ANI Announces Launch of Tolterodine Extended-Release Capsules

February 25, 2020
BAUDETTE, Minnesota (January 24, 2019) - ANI Pharmaceuticals, Inc. (“ANI”) (Nasdaq: ANIP) today announced the launch of Tolterodine Extended-Release Capsules, 2mg and 4 mg. The current annual U.S. market for this product is approximately $101 million, according to IQVIA.

Arthur S. Przybyl, ANI’s President and CEO commented, “This is our second generic product launch in 2020 and comes from the recently announced acquisition of 23 commercial and pipeline drugs. This is also the second of two drugs that was developed by Inventia Healthcare Limited as part of a manufacturing and commercialization partnership that includes our recently launched Paliperidone Extended Release tablets. The launch of Tolterodine ER capsules expands our commercial generic portfolio to 48 drugs.”

About Tolterodine Extended-Release Capsules

Tolterodine Tartrate Extended-Release Capsules are indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. 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.

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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