ANI Pharmaceuticals Announces Launch of Nebivolol Tablets

September 17, 2021

-- Current annual market for reference listed drug (“RLD”) Bystolic® totals more than $1 billion --

-- Simultaneous launch from two manufacturing sites --

BAUDETTE, Minn.--(BUSINESS WIRE)-- ANI Pharmaceuticals, Inc. (“ANI” or the “Company”) (Nasdaq: ANIP) today announced the launch of Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg.

ANI’s Nebivolol Tablets is the generic version of the reference listed drug (“RLD”) Bystolic ®. The current annual U.S. market for Bystolic 2.5 mg, 5 mg, 10 mg, and 20 mg strengths is approximately $1.05 billion, according to IQVIA/IMS Health, a leading healthcare data and analytics provider.

"The launch of Nebivolol Tablets highlights our research and development capabilities. On day one, we simultaneously launched across two manufacturing sites, including our site in Baudette, Minnesota, thus showcasing our ability to secure the supply chain for patients and customers,” stated Nikhil Lalwani, President and CEO of ANI Pharmaceuticals, Inc.

About Nebivolol Tablets

Nebivolol Tablets are indicated for the treatment of hypertension, to lower blood pressure and may be used alone or in combination with other antihypertensive agents. For more information, including the complete list of indications and usages, please see the Full Prescribing Information.

About ANI

ANI Pharmaceuticals, Inc. is a diversified bio-pharmaceutical company serving patients in need by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceutical products. Our team is focused on delivering sustainable growth by building a successful Purified Cortrophin Gel® franchise, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our North American manufacturing capabilities. 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, those relating to the development, manufacturing and commercialization of the product and any additional product launches from the Company’s generic pipeline, 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 successful launch of new products; competition from other products; 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 (“SEC”), including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as other filings with the SEC. 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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