

# SMALL-CAP STARS SPRING CONFERENCE 2015

June 10 - Convene - Times Square NYC



**Critical Outcome**  
Technologies Inc.

**The Future of Drug Discovery has Arrived:  
Redefining Drug Development**

June 2015

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A biopharmaceutical company rapidly developing targeted therapies to better meet the needs of patients

- TSX-V: COT
- OTCQB: COTQF



- 1** COTI-2 – lead program in oncology entering Phase 1 in second half of calendar 2015
- 2** CHEMSAS<sup>®</sup> – proprietary drug discovery engine using machine learning algorithms
- 3** Strong pipeline of follow-on opportunities in oncology