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Cascadian Therapeutics Announces 2018 Outlook and Recent Progress

SEATTLE, Jan. 04, 2018 (GLOBE NEWSWIRE) -- Cascadian Therapeutics, Inc. (NASDAQ:CASC), a clinical-stage biopharmaceutical company, today announced an overview of recent progress for tucatinib, an investigational oral, small molecule kinase inhibitor that is highly selective for HER2 and the Company's lead product in development for the treatment of HER2 overexpressing cancers, in addition to several anticipated key objectives for 2018.

"2017 was a very productive year across all aspects of our business, and we delivered on our key objectives we set at the beginning of the year," said Scott D. Myers, President and Chief Executive Officer of Cascadian Therapeutics. "Our pivotal registrational trial of tucatinib for patients with HER2-positive metastatic breast cancer with or without brain metastases remains on track and enrolling patients in North America, Western Europe and Australia. In 2018, we plan to update the market on HER2CLIMB enrollment status after carefully assessing our European site performance. We also look forward to the interim results from a Phase 2 study of tucatinib in HER2 amplified metastatic colorectal cancer, known as MOUNTAINEER, where there is an increasing need for effective and well-tolerated treatment options."

Recent Progress Update

The following accomplishments occurred during the fourth quarter of 2017:

Tucatinib Development

- In December 2017, the Company reported results from a subgroup analysis from its two ongoing combination studies of tucatinib, which demonstrated prolonged progression-free survival benefit regardless of presence of brain metastases or patient characteristics. These results were presented at the 2017 San Antonio Breast Cancer Symposium (SABCS).
- In December 2017, the first patient was enrolled in the investigator-initiated Phase 1b/2 trial known as TULiP that is evaluating tucatinib in combination with an aromatase inhibitor and CDK4/6 agent for patients with hormone receptor-positive and HER2-positive (HR+/HER2+) metastatic breast cancer. Based on the activity of tucatinib in combination with multiple agents in patients with brain metastases observed in prior studies, the trial will also include these patients.
- As of December 2017, the investigator-initiated open label Phase 2 study of tucatinib in combination with trastuzumab for patients with HER2+/RAS wild type metastatic colorectal cancer, known as MOUNTAINEER, was enrolling ahead of the lead investigator's anticipated timeline.
- As of December 2017, the Company has successfully manufactured sufficient supply of tucatinib to complete all currently ongoing trials, including HER2CLIMB.

Regulatory

- In December 2017, the European Medicines Agency (EMA) granted a full product-specific waiver for the Pediatric Investigation Plan (PIP), which means the Company is exempt from any requirements to perform pediatric development of tucatinib for the treatment of HER2+ metastatic breast cancer.
- In December 2017, EMA's Scientific Advice Working Group provided guidance on the planned manufacturing program for tucatinib, to ensure that Cascadian's manufacturing plans will be acceptable for filing and commercial release in the EU.
- In November 2017, Health Canada validated the potential for the ongoing HER2CLIMB pivotal clinical trial and nonclinical programs to be sufficient for tucatinib registration, if data are supportive.

Corporate

- In December 2017, Cascadian Therapeutics was officially added to the Nasdaq Biotechnology Index.
- As of September 30, 2017, cash, cash equivalents and investments totaled $113 million and no debt. The Company plans to provide 2018 guidance during its fourth quarter and year-end 2017 results announcement.

2018 Key Objectives Planned

The Company plans to pursue the following key objectives during 2018:

- Continue enrolling the HER2CLIMB randomized pivotal trial of tucatinib in locally advanced or metastatic HER2+ breast cancer with and without brain metastases and provide an update on planned enrollment completion as appropriate.
- Publish data from two Phase 1b studies of tucatinib in combination with other approved agents in HER2+ breast cancer in peer-reviewed journals.
- Report on early interim results from the investigator-initiated study of tucatinib in HER2+ amplified, metastatic colorectal cancer known as MOUNTAINEER.
- Pursue PRIME (PRIority MEdicines) designation with the EMA for tucatinib for the treatment of patients with metastatic colorectal cancer.
- Complete manufacture of registration lots that will be used to support the planned filing of a New Drug Application, or NDA, for tucatinib.
- Identify development partners for Chk1 and TIGIT preclinical programs.
- Explore potential ex-U.S. partnership opportunities for tucatinib to support development and commercialization in Europe and Asia and support funding of a U.S. launch.

About Tucatinib

Tucatinib is an investigational, orally bioavailable, potent tyrosine kinase inhibitor that is highly selective for HER2 without inhibition of EGFR. Inhibition of EGFR has been associated with clinical 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+) are more aggressive and historically have been associated with poor overall survival, compared with HER2-negative cancers.

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.

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 SABCS Annual Meeting 2016. December 9, 2016 (Poster P4-21-01).

Source: Cascadian Therapeutics, Inc.

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