



# Press Release

**FOR IMMEDIATE RELEASE**

## **CRITICAL OUTCOME TECHNOLOGIES INC. ANNOUNCES INTENTIONS TO PREPARE A PHASE 1B HEALTH CANADA CLINICAL TRIAL SUBMISSION**

**London, Ontario (December 18, 2007): Critical Outcome Technologies Inc. (TSX Venture: COT),** announced today that the Company intends to prepare a Phase 1B Health Canada clinical trial submission based on positive preclinical results for its small cell lung cancer (SCLC) drug, COTI-2. The Company anticipates that the first patient will be registered in a Phase 1B trial in 12-15 months.

“The acquisition of DDP Therapeutics and the repatriation of the SCLC small molecule library marks an exciting time in the development of Critical Outcome Technologies Inc. (COTI),” said Mr. John Drake, Chairman and CEO of COTI. “Over the last 12 months the first three compounds from this library of 10 novel, optimized compounds have produced promising results from preclinical testing. We are equally excited that the performance of the lead compounds in preclinical testing was predicted by our proprietary technology CHEMSAS®, providing validation for what we believe is a leading edge drug discovery technology.”

“The decision to advance one of these compounds to a Phase 1B Health Canada clinical trial was based on the excellent results we have seen in virtually all preclinical experiments completed to date,” said Dr. Wayne Danter, President and CSO of COTI. “COTI-2 shows efficacy against multiple cancers and low toxicity. Several pharmaceutical organizations have shown interest in in-licensing COTI-2 and we continue to evaluate our options pertaining to a licensing arrangement. While we welcome a partnership in the execution of a Phase 1B clinical trial, our most current private placement provides adequate resources for our organization to move forward independently.”

### **About COTI-2**

COTI-2 is a novel, easily synthesized small molecule originally designed and optimized for oral treatment of SCLC. With 240,000 new cases per year, and frequent resistance to chemotherapy, an orally available, effective treatment to SCLC that has activity against multiple cancers is an attractive in-licensing opportunity for pharmaceutical organizations. COTI-2 has shown highly promising preclinical results indicating:

- Inhibition of Akt/PKB phosphorylation in cancer cells resulting in apoptosis or programmed cell death.
- Excellent *in vitro* activity in several human cancer cell lines including SCLC.
- *In vitro* activity at very low nanomolar dose levels in 4 aggressive human brain cancer cell lines.
- Low acute toxicity in escalating dosing according to standard test protocols. Examination of tissues and organs from treated animals demonstrated no drug induced abnormalities.



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- Repeated doses with COTI-2 have not produced any evidence of emerging *in vitro* resistance in human SCLC. In comparison, repeated treatment with current SCLC drugs Cisplatin and Paclitaxel does produce resistance compared with parental cell lines.
- Excellent *in vitro* efficacy in human SCLC lines with known resistance to both Cisplatin and Paclitaxel.
- Good *in vitro* metabolic stability in a human liver microsomal enzyme system with effective drug retention.
- Significant *in vivo* activity/growth inhibition in an athymic mouse model of human SCLC compared with Cisplatin and Paclitaxel.
- Significant *in vivo* activity/growth inhibition in 2 other separate athymic mouse models of human SCLC.

Based on these encouraging preclinical results COTI is moving forward immediately with its plans to complete the necessary animal pharmacokinetic and toxicity testing (i.e. PK/Tox testing) required for the submission of an Investigational New Drug (IND) application to Health Canada within the next 12-15 months.

## **About Small Cell Lung Cancer (SCLC)**

SCLC is an aggressive form of tobacco induced Lung Cancer that accounts for approximately 20% of all lung cancers world-wide. Current best therapy results in initial remission in 70% of treated patients. Unfortunately, the initial response to therapy is usually short lived and when the disease returns it is typically resistant to currently available therapies. Even with best current therapies the median survival time from diagnosis is approximately 12 months. COTI-2 was designed to specifically address this large unmet medical need for a novel and effective therapy with low toxicity. SCLC is a member of a larger group of neuroendocrine cancers including many types of aggressive and poorly treated brain cancers.

## **Notice to Readers**

Information contained in this press release may contain certain statements which constitute “forward looking statements” within the meaning of the Securities Act (Ontario) and applicable securities laws. These forward-looking statements, by their nature, are not guarantees of future performance and are based upon management’s current expectations, estimates, projections and assumptions. COTI operates in a highly competitive environment that involves significant risks and uncertainties which could cause actual results to differ materially from those anticipated in these forward-looking statements. Management of COTI considers the assumptions on which these forward-looking statements are based to be reasonable, but as a result of the many risk factors, cautions the reader that actual results could differ materially from those expressed or implied in these forward looking statements. Information in this press release should be considered accurate only as of the date of the release and may be superseded by more recent information disclosed in later press releases, filings with the securities regulatory authorities or otherwise.

## **About Critical Outcome Technologies Inc. (COTI)**

COTI is formed around a unique computational platform technology called CHEMSAS®, which allows for the accelerated identification, profiling and optimization of targeted small molecules potentially effective in the



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treatment of human diseases for which current therapy is either lacking or ineffective. COTI's business is focused on the discovery and pre-clinical development of libraries of novel, optimized lead molecules for the treatment of specific cancers, HIV and multiple sclerosis. Currently, five targeted libraries of lead compounds (small cell lung cancer, multiple sclerosis, HIV integrase inhibitors, colorectal cancer, and acute myelogenous leukemia in adults) are under active development.

For further information, please visit the website [www.criticaloutcome.com](http://www.criticaloutcome.com) or contact:

Michael Barr, Director of Business Development and Marketing

519-858-5157

[mbarr@criticaloutcome.com](mailto:mbarr@criticaloutcome.com)

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