

Critical Outcome Technologies Announces Pharmacokinetic Data From Phase 1 Dose Escalation Portion of COTI-2 Trial in Gynecological Malignancies

London, Ontario and Boston, MA (November 15, 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 pharmacokinetic (PK) data 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.

“We are encouraged to see these PK data from our Phase 1 trial in gynecological malignancies,” said Alison Silva, President & Chief Executive Officer. “These promising PK signals build on the safety and tolerability data we announced earlier this year, and reinforce our commitment to the continued advancement of COTI-2 through clinical development. We look forward to updating you on further progress in this trial as we continue to analyze secondary and exploratory endpoint data from the gynecological arm and enroll patients in the head and neck squamous cell carcinoma (HNSCC) expansion arm.”

“As part of our analyses, we found the half-life of COTI-2 was substantially longer than other treatments targeting mutant p53,” said Richard Ho, M.D., Ph.D., Chief Scientific Officer. “Combined with our data suggesting rapid absorption and lack of long-term drug accumulation, our findings support the potential for daily oral dosing of COTI-2, a crucial advantage for our compound.”

In August 2017, the Company announced completion of the dose-escalation portion of its Phase 1 trial of COTI-2 in gynecological malignancies. The trial enrolled 24 patients with ovarian, fallopian tube, primary peritoneal, endometrial or cervical cancer that was recurrent, metastatic or unresectable and for which no effective or curative measures existed. Patients were administered doses of COTI-2 ranging from 0.25 mg/kg to 1.7 mg/kg orally 5 days per week. COTI-2 was generally safe and well-tolerated by patients at doses up to 1.7 mg/kg.

Pharmacokinetic data across all dose levels showed rapid oral absorption, 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, is approximately 8 to 10 hours, and this exposure is 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.

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 additional secondary and exploratory endpoint data are available by year-end.

COTI is also currently enrolling patients in the head and neck squamous cell carcinoma 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 head and neck squamous cell carcinoma in a Phase 1 clinical trial at the MD Anderson Cancer Center at the University of Texas and the Lurie Cancer Center at Northwestern University. The Company has secured orphan drug status in the United States for COTI-2 for the treatment of 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 early 2018.

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