

## **CRITICAL OUTCOME TECHNOLOGIES PLANNING PHASE 1 CLINICAL TRIAL OF COTI-2 IN RECURRENT HEAD AND NECK CANCERS**

### ***Company signs agreement with Dr. John Yoo of Western University for continued evaluation of COTI's p-53 dependent treatment***

**London, Ontario (January 20, 2015):** Critical Outcome Technologies Inc. (“COTI” or the “Company”) (TSX Venture: COT; OTCQB: COTQF), the biopharmaceutical company that uses machine learning to rapidly develop targeted therapies, announced today that it has executed a material transfer agreement (“MTA”) with Dr. John Yoo, MD, FRCSC, FACS, and his team at the London Health Sciences Centre’s London Regional Cancer Program and Western University, for the continued evaluation of COTI-2 for the treatment of patients with recurrent head and neck squamous cell cancer (“HNSCC”).

“We have tested over 1,500 chemotherapeutic agents in our head and neck cancer cell lines and COTI-2 is the most active drug that we have ever seen in our lab by an exponential factor,” said Dr. John Yoo, Chair and City-wide Chief, Department of Otolaryngology – Head and Neck Surgery at the London Hospitals and the Schulich School of Medicine & Dentistry, Western University. “Based on extremely promising cell line and animal studies, the next logical step is to try to help patients. We are eager to study COTI-2 in patients with recurrent HNSCC as well as other types of cancers.”

“COTI-2 represents a potential breakthrough treatment for recurrent head and neck cancers,” said Dr. Wayne Danter, President and CEO. “We are energized by the potential for COTI-2 given the central importance of p53 gene mutations in the most difficult to treat HNSCC tumors. Based on our preclinical test data and the substantial unmet medical need, we are now in the planning stages for a Canadian Phase 1 clinical trial of oral COTI-2 in patients with recurrent HNSCC, led by the Head and Neck Surgical Oncology team at Western’s Schulich School of Medicine & Dentistry.”

Dr. Yoo has focused his group’s translational research on the personalized treatment of head and neck cancers, evaluating the impact of novel drugs and drug candidacy on human HNSCC and other cancers of the head and neck. As a surgical oncologist and the Chief of the Division of Head & Neck Oncology and Reconstructive Surgery, he has seen first-hand the results of his group’s evaluation of the effectiveness of more than 1,500 compounds in the context of cancer gene mutation profiling. Their preliminary findings with single agent COTI-2 in HNSCC in vitro tumor models show tremendous promise with results indicating that human HNSCC cells that express p53 mutations as well as those with wild type p53 are both highly-sensitive to COTI-2. This cellular sensitivity is consistent with previous results from Dr. Jeff Myers lab in HNSCC at MD Anderson Cancer Center and the p53-dependent mechanism of action confirmed by Dr. Mills at MD Anderson in gynecological cancers.

#### **About COTI-2**

COTI-2 is a small molecule activator of misfolded mutant p53 protein currently in late pre-clinical development. Extensive studies have demonstrated COTI-2’s ability to restore mutant p53 function and thus induce cancer cell death in many common p53 mutations.

## **About Head and Neck Squamous Cell Cancer**

HNSCC is the sixth most common cancer with approximately half a million new cases annually worldwide. HNSCC is a major health care issue because of its increasing incidence. Oropharyngeal cancers (cancers of the throat, tonsils, and tongue) are increasing at a rate of 5% per year. In North America, HNSCC is still considered to be an uncommon disease, representing approximately 3% of all new malignancies, and therefore represents another opportunity for COTI-2 to obtain the advantages of an Orphan Disease Designation similar to that obtained for ovarian cancer.

For early stage HNSCC tumors, effective therapies currently include surgery or radiation. Most patients present with advanced stage disease requiring multimodality therapy that includes surgery, radiation, and platinum-based chemotherapy. Unfortunately, p53 mutations occur in 30-70% of HNSCC tumors and these tumors carry a poor prognosis as conventional treatment that includes cisplatin is often ineffective. Overall, the five-year survival rate of HNSCC patients is 40-50% and much worse for advanced stage disease. The likelihood of survival after disease recurrence is extremely low.

## **About Western University and London Health Sciences Centre**

Western delivers an academic experience second to none. Since 1878, The Western Experience has combined academic excellence with life-long opportunities for intellectual, social and cultural growth in order to better serve our communities. Our research excellence expands knowledge and drives discovery with real-world application. Western attracts individuals with a broad worldview, seeking to study, influence and lead in the international community.

The London Health Sciences Centre (“LHSC”) is one of Canada’s largest tertiary care university-affiliated hospitals with a strong oncology program. The London Regional Cancer Program based at LHSC is home to one of the largest head and neck cancer programs in Canada and sees over 400 new head and neck cancer patients annually.

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

COTI is a biopharmaceutical company using machine learning to rapidly develop targeted therapies. COTI’s proprietary artificial intelligence platform, 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](http://www.criticaloutcome.com) or contact:

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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, “...we are now in the planning stages for a Canadian Phase 1 clinical trial of oral COTI-2 in patients with recurrent HNSCC, led by the Head and Neck Surgical Oncology team at Western’s Schulich School of Medicine & Dentistry” 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.

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