



## **ANI Pharmaceuticals Announces FDA Approval and Immediate Launch of Nilutamide Tablets, the First Generic Competitor to Nilandron®**

July 18, 2016

**BAUDETTE, Minnesota (July 18, 2016)** - ANI Pharmaceuticals, Inc. ("ANI") (Nasdaq: ANIP) today announced that it has received approval from the U.S. Food and Drug Administration ("FDA") of the Abbreviated New Drug Application ("ANDA") for nilutamide tablets. Trailing twelve-month sales of Nilandron® were \$23 million according to IMS Health. ANI will immediately launch the product.

Arthur S. Przybyl, ANI's President and CEO stated, "The nilutamide approval exemplifies ANI's strategic focus to introduce high barrier niche generic products. We are excited to have secured approval for a first-to-market generic that represents ANI's second entry into the anti-cancer market and leverages our specialized high-potent manufacturing capability at our plant in Baudette, MN.

"The nilutamide launch is ANI's eighth new product launch since the beginning of the second quarter of 2016. The previously-announced launches were hydrocortisone rectal cream 1% and 2.5%, Inderal® LA capsules, propranolol ER capsules, mesalamine enema, fenofibrate 50mg and 150mg capsules, oxycodone 5mg capsules, and hydroxyprogesterone caproate injection USP 250mg/mL. The launches are the direct result of internal product development, acquisitions and partnered distribution and represent the combined strategic approach to ANI's product line expansion."

### **About Nilutamide tablets**

Nilutamide tablets are indicated for use in combination with surgical castration for the treatment of metastatic prostate cancer (Stage D2).

For maximum benefit, nilutamide treatment must begin on the same day as or on the day after surgical castration.

### **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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