

## **Press Release**

# CRITICAL OUTCOME TECHNOLOGIES APPLIES FOR ORPHAN DRUG DESIGNATION FOR COTI-2 TREATMENT OF OVARIAN CANCER

### Orphan Drug Designation Could Serve Unmet Medical Need and Provide Significant Financial Benefits

London, Ontario (April 4, 2014): Critical Outcome Technologies Inc. ("COTI" or the "Company") (TSX-V: COT), the bioinformatics and accelerated drug discovery company, announced today it has submitted an Orphan Drug Application to the U.S. Food and Drug Administration (FDA) for its lead cancer drug candidate, COTI-2, for the treatment of ovarian cancer.

"We believe that COTI-2, with its p53 dependent mechanism of action, represents a significant therapeutic advantage over treatments currently available for ovarian and other gynecological cancers," said Dr. Wayne Danter, President and CEO. "The fact that more than 95% of ovarian cancers have a p53 gene mutation, combined with the extent of the unmet medical need in ovarian cancer patients, makes a treatment for this indication one of our top priorities. If COTI-2 is granted Orphan Drug status, the financial benefits in the future could be substantial and COTI-2 would be directed down a unique development pathway within the FDA, including the possibility of an expedited regulatory process and the potential for fewer patients to be required in clinical trials."

The Orphan Drug Designation may qualify the Company for several benefits under the U.S. Orphan Drug Act of 1983 (ODA), as amended. These benefits may include a seven-year period of orphan drug exclusivity upon product approval, fee reductions, assistance in study design from the FDA, potential for expedited drug development and eligibility for drug grants.

#### **About Orphan Drug Designation**

Under the Orphan Drug Act, the FDA may grant the Orphan Drug Designation to facilitate drug development for drugs that target conditions affecting fewer than 200,000 patients in the United States each year, while providing a significant therapeutic advantage over existing therapies. The first new drug application to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication.

#### **About Critical Outcome Technologies Inc.**

COTI is a leading-edge technology company specializing in accelerating the discovery and development of small molecules – dramatically reducing the time and cost to bring new drugs to market. COTI's proprietary artificial intelligence system, CHEMSAS®, utilizes a series of predictive computer models to

identify compounds with a high probability of being successfully developed from disease specific drug discovery through chemical optimization and preclinical testing. These compounds are targeted for a variety of diseases, particularly those for which current treatments are either lacking or ineffective.

For more information, visit www.criticaloutcome.com or contact:

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Information contained in this press release may contain certain statements, which constitute "forwardlooking statements" within the meaning of the Securities Act (Ontario) and applicable securities laws. For example, the statement "... the financial benefits in the future could be substantial and COTI-2 would be directed down a unique development pathway within the FDA, including the possibility of an expedited regulatory process and the potential for fewer patients to be required in clinical trials" and "... may qualify the Company for several benefits under the U.S. Orphan Drug Act of 1983 (ODA), as amended. These benefits may include a seven-year period of orphan drug exclusivity upon product approval, fee reductions, assistance in study design from the FDA, potential for expedited drug development and eligibility for drug grants" are forward-looking statements. 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.

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