

## FOR IMMEDIATE RELEASE

### **COTI-2 RECEIVES FAVOURABLE INDEPENDENT PRE-INVESTIGATIONAL NEW DRUG GAP ANALYSIS REPORT**

**London, Ontario (May 11, 2010): Critical Outcome Technologies Inc. (COTI) (TSX Venture: COT)** announced today that it received a favourable Pre-Investigational New Drug (pre-IND) gap analysis report from an independent team that reviewed its novel oncology drug candidate COTI-2. This represents an important milestone as the Company draws closer to a Phase 1 clinical trial.

This gap analysis is conducted prior to an initial meeting with the U.S. Food and Drug Administration (FDA) to identify potential deficiencies in the preclinical development program of a new chemical entity being considered for human clinical trials. A thorough analysis of the preclinical data package for COTI-2 by an independent team of scientific and regulatory consultants revealed no deficiencies in the COTI-2 program.

As a result, TGen Drug Development (TD2), and its investigator, Dr. Daniel Von Hoff will work with COTI to arrange an initial meeting with the FDA. COTI intends to begin the remaining IND-enabling studies with the intention of commencing a Phase 1 clinical trial in 2011. COTI will share this development with parties who have expressed a licensing interest in COTI-2, including all parties the Company met with at BIO 2010, held last week in Chicago, IL.

“We are quite pleased with this important development. We can now proceed with completing the IND enabling experiments and we look forward to our initial meeting with the FDA regarding the COTI-2 clinical development program,” said Dr. Wayne R. Danter, COTI’s President and Chief Scientific Officer.

#### **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. For example, the statement “intends to begin the remaining IND-enabling studies with the intention of commencing a Phase 1 clinical trial in 2011” is a forward-looking statement. 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 COTI-2**

COTI-2 is a novel small molecule that acts by inhibition of Akt/PKB (Protein kinase B) phosphorylation that leads to caspase-9 activation in cancer cells resulting in apoptosis or programmed cell death. COTI-2 is easily synthesized and has good *in vitro* and *in vivo* efficacy against multiple cancers including small cell lung, non-small cell lung, colon, brain, ovarian, endometrial, triple negative breast and pancreatic cancers. COTI-2 test results show it to be highly effective as a single agent therapy and as a combination therapy in a number of animal models of human cancers. COTI-2 differs from other cancer treatments in that other treatments involve the killing of healthy growing and dividing cells in the body resulting in significant toxic side effects while COTI-2 appears to target and destroy cancer cells only and has demonstrated low toxicity in normal human cells compared to human cancer cells. The combined scientific evidence indicates that COTI-2 is an ideal agent for combination therapy with current standard agents for a number of cancers. COTI is currently evaluating partners to share in the risk/reward of development via a licensing agreement for COTI-2. To request a non-confidential data package or discuss a partnership concerning COTI-2 please contact Michael Barr, Director of Business Development and Marketing at [mbarr@criticaloutcome.com](mailto:mbarr@criticaloutcome.com).

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

COTI is formed around a unique computational platform technology called CHEMSAS<sup>®</sup>, which allows for accelerated identification and optimization of targeted small molecules potentially effective in the treatment of human diseases for which current therapy is either lacking or ineffective. COTI is focused on preparing its lead anti cancer compound, COTI-2, for an Investigational New Drug filing in the USA in 2011. In addition to COTI-2, the company has a significant preclinical pipeline targeting large market opportunities such as: small cell lung and colorectal cancer, adult acute leukemia and other cancers, multiple sclerosis, HIV integrase, and Alzheimer's disease. For further information, visit [www.criticaloutcome.com](http://www.criticaloutcome.com).

### **About TD2**

TGen Drug Development (TD2), a wholly owned subsidiary of the Translational Genomics Research Institute (TGen), is a 501(c) 3 non-profit organization. TD2 provides innovative services for oncology focused biopharmaceutical companies using a dedicated team of professionals with broad experience and understanding in drug development. TD2 is uniquely positioned to support the need for improved and accelerated development of new chemical entities (NCE's) for life-threatening diseases. TD2 uses a unique combination of experience gained through its contract research organization business, and an integrated suite of proprietary and non-proprietary tools, preclinical study execution, regulatory affairs assistance, clinical trial design and management, and drug development experts to successfully move therapeutics towards regulatory approval. TD2 is dedicated to reducing the risks and uncertainty inherent in the drug development process. For more information, visit [www.td2.org](http://www.td2.org)

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