ANI Pharmaceuticals Announces Approval of Vancomycin Hydrochloride for Oral Solution USP, 250mg/5ml

June 20, 2019

BAUDETTE, Minnesota (June 20, 2019) - ANI Pharmaceuticals, Inc. (“ANI”) (Nasdaq: ANIP) today announced that it has received FDA approval of its Prior Approval Supplement for Vancomycin Hydrochloride for Oral Solution USP, 250 mg/5 ml, indicated for the treatment of various infections. ANI intends to launch the product prior to October 2019. In order to assist patients and prescribers with dosing flexibility, ANI will commercialize Vancomycin for Oral Solution, now with a mixed berry flavor, in three packaging configurations – 80 mL, 150 mL and 300 mL.

Vancomycin for Oral Solution will compete in a current market estimated to exceed $450 million annually, including all drugs indicated for treatment of enterocolitis caused by Staphylococcus aureus (including methicillin-resistant strains) and antibiotic-associated pseudomembranous colitis caused by C. difficile.

ANI acquired the ANDA for Vancomycin for Oral Solution in 2014 in an acquisition that included the NDA for Vancocin® 125 mg and 250 mg capsules and approved ANDAs for Vancomycin Hydrochloride Injection 500 mg, 1 gm and 10 gm.

Arthur S. Przybyl, ANI’s President and CEO stated, "Our acquisition of the Vancocin® assets in 2014 continues to create substantial incremental value for ANI. This exciting approval represents yet another successful re-commercialization effort of an acquired discontinued ANDA and underscores the capabilities of ANI’s product development and tech transfer group. Incorporating enhanced taste masking, a patient friendly presentation and improved dosing flexibility, our team successfully modernized this product to address the needs of today’s prescribers and patients. We are excited to re-launch this FDA approved product into a marketplace that is currently dominated by compounded vancomycin oral solutions. We intend to pursue the removal of these unapproved compounded products from commercial distribution.”

About Vancomycin Hydrochloride for Oral Solution USP

Vancomycin Hydrochloride for Oral Solution is administered orally for treatment of enterocolitis caused by Staphylococcus aureus (including methicillin-resistant strains) and antibiotic-associated pseudomembranous colitis caused by C. difficile.

About ANI

ANI Pharmaceuticals, Inc. (the “Company” or “ANI”) is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. The Company's targeted areas of product development currently include narcotics, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. For more information, please visit our website www.anipharmaceuticals.com.

Forward-Looking Statements

To the extent any statements made in this release deal with information that is not historical, these are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about price increases, the Company’s future operations, products financial position, operating results and prospects , the Company’s pipeline or potential markets therefor, and other statements that are not historical in nature, particularly those that utilize terminology such as “anticipates,” “will,” “expects,” “plans,” “potential,” “future,” “believes,” “intends,” “continue,” other words of similar meaning, derivations of such words and the use of future dates.

Uncertainties and risks may cause the Company's actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to, the risk that the Company may face with respect to importing raw materials; increased competition; acquisitions; contract manufacturing arrangements; delays or failure in obtaining product approval from the U.S. Food and Drug Administration; general business and economic conditions; market trends; products development; regulatory and other approvals and marketing.

More detailed information on these and additional factors that could affect the Company's actual results are described in the Company's filings with the Securities and Exchange Commission, including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as its proxy statement. All forward-looking statements in this news release speak only as of the date of this news release and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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