



## **ANI Pharmaceuticals Announces Launch of Mexiletine Hydrochloride Capsules**

June 30, 2020

BAUDETTE, Minn., June 30, 2020 /PRNewswire/ -- ANI Pharmaceuticals, Inc. ("ANI") (Nasdaq:[ANIP](#)) today announced the launch of Mexiletine Hydrochloride Capsules USP, 150mg, 200mg and 250mg. The current annual U.S. market for this product is approximately \$16 million, according to IQVIA/IMS Health.

Patrick Walsh, ANI's Interim President and CEO, stated, "This is our sixth generic product launch in 2020. The launch represents an important milestone for ANI in the integration of our Oakville, Canada manufacturing site, acquired in August 2018. Mexiletine is the first new ANI product launch from the Oakville site. I congratulate the team in Oakville on achieving this milestone; we look forward to additional ANI product launches from this plant in the future."

### **About Mexiletine Hydrochloride Capsules USP**

Mexiletine Hydrochloride Capsules are indicated for the treatment of documented ventricular arrhythmias, such as sustained ventricular tachycardia, that, in the judgment of the physician, are life-threatening. Because of the proarrhythmic effects of mexiletine, its use with lesser arrhythmias is generally not recommended. Treatment of patients with asymptomatic ventricular premature contractions should be avoided.

Initiation of mexiletine treatment, as with other antiarrhythmic agents used to treat life-threatening arrhythmias, should be carried out in the hospital.

Antiarrhythmic drugs have not been shown to enhance survival in patients with ventricular arrhythmias.

### **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, those relating to the development, manufacturing and commercialization of the product and any additional product launches from the Oakville, Canada manufacturing site 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; 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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