July 11, 2017

Cascadian Therapeutics Announces Positive Regulatory Update for Tucatinib in Europe

EMA Confirms Single HER2CLIMB Trial, If Positive, Could Support Approval

SEATTLE, July 11, 2017 (GLOBE NEWSWIRE) -- Cascadian Therapeutics, Inc. (NASDAQ:CASC), a clinical-stage biopharmaceutical company, today announced the outcome of discussions with the European Medicines Agency (EMA) regarding the development of tucatinib, an investigational medicine for the treatment of HER2-positive metastatic breast cancer. Following these discussions, the Company has received confirmation that positive results from its ongoing pivotal trial of tucatinib, known as HER2CLIMB, could serve as a single registrational trial for submission of a Marketing Authorization Application (MAA) to the EMA and potential marketing approval. The Company had received similar confirmation from the U.S. Food and Drug Administration (FDA) in 2016.

"Our interactions with regulators in the U.S. and Europe continue to support the design of our pivotal trial as a registrational pathway for tucatinib in both regions," said Marc Lesnick, Ph.D., Senior Vice President Regulatory Affairs and Quality at Cascadian Therapeutics. "We look forward to continued productive discussions in our future interactions with the EMA, the FDA and other health authorities."

Scott Myers, President and Chief Executive Officer, Cascadian Therapeutics, added, "This is an important milestone for the company. We had anticipated providing an update on our European regulatory strategy later this year; and we are pleased with this early feedback from the EMA that the current design of the global HER2CLIMB trial, if positive, could support approval and a potentially shorter path to the European market for tucatinib. Site and patient enrollment is currently ahead of schedule in North America, and we are now poised to begin enrolling patients in HER2CLIMB in other countries."

About Tucatinib

Tucatinib is an investigational, orally bioavailable, potent tyrosine kinase inhibitor that is highly selective for HER2 without significant inhibition of EGFR. Inhibition of EGFR has been associated with significant toxicities, including skin rash and diarrhea. Tucatinib has shown activity as a single agent and in combination with both chemotherapy and other HER2 directed agents such as trastuzumab.[1,2] Studies of tucatinib in these combinations have shown activity both systemically and in brain metastases. HER2 is a growth factor receptor that is overexpressed in multiple cancers, including breast, ovarian and gastric cancers. HER2 mediates cell growth, differentiation and survival. Tumors that overexpress HER2 (HER2-positive) are more aggressive and historically have been associated with poor overall survival, compared with HER2-negative cancers.

About HER2CLIMB Pivotal Trial

HER2CLIMB is a randomized (2:1), double-blind, placebo-controlled pivotal clinical trial comparing tucatinib vs. placebo, each in combination with capecitabine and trastuzumab and without loperamide or budesonide prophylaxis, in patients with locally advanced or metastatic HER2-positive breast cancer who have had prior treatment with a taxane, trastuzumab, pertuzumab and ado-trastuzumab emtansine, also known as T-DM1. The primary endpoint is progression-free survival (PFS) based upon independent radiologic review. Key objectives related to assessing activity in brain metastases include a key secondary endpoint of PFS in a subset of patients with brain metastases. All patients will be followed for overall survival. HER2CLIMB is currently enrolling patients in the United States, Canada, Western Europe and Australia. Additional information is available at www.HER2CLIMB.com.

About HER2-Positive Metastatic Breast Cancer

Patients with HER2-positive breast cancer have tumors with high levels of a protein called human epidermal growth factor receptor 2 (HER2), which promotes the aggressive spread of cancer cells. The American Cancer Society estimates that 20-25 percent of the approximately 246,660 annual new cases of breast cancer diagnoses in the U.S. are HER2-positive. Historically, HER2 disease has been associated with shorter survival times as well as a higher risk of recurrence and CNS disease (brain metastases). Approximately 30 to 50 percent of HER2-positive breast cancer patients develop brain metastases over time.[3,4] Over the past two decades, the approvals of four targeted treatments (trastuzumab, pertuzumab,

lapatinib, and T-DM1) have led to improved time to progression and survival rates of patients with HER2-positive breast cancer. Despite these advances, there is still a significant need for new therapies that can impact metastatic disease, including brain metastases, and be tolerated for longer periods of time.

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-positive breast cancer with and without brain metastases, who have previously been treated with a taxane, trastuzumab, pertuzumab and T-DM1. Additional details on HER2CLIMB can be found at www.HER2CLIMB.com or www.clinicaltrials.gov. 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," "could" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include Cascadian Therapeutics' expectations regarding clinical development activities, timing of additional data, potential benefits of its product candidates, results of clinical trials of tucatinib, and the potential regulatory approval of tucatinib.

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, and its ability to adequately obtain and protect its intellectual property rights. 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.

References:

1. Moulder, S. et al., *Phase 1 Study of ONT-380, a HER2 Inhibitor, in Patients with HER2+ Advanced Solid Tumors, with an Expansion Cohort in HER2+ Metastatic Breast Cancer.* Clin Cancer Res, May 2017.
2. Hamilton, E. et al., *Efficacy of a Phase 1b Study of Tucatinib (ONT-380), an Oral HER2-Specific Inhibitor, in Combination with Capecitabine and Trastuzumab in HER2+ Metastatic Breast Cancer, Including Patients with Brain Metastases*. Presented at the San Antonio Breast Cancer Symposium (SABCS) Annual Meeting 2016, San Antonio, TX, December 9, 2016 (Poster P4-21-01).
3. Metro, et al., *Clinical outcome of patients with brain metastases from HER2-positive breast cancer treated with lapatinib and capecitabine*. Annals of Oncology, vol. 212, no. 3, pp. 625-630, 2011.
4. Ramakrishna N., et al., Journal of Clinical Oncology 32, no. 19 (July 2014) 2100-2108.

Investor and Media Contact:
Monique Greer
Cascadian Therapeutics
206-801-2107
mgreer@cascadianrx.com