Press Release

CRITICAL OUTCOME TECHNOLOGIES PURSUES ORPHAN DRUG DESIGNATION FOR COTI-2 INTENDED TO TREAT LI-FRAUMENI SYNDROME

Continues clinical development expansion as the Company approaches its Phase 1 gynecological cancers trial with COTI-2

London, Ontario (December 2, 2015): Critical Outcome Technologies Inc. ("COTI" or the "Company") (TSX Venture: COT; OTCQB: COTQF), announced today that it submitted an Orphan Drug Application intended for the treatment of Li-Fraumeni Syndrome (LFS) to the U.S. Food and Drug Administration (FDA) for its lead cancer drug candidate, COTI-2.

"We believe that COTI-2's impact on cancer treatment will be far-reaching," said Dr. Wayne Danter, President and CEO. "As we have noted in the past, we are pursuing multiple cancer indications with our lead asset, COTI-2. The prevalence of p53 gene mutations among people with LFS makes this a highly relevant target for COTI-2 and its unique mechanism of action. Obtaining an Orphan Drug Designation for COTI-2 in the treatment of LFS is therefore very attractive to us as the strong scientific rationale, limited competition in a niche market, and significant unmet medical need offers substantial motivation and incentive."

In addition to potential financial benefits, Orphan Drug Designation may result in COTI-2 being directed down a unique development pathway within the FDA, providing the possibility of an expedited regulatory process and the potential of fewer patients being required for clinical trials. The Orphan Drug Designation may also qualify the Company for several financial 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 development grants.

"Over the past six months the Company has been working closely with MD Anderson through its various internal review committees and processes to finalize the Clinical Trial Agreement for the Phase 1 clinical trial of COTI-2 in gynecological cancers," said Dr. Danter. "We expect to have the agreement signed in the near future and in anticipation of this, and subject to receiving the final signed agreement, we foresee commencing the trial in mid-December. During this review process, we have pursued a number of indications and combination treatment opportunities for COTI-2 with a variety of potential development partners. The application for Orphan Drug Designation for LFS is an important step in broadening the therapeutic scope of COTI-2."

About Li-Fraumeni Syndrome

LFS is a rare disorder that greatly increases the risk of developing several types of cancer, particularly in children and young adults. The risk of developing any invasive cancer (excluding skin cancer) is approximately 50% by age 30 (1% in the general population) and 90% by age 70. The exact number of the people affected by LFS worldwide is unclear with estimates of up to 10,000 people in the U.S., 10,000-25,000 in the United Kingdom and as many as 100,000 in the southern states of Brazil. LFS is characterized by early onset of tumors, multiple tumors within an individual, and multiple affected family members. In contrast to other inherited cancer syndromes, which are predominantly characterized by site-specific cancers, LFS presents with a variety of tumor types. Early onset breast cancer accounts for 25% of all the cancers in this syndrome. This is followed by soft tissue sarcomas 20%, bone sarcoma 15%, and brain tumors, especially glioblastomas, 13%. Other tumours seen in this syndrome include leukemia, lymphoma, and adrenocortical carcinoma.

LFS is most commonly caused by gene mutations in the p53 tumor suppressor gene such that approximately 70% of families with LFS having a p53 mutation. Normal p53 prevents cancer development by eliminating and inhibiting abnormal cell growth, therefore, cells with mutant p53 are more likely to become cancerous and metastatic. Most people with LFS have a genetic mutation that was passed on from a parent. Occasionally, LFS can result from a new gene mutation, without having had parents affected or a family history of cancer.

About the 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.

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

Dr. Wayne Danter
President & CEO
Tel: 519-858-5157
Email: wdanter@criticaloutcome.com

Paul Papi
Vice President Investor Relations
Tel: 508-444-6790 / 519-858-5157
Email: ppapi@criticaloutcome.com

Follow @CriticalOutcome on Twitter at http://twitter.com/CriticalOutcome

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 "… in addition to potential financial benefits, Orphan Drug Designation may result in COTI-2 being directed down a unique development pathway within the FDA, providing the possibility of an expedited regulatory process and the potential of fewer patients being required for clinical trials …" and "… may also qualify the Company for several financial benefits under the U.S. Orphan Drug Act of 1983 (ODA), as amended …" and "We expect to have the agreement signed in the near future and in anticipation of this, and subject to receiving the final signed agreement, we foresee commencing the trial in mid-December" are forward-looking statements. 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.

Neither TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.