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Cascadian Therapeutics Announces 2017 Outlook and Recent Drug Portfolio Progress

SEATTLE, Jan. 05, 2017 (GLOBE NEWSWIRE) -- Cascadian Therapeutics, Inc. (NASDAQ:CASC), a clinical-stage biopharmaceutical company, today announced an overview of recent progress for its investigational drug portfolio in addition to several anticipated key objectives for 2017.

"In 2016, we refocused our resources on the development of our small molecule HER2 inhibitor, tucatinib, and have entered 2017 with clear priorities and with an enhanced team that has late-stage development experience," said Scott D. Myers, President and Chief Executive Officer of Cascadian Therapeutics. "In the fourth quarter of 2016, following a very collaborative meeting with the FDA, we amended the ongoing HER2CLIMB Phase 2 trial of tucatinib so that, if successful, HER2CLIMB could serve as a single pivotal registration trial. Updated data from the ongoing Phase 1b Triplet combination study continues to show a tolerable safety profile and encouraging anti-tumor activity in a heavily pre-treated population, including those with and without brain metastases. With a clear, accelerated regulatory pathway for the advancement of tucatinib in the United States, a solid balance sheet and an expanded talented leadership team, we plan to spend more time on our ex-U.S. strategy for tucatinib and to continue building for success in 2017 and beyond."

Recent Progress Update

Tucatinib — targeted HER2 inhibitor

- In December 2016, Cascadian announced that following a recent meeting with the U.S. Food and Drug Administration (FDA) it has amended the HER2CLIMB Phase 2 clinical trial of its investigational product, tucatinib, by increasing the sample size so that, if successful, the trial could serve as a single pivotal study to support registration. HER2CLIMB is a randomized (2:1), double-blind, controlled pivotal clinical trial comparing tucatinib in combination with capecitabine and trastuzumab vs. placebo in combination with capecitabine and trastuzumab in patients with locally advanced or metastatic HER2-positive breast cancer who have had prior treatment with a taxane, trastuzumab, pertuzumab and T-DM1. The primary endpoint is progression-free survival (PFS) based upon independent radiologic review, and the sample size is increased to approximately 480 patients, including patients who enrolled in HER2CLIMB to date. Patients will also be followed for overall survival, which is a secondary endpoint. Key objectives related to assessing activity in brain metastases include a secondary endpoint of PFS in a subset of patients with brain metastases.

- In December 2016, researchers presented updated results from the Company's ongoing Phase 1b Triplet combination study (tucatinib with capecitabine and trastuzumab) at the 2016 San Antonio Breast Cancer Symposium (SABCS). Results showed that tucatinib continues to be well tolerated in this combination, with an updated median progression-free survival (PFS) of 7.8 months, an overall response rate (ORR) of 61 percent and a median duration of response (DoR) of 10 months. Patients treated with the Triplet combination previously received a median of 3 HER2-targeted agents, such as trastuzumab, pertuzumab, lapatinib and T-DM1.

CASC-578 - a novel Chk1 cell cycle inhibitor

During the fourth quarter and during 2016, the following progress was made in the CASC-578 program:

- Non-GLP repeat dose tolerability studies were conducted in rats and cynomolgus monkeys to establish drug tolerability and identify dose ranges to test in future IND enabling GLP toxicology studies.

- A GLP safety pharmacology study was conducted in cynomolgus monkeys to evaluate multiple cardiovascular safety endpoints. The results of this study indicate CASC-578 has an acceptable safety profile at the doses tested and support further development of the drug.

- CASC-578 was evaluated *in vitro* in a large panel of tumor derived cell lines to define its activity as a single agent in both solid and hematological cancers and to identify potential biomarkers to define tumor genotypes most likely to respond to the drug. The results of this study demonstrated CASC-578 can inhibit the growth of a subset of tumor derived cell lines from both solid and hematological malignancies with IC50 values as low as 30 nM and several

candidate biomarkers were identified that correlate with potency in responsive cell lines.

- To better define the pharmacological activity and therapeutic index of CASC-578, several in vivo studies were conducted in mice using human xenograft models of acute leukemia, mantle cell lymphoma and non-small cell lung cancer. The results of these experiments showed CASC-578 inhibited, and in some cases, regressed established tumors as a single agent.

Corporate Update

- In January 2017, the Company announced the appointment of Marc L. Lesnick, Ph.D., as Senior Vice President, Regulatory Affairs and Quality.
- As of September 30, 2016, cash, cash equivalents and investments totaled $71.6 million and no debt. The Company plans to provide 2017 guidance in its fourth quarter and year-end 2016 results announcement.

2017 Key Objectives Planned

Focus on HER2CLIMB pivotal trial enrollment: Expand the HER2CLIMB trial to sites in Europe, Australia and Israel in the first half of 2017.

Report new data at scientific meetings: Report new data analyses from tucatinib and the Chk1 cell cycle inhibitor at scientific meetings in 2017.

Explore tucatinib's utility in other clinical settings: Support the initiation of select investigator-sponsored combination trials, including trials in HER2-positive amplified, metastatic colorectal cancer and in combination with palbociclib and letrozole in HER2-positive, hormone-receptor positive metastatic breast cancer.

Define next steps for CASC-578: Complete pharmacology studies in the first half of 2017 and make go/no-go decision on IND-enabling studies for CASC-578 in the second half of 2017.

Pursue capital options: Evaluate all available financing vehicles, including non-dilutive options such as out-licensing tucatinib regional rights.

About Cascadian Therapeutics

Cascadian Therapeutics is a clinical-stage biopharmaceutical company dedicated to developing innovative product candidates for the treatment of cancer. The lead investigational product candidate, tucatinib, also known as ONT-380, is an oral, selective small molecule HER2 inhibitor. Cascadian Therapeutics is conducting a pivotal trial named HER2CLIMB to evaluate tucatinib versus placebo in combination with capecitabine and trastuzumab in patients with late stage HER2+ breast cancer, with and without brain metastases. Additional details can be found at www.clinicaltrials.gov (Identifier: NCT02614794) or www.HER2CLIMB.com. For more information and to sign up for email alerts or RSS feeds, 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 and preclinical development activities, 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 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, 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 are encouraged to review the documents filed with the securities regulators in the United States on EDGAR and in Canada on SEDAR. Except as required by law, Cascadian Therapeutics does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.

Additional Information
Additional information relating to Cascadian Therapeutics can be found on EDGAR at www.sec.gov and on SEDAR at www.sedar.com.

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