococcus pneumoniae, H. influenza type B, cytomegalovirus ("CMV"), measles, tetanus, etc.) as well as plasma from donors tested to have high levels of neutralizing antibodies to respiratory syncytial virus ("RSV"). ADMA is pursuing an indication for the use of this specialty polyclonal IVIG product for treatment of patients diagnosed with PIDD. Polyclonal antibodies are the primary active component of IVIG products. 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. Data review which has been published in peer reviewed journals indicates that the polyclonal antibodies present in RI-002 support its ability to prevent infections in immune-compromised patients. This data and other information about RI-002 or ADMA Biologics products can be found on the Company website at: www.admabiologics.com/therapies and www.admabiologics.com. RI-002 is protected by U.S. Patents: 9,107,906, 9,714,283, 9,815,886 and 9,969,793, the latter of which affords the Company patent exclusivity for the use of an immune globulin as a prevention and/or treatment for any type of respiratory infection.

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") 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 lead product candidate, RI-002. 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 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 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 and our ability to realize increased prices for plasma growth in the plasma collection industry. 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.

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Source: ADMA Biologics, Inc.