



Critical Outcome
Technologies Inc.



Advancing the Treatment of Cancer Through Targeted Therapeutics

15 August 2017

CONFIDENTIAL

Company and Pipeline Synopsis

Clinical stage biotech company focused on the development of novel therapeutics for the treatment of cancers and other unmet medical needs

- **Lead drug candidate is COTI-2, targeting p53**
 - Completed patient dosing of Phase 1 trial for the treatment of gynecological malignancies
 - Safety & tolerability readout in Q3 2017
 - Secondary and exploratory endpoint analysis in process: available by year-end 2017
 - Initiated expansion arm of Phase 1 trial for the treatment of head and neck squamous cell carcinoma (HNSCC)
- **Second drug candidate is COTI-219, targeting KRAS**
 - Currently in IND-enabling studies
 - IND filing expected in early 2018
- **Pipeline-generating CHEMSAS[®] platform** – in silico high throughput screening for molecule identification
- Publicly traded company TSX-V: COT OTCQB: COTQF



COTI-2 Phase 1 in Gynecological Malignancies Complete

Completed patient dosing of Phase 1 trial for the treatment of gynecological malignancies:

- COTI-2 safe and well-tolerated at doses up to 1.7 mg/kg
- Secondary and exploratory endpoint data expected by year-end
- Enrolling patients in head and neck squamous cell carcinoma arm (HNSCC)

COTI-2 product profile:

- Oral small molecule
- FDA orphan drug status for ovarian cancer
- Preclinical studies exhibit low toxicity, high oral bioavailability and strong p53-dependent efficacy

Gynecological malignancies:

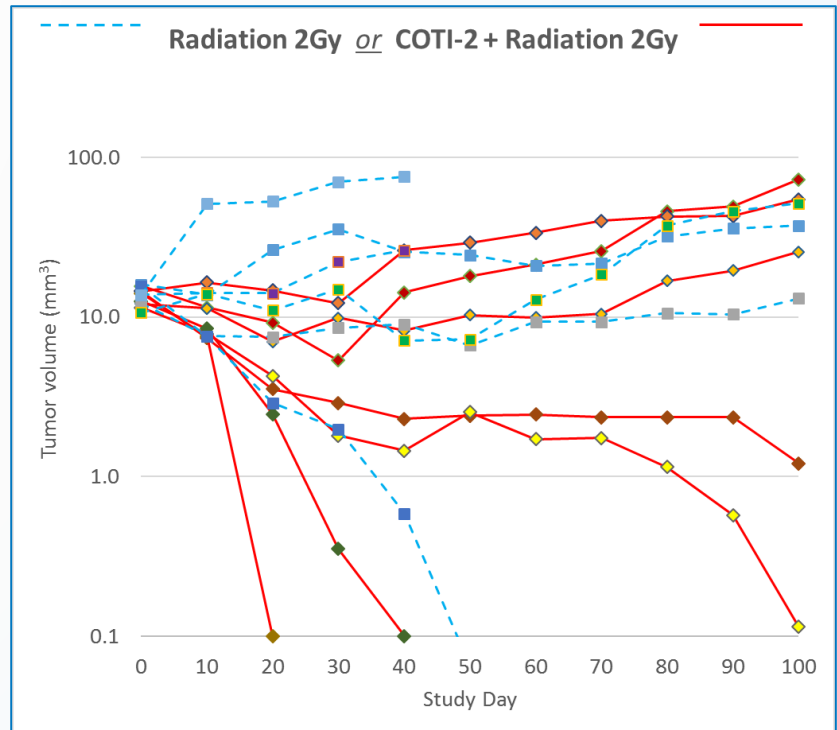
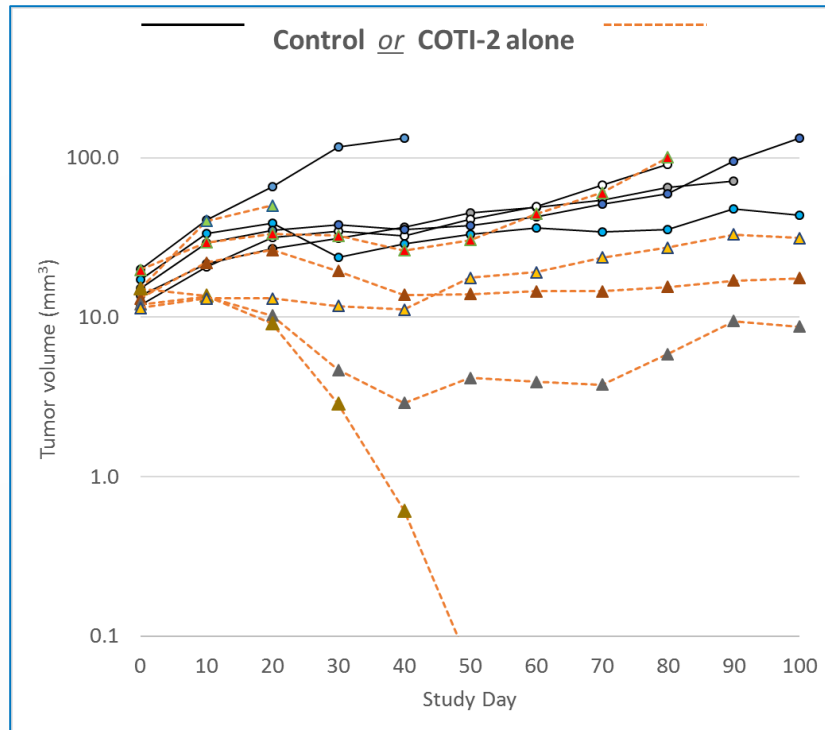
- ~100,000 patients are diagnosed with gynecological cancer per year; disease affects ~1.2M women in total (US)
- Mutant p53 occurs in ~50% of recurrent disease (~15-20,000 patients per year) and in ~96% of high-grade serous ovarian cancer
- Current standards of care (surgery, radiation, chemotherapy) associated with increased morbidity and high toxicity

