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Cascadian Therapeutics Receives Pediatric Investigation Plan Waiver from the European Medicines Agency

Removes Requirement for Pediatric Clinical Studies to Support Tucatinib Market Authorization Application for Treatment of Metastatic Breast Cancer in Europe

SEATTLE, Jan. 02, 2018 (GLOBE NEWSWIRE) -- Cascadian Therapeutics, Inc. (NASDAQ:CASC), a clinical-stage biopharmaceutical company, today announced that it received a product-specific pediatric waiver from the European Medicines Agency (EMA) for tucatinib, Cascadian's lead product candidate, which is currently in a pivotal clinical trial for the treatment of HER2+ metastatic breast cancer.

"This pediatric waiver is another important milestone in the European regulatory process, and will allow Cascadian to submit a marketing authorization application for tucatinib for the treatment of HER2+ metastatic breast cancer to the EMA following completion of the HER2CLIMB pivotal trial, without the requirement to conduct clinical studies in the pediatric population prior to approval or post-approval," said Scott D. Myers, President and Chief Executive Officer of Cascadian Therapeutics.

As part of the regulatory process for the registration of new medicines with the EMA, pharmaceutical companies are required to have in place an approved Pediatric Investigation Plan (PIP) prior to MAA filing that outlines the clinical development strategy for studying the investigational product in the pediatric population. In some instances, a waiver from required pediatric studies for certain conditions may be granted by the EMA when development of a medicine for use in children is not feasible or appropriate.

In July 2017, Cascadian received confirmation from the EMA that positive results from the HER2CLIMB pivotal trial could serve as a single registrational trial for submission of an MAA to the EMA for potential marketing approval. Cascadian received similar confirmation from the U.S. Food and Drug Administration (FDA) in 2016. The FDA has granted tucatinib orphan drug designation for the treatment of breast cancer patients with brain metastases. Tucatinib has also received Fast Track designation for the treatment of advanced HER2+ metastatic breast cancer from the FDA.

About Cascadian Therapeutics

Cascadian Therapeutics is a clinical-stage biopharmaceutical company dedicated to developing innovative product candidates for the treatment of cancer. Its lead product candidate, tucatinib, is an investigational oral, selective small molecule HER2 inhibitor. Cascadian Therapeutics is conducting a randomized, double-blind, controlled pivotal clinical trial called HER2CLIMB, which is comparing tucatinib vs. placebo, each in combination with capecitabine and trastuzumab, in patients with locally advanced or metastatic HER2+ breast cancer with and without brain metastases, who have previously been treated with trastuzumab, pertuzumab and T-DM1. Additional details on HER2CLIMB can be found at www.HER2CLIMB.com or www.clinicaltrials.gov. Tucatinib is also being studied in other cancers through investigator initiated studies, including HER2+ metastatic colorectal cancer and earlier lines of HR+/HER2+ metastatic breast cancer. For more information, please visit www.cascadianrx.com.

Forward-Looking Statements

In order to provide Cascadian Therapeutics' investors with an understanding of its current results and future prospects, this release contains statements that are forward-looking. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "will," "intends," "potential," "possible" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include Cascadian Therapeutics' expectations regarding clinical development activities, HER2CLIMB enrollment, timing of additional data, potential benefits of its product candidates, and its use and adequacy of cash reserves and future financings and financial results.

Forward-looking statements involve risks and uncertainties related to Cascadian Therapeutics' business and the general economic environment, many of which are beyond its control. These risks, uncertainties and other factors could cause Cascadian Therapeutics' actual results to differ materially from those projected in forward-looking statements, including the risks associated with the costs and expenses of developing its product candidates, the adequacy of financing and cash,

cash equivalents and investments, changes in general accounting policies, general economic factors, achievement of the results it anticipates from its preclinical development and clinical trials of its product candidates, the receipt of regulatory approvals, its ability to adequately obtain and protect its intellectual property rights, and other factors discussed under the caption "Risk Factors" in Cascadian Therapeutics' Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2017 filed with the Securities and Exchange Commission. Although Cascadian Therapeutics believes that the forward-looking statements contained herein are reasonable as of the date hereof, it can give no assurance that its expectations are correct. All forward-looking statements are expressly qualified in their entirety by this cautionary statement. For a detailed description of Cascadian Therapeutics' risks and uncertainties, you should review the documents filed by Cascadian Therapeutics with the securities regulators in the United States on EDGAR and in Canada on SEDAR. Cascadian Therapeutics does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof, except to the extent required by law.

Source: Cascadian Therapeutics, Inc.

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