Press Release

Critical Outcome Technologies Announces Pharmacodynamic Data and Positive Signals of Efficacy from Phase 1 Dose Escalation Portion of COTI-2 Trial in Gynecological Malignancies

Establishes recommended Phase 2 dose in ovarian cancer based on strong safety, tolerability and pharmacokinetic data

London, Ontario and Boston, MA (December 19, 2017): Critical Outcome Technologies Inc. (TSX Venture: COT; OTCQB: COTQF) ("COTI" or the "Company"), a clinical stage biopharmaceutical company advancing a pipeline of targeted therapies for the treatment of cancer, today announced pharmacodynamic (PD) data and positive signals of efficacy from the dose-escalation portion of its Phase 1 trial of COTI-2 in gynecological malignancies that support the continued development of COTI-2 as a potential treatment for patients.

"The growing body of data we have accumulated from our Phase 1 trial in gynecological malignancies reinforces our confidence in the treatment potential of our lead clinical candidate, COTI-2," said Alison Silva, President & Chief Executive Officer. "Combined with the findings we announced earlier this year, these new data further validate the promising pharmacological profile of COTI-2. Scientifically, we are well-positioned to continue advancing COTI-2 through clinical development, and we expect to report additional data in the year ahead as we continue analysis of the gynecological arm and complete enrollment in the head and neck squamous cell carcinoma (HNSCC) expansion arm."

"After closely reviewing the safety, tolerability, and pharmacokinetic data for COTI-2 released earlier this year, we are pleased to announce we have established a recommended Phase 2 dose for COTI-2 in ovarian cancer," said Richard Ho, M.D., Ph.D., Chief Scientific Officer. "We are also encouraged by the analyses of secondary and exploratory outcome measures announced today, including the positive signals of efficacy which suggest COTI-2 may be a potentially efficacious treatment for patients. We look forward to further exploring these signals as we advance COTI-2 to the next stage of clinical development."

Phase 1 Trial of COTI-2 in Gynecological Malignancies

The trial enrolled twenty-four patients with a median age of 60 years with ovarian, fallopian tube, endometrial or cervical cancer that was recurrent, metastatic or unresectable and for which no effective or curative measures existed. These patients were heavily pretreated and received a median of 5 previous courses of chemotherapy. Patients were administered doses of COTI-2 ranging from 0.25 mg/kg to 1.7 mg/kg orally 5 days per week. Primary outcome measures were designed to evaluate safety and tolerability and determine the maximum tolerated dose and recommended phase 2 dose for COTI-2. Secondary and exploratory outcome measures were designed to evaluate pharmacodynamics and various signals of efficacy.

Primary Outcome Measures

In August 2017, the Company announced completion of the dose-escalation portion of its Phase 1 trial of COTI-2 in gynecological malignancies. COTI-2 was generally safe and well tolerated at doses up to 1.7 mg/kg, with the most commonly reported drug-related adverse effects being nausea (observed in approximately 42% of patients), vomiting (29%), fatigue (21%), and abdominal pain (17%). No clinically significant cardiac toxicity was observed, and no grade 4 toxicities were reported.

Today, the Company announced it has established a recommended Phase 2 dose for COTI-2 in ovarian cancer of 1.0 mg/kg orally 5 days per week.

Secondary and Exploratory Outcome Measures

In November 2017, the Company announced pharmacokinetic (PK) data demonstrating rapid oral absorption across all dose levels, with the highest concentrations of COTI-2 measured at approximately one hour after dosing. The mean half-life, or the time it takes for the drug to fall to half of its peak levels, was approximately 8 to 10 hours, and this exposure was in the expected therapeutic range based on preclinical data in gynecological malignancies. In addition, there was no evidence of long-term drug accumulation following multiple cycles of treatment. Following the last cycle of treatment, clearance of the drug takes approximately one week.

In this first Phase 1 trial, 15 patients were evaluated for secondary and exploratory outcome measures, including various signals of efficacy measured using RECIST criteria[1]. Eleven (11) of the 15 patients evaluated for secondary and exploratory outcome measures had ovarian cancer. Twelve (12) of the 15 patients evaluated for secondary and exploratory outcome measures were genetically-profiled; 9 of the 12 genetically-profiled patients exhibited a variety of p53 mutations. One (1) of the 15 patients evaluated for secondary and exploratory outcome measures was determined to have overall stable disease. Four (4) of the 15 patients evaluated for secondary and exploratory outcome measures were determined to have progressing disease, but stable target lesions; target lesions are lesions specifically chosen and measured to assess whether a patient's tumor burden is increasing or decreasing. Five (5) of the 15 patients evaluated for secondary and exploratory outcome measures were determined to have progressing disease but stable non-target tumors; stable non-target tumors indicate that no new lesions were identified. Patients were also assessed for Cancer Antigen-125 (CA-125) levels, a protein found in the blood which can be used to monitor certain cancers. One patient in the study was observed to have a decrease in CA-125.

COTI is continuing to analyze results from the gynecological arm of its Phase 1 trial of COTI-2, and expects to provide an update when further data are available in the first quarter of 2018.

COTI is also currently enrolling patients in the HNSCC dose-escalation arm of its Phase 1 trial of COTI-2, and expects to report top-line data in 2018.

About Critical Outcome Technologies Inc.

COTI is a clinical stage biotech company that uses proprietary artificial intelligence technologies to pursue a targeted and transformational approach to treating cancer and other unmet medical needs. COTI's CHEMSAS® technology accelerates the discovery and development of novel drug therapies, allowing the Company to build a pipeline of potential drug candidates faster and with a higher probability of success than traditional methods.

The Company's lead compound, COTI-2, has a novel p53-dependent mechanism of action with selective and potent anti-cancer activity. P53 mutations occur in over 50% of all cancers. COTI-2 is initially being evaluated for the treatment of gynecologic cancers and in a Phase 1 clinical trial at the MD Anderson Cancer Center ("MDACC") at the University of Texas and the Lurie Cancer Center at Northwestern

University and for head and neck squamous cell carcinoma at MDACC. The Company has secured orphan drug status in the United States for COTI- 2 for the treatment of recurrent ovarian cancer. Preclinical data suggests that COTI-2 could dramatically improve the treatment of cancers with mutations in the p53 gene.

The Company's second lead compound, COTI-219, is a novel oral small molecule compound targeting the mutant forms of KRAS without inhibiting normal KRAS function. KRAS mutations occur in up to 30% of all cancers and represent a tremendous unmet clinical need and a desirable drug target. COTI-219 is undergoing IND-enabling studies to support a regulatory submission in 2018.

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References

[1] Eisenhauer et al, 2009. European Journal of Cancer: 45; 228-247

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