



## **ANI Pharmaceuticals Announces Approval and Launch of Oxycodone Hydrochloride Oral Solution, 100 mg/5mL**

September 1, 2017

**BAUDETTE, Minnesota (September 1, 2017)** - 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 Oxycodone Hydrochloride Oral Solution USP, 100 mg/5 mL (20 mg/mL). The current annual U.S. market for this product is approximately \$14.5 million, according to IMS Health. ANI expects to begin shipping to its customers immediately.

Arthur S. Przybyl, ANI's President and CEO stated, "We are pleased to announce the launch of our fourth generic product this year. The product was developed internally at ANI and leverages both our liquid manufacturing and controlled substance capabilities." Arthur S. Przybyl, ANI's President and CEO stated, "This is the seventh product that ANI has successfully re-commercialized from its portfolio of acquired discontinued ANDA products. Through the end of the first quarter of 2017, ANI had re-commercialized five of the 54 acquired products. Since the launch of the first product in December 2014 through the end of the first quarter of 2017, these five products have generated cumulative net revenues of \$22 million and cumulative gross profit of \$12 million to ANI. We are pleased with the results of these launches and, while these products have been instrumental in building our base business, the opportunity to re-commercialize additional products from this acquired pipeline continues to represent a substantial growth opportunity for ANI."

### **About Oxycodone HCl Oral Solution**

Oxycodone Hydrochloride Oral Solution 100 mg/5 mL (20 mg/mL) is an opioid agonist indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

### **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) [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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