COTI-2 Phase 1 in Gynecological Malignancies Complete

Primary Objectives:

1. Evaluate the safety and tolerability of COTI-2
 - 24 patients were enrolled; half of these patients continued on treatment past cycle 1 (28 days), with a subset completing up to 4 cycles of treatment
 - COTI-2 was administered at increasing dose levels between 0.25 - 1.7 mg/kg
 - Most common drug-related Adverse Events (AEs) were nausea and vomiting, fatigue and abdominal pain
2. Determine maximum tolerated dose and recommended Phase 2 dose of COTI-2
 - Dose levels of up to 1.7 mg/kg were safe and well tolerated
 - Recommended Phase 2 dose will be determined by data from the two expansion cohorts in HNSCC and ovarian cancer

Pre-clinical Efficacy Data Supporting Additional COTI-2 Indication: Head and Neck Cancers



- COTI-2, whether as a single agent or in combination with radiation, produced tumor growth inhibition relative to untreated controls in the p53-mutated head and neck cancer cell line
 - COTI-2 + radiation (2 Gy) has better tumor suppression and tumor cure effect compared with COTI-2 or radiation alone
 - Tumor growth regression was as follows: COTI-2 alone (1/6), radiation alone (1/6), COTI-2 + radiation (4/7)

COTI-2 Phase 1 Trial in Head and Neck Cancers Initiated

COTI-2 Phase 1 HNSCC trial:

- Clinical trial site – MD Anderson Cancer Center
- Initial safety and tolerability trial initiated
- Primary readout expected in Q2 2018
- FDA orphan drug designation application submitted and awaiting Agency feedback

Head and Neck Small Cell Carcinoma (HNSCC):

- ~65,000 patients are diagnosed with head and neck squamous cell carcinoma (HNSCC) per year; disease predominantly affects men, with approximately 447,000 patients identified (US)
- ~40-50% HNSCC associated with mutant p53
- Current treatments include surgery, radiotherapy and chemotherapy
- Approximately 13,000 deaths from HNSCC in the US per year, representing a clear unmet need for additional treatment options

COTI Pipeline – All Internally Discovered & Owned

	Program	Indication	Target	CHESMAS	Selection	Synthesis	Pre-Clinical	Phase 1
Core Programs	COTI-2 (Targeting p53)	Advanced or recurrent gynecological malignancies	▶					
		Ovarian & HNSCC expansion cohort	▶					
		P53 basket	▶					
		Soft tissue sarcoma	▶					
		Combination therapy	▶					
	COTI 219 (Targeting KRAS)	Multiple oncology indications	▶					
Early Stage Programs	COTI-4	Multiple oncology indications	▶					
	COTI-AML	AML	▶					
	COTI-HIV	HIV	▶					
	COTI-SOX9	SOX9	▶					
	COTI-MRSA	MRSA	▶					
	COTI-MS	Multiple Sclerosis	▶					
	COTI-AZ	Alzheimer's	▶					

Corporate Objectives 2016-2018

COMPLETED

CORPORATE

- ✓ Designated next preclinical candidate for clinical development
- ✓ Opened US office (Boston, MA)

COTI-2

- ✓ Entered into first-in-man clinical trial (US Investigational New Drug application)
- ✓ Completed Phase 1 clinical trial in gynecological malignancies at MDACC and NWU
- ✓ Published first scientific article in Oncotargets
- ✓ Broadened the clinical landscape (head and neck cancer, p53 basket trial)

COTI-219

- ✓ Initiated GMP manufacturing and IND-enabling studies

UPCOMING

CORPORATE

- Strengthen the balance sheet to execute on corporate strategies
- Opportunistically pursue regional or co-development partnerships for COTI-2, pipeline programs and other technologies

COTI-2

- Initiate combination trials with COTI-2
- Obtain additional orphan drug designations
- Complete secondary and exploratory endpoint data analysis for gynecological malignancies dose escalation phase and recommend Phase 2 dose level

COTI-219

- File IND in early 2018
- Launch first-in-man trial in early 2018

Key Company Facts

Trading	
TSX Venture ⁽²⁾	COT
Recent closing price ⁽³⁾	\$1.08
52 week range ⁽³⁾	\$1.03 - 7.60
Market capitalization ⁽³⁾	\$16,109,112
Capital	
Cash ⁽⁴⁾	\$939 k
Basic shares outstanding ⁽³⁾	14,915,844
Options outstanding ⁽³⁾	1,210,932
Warrants outstanding ⁽³⁾	1,992,277
Fully diluted shares outstanding ⁽³⁾	18,119,053
Board & management control ⁽³⁾ ⁽⁵⁾	12.1%

(1) All \$ amounts in CAD

(2) COTI also trades on the OTCQB as COTQF but amounts are for the TSXV only

(3) As of the close of business Aug 8, 2017 – post consolidation of Jun 30, 2017

(4) As at June 30, 2017 consisting of cash, cash equivalents and investments

(5) On a fully diluted basis

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