



## **ANI Pharmaceuticals Announces Launch of Vancomycin Hydrochloride for Oral Solution USP, 250mg/5mL**

September 11, 2019

**BAUDETTE, Minnesota (September 11, 2019)** - ANI Pharmaceuticals, Inc. ("ANI") (Nasdaq: ANIP) today announced the launch of Vancomycin HCl for Oral Solution, 250mg per 5mL (the generic equivalent to ANI's Vancocin® for Oral Solution). To facilitate ease of administration the drug now includes a mixed berry taste, can be administered via nasogastric tube and does not contain any ingredients made with gluten-containing grain (wheat, barley, rye). The dye-free product is delivered in a single bottle format requiring simple reconstitution and offers dosing flexibility achieved through the availability of three different size bottles: 80mL, 150mL and 300mL. ANI estimates that the current annual U.S. vancomycin market is approximately \$450 million.

Arthur S. Przybyl, ANI's President, and CEO stated, "This launch represents yet another successful re-commercialization for ANI of a previously discontinued drug and is our fourth generic product introduction in 2019. Our launch of Vancomycin for Oral Solution addresses an unmet need in the treatment of staph and C-diff infections and provides patients, physicians and pharmacists with a convenient, FDA-approved oral solution of vancomycin in addition to the currently available capsule and injectable forms. We are supporting this launch with an awareness campaign that leverages the existing virtual marketing infrastructure that we use to support our brand portfolio.

### **About Vancomycin for Oral Solution**

Vancomycin Hydrochloride for Oral Solution is a prescription medication administered orally for treatment of enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains) and antibiotic-associated pseudomembranous colitis caused by *Clostridium difficile*. Parenteral administration of vancomycin is not effective for the above indications; therefore, Vancomycin Hydrochloride for Oral Solution must be given orally for these infections. Orally administered Vancomycin Hydrochloride for Oral Solution is not effective for other types of infection.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Vancomycin Hydrochloride for Oral Solution and other antibacterial drugs, Vancomycin Hydrochloride for Oral Solution should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

For more information, including the complete list of indications and usages, please see the Full Prescribing Information.

### **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](http://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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