ANI Pharmaceuticals Announces Approval of Morphine Sulfate Oral Solution

April 18, 2018

BAUDETTE, Minnesota (April 18, 2018) - ANI Pharmaceuticals, Inc. (“ANI”) (Nasdaq: ANIP) today announced that it has received approval from the U.S. Food and Drug Administration (“FDA”) of its Abbreviated New Drug Application (“ANDA”) for Morphine Sulfate Oral Solution 10mg/5mL, 20mg/5mL and 100mg/5mL. The current annual U.S. market for this product is approximately $17 million, according to Iqvia/IMS Health. ANI expects to begin shipping product to its customers in the near future.

Arthur S. Przybyl, ANI’s President and CEO stated, “We are pleased to announce the approval of this internally developed generic product, which leverages both our liquid manufacturing and controlled substance capabilities. In addition to the standard packaging formats, we intend to launch the product in a unit dose configuration. This represents the sixth approval of a generic product from our internally developed pipeline.”

About Morphine Sulfate Oral Solution

Morphine Sulfate Oral Solution is indicated for the management of acute and chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Morphine Sulfate Oral Solution 100 mg per 5 mL (20 mg/mL) is indicated for the relief of acute and chronic pain in opioid-tolerant patients.

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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