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Atara Bio Receives FDA Orphan Drug Designation for STM 434, Atara Bio's Activin Inhibitor for Ovarian Cancer

SOUTH SAN FRANCISCO, Calif., Oct. 20, 2015 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq:ATRA), a biopharmaceutical company with a focus on developing meaningful therapies for patients with unmet medical needs in diseases that have seen limited therapeutic innovation, today announced that the U.S. Food and Drug Administration (FDA) Office of Orphan Products Development (OOPD) granted orphan drug designation for the Company's activin inhibitor, STM 434, for ovarian cancer.

"Ovarian cancer is an aggressive tumor type with a significant unmet need for patients," said Isaac Ciechanover, M.D., President and Chief Executive Officer of Atara Bio. "The receipt of an orphan drug designation for STM 434 is another important milestone for Atara Bio and the progress of our molecularly targeted programs."

Orphan drug designation is granted by the FDA OOPD to novel drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S. The OOPD provides incentives for sponsors to develop products for rare diseases, which may include tax credits towards the cost of clinical trials and prescription drug user fee waivers. The orphan drug designation also would entitle Atara Bio to a seven-year period of marketing exclusivity in the United States for STM 434 if it receives FDA approval for the treatment of ovarian cancer.

Ovarian cancer is the fifth leading cause of cancer death in women in the United States. According to the National Cancer Institute, there were an estimated 22,240 new cases of ovarian cancer and 14,030 ovarian cancer deaths in the United States in 2013. Surgery and cytotoxic chemotherapies are widely used to treat ovarian cancer; however, the outcomes have changed little in 40 years. The proportion of all ovarian cancer patients surviving five years after diagnosis was only 44% based on the National Cancer Institute SEER database for women diagnosed from 2003 to 2009.

About STM 434

STM 434, one of Atara Bio's molecularly-targeted product candidates, is a fusion protein that binds Activin A and other ligands of the ActR2B receptor. Activin has been shown to be involved in the growth and proliferation of ovarian cancer and other tumors, with published evidence of its role at both the genetic, or messenger RNA, and protein levels. Activin expression is one of a few biomarkers associated with larger tumor volume and poorer outcomes, including shortened survival, in a variety of malignancies including ovarian cancer. We are currently testing STM 434 in a three part Phase 1 clinical study designed to enroll approximately 66 patients with advanced ovarian cancer and other solid tumors. Part 1 is a dose escalation in patients with advanced solid tumors; Part 2 is a monotherapy dose

expansion in patients with advanced ovarian cancer, including clear cell and granulosa cell tumors; and Part 3 is designed to study STM 434 in combination with chemotherapy in patients with advanced ovarian cancer. We expect to have initial data from the dose escalation portion of the study in the first half of 2016.

About Atara Biotherapeutics, Inc.

Atara Biotherapeutics, Inc. is a biopharmaceutical company focused on developing meaningful therapies for patients with unmet medical needs in diseases that have seen limited therapeutic innovation. Atara Bio's programs include molecularly targeted product candidates and T-cell product candidates. Molecularly targeted product candidates include PINTA 745, STM 434 and ATA 842. These product candidates target myostatin and activin, members of the TGF-beta family of proteins, and have demonstrated the potential to have therapeutic benefit in a number of clinical indications. T-cell product candidates include EBV-CTL, CMV-CTL and WT1-CTL.

Forward-Looking Statements

This press release contains or may imply "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Because such statements deal with future events and are based on Atara Bio's current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Atara Bio could differ materially from those described in or implied by the statements in this press release. For example, forward-looking statements include statements regarding: a seven-year period of marketing exclusivity in the United States if STM 434 receives FDA approval for the treatment of ovarian cancer; the fact that the STM 434 Phase 1 clinical study is designed to enroll approximately 66 patients; and the expectation to have initial data from the dose escalation portion of the STM 434 Phase 1 clinical study in the first half of 2016.These forward-looking statements are subject to other risks and uncertainties, including those discussed under the heading "Risk Factors" in Atara Bio's quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 6, 2015, including the documents incorporated by reference therein and subsequent filings with the SEC. Except as otherwise required by law, Atara Bio disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date hereof, whether as a result of new information, future events or circumstances or otherwise.

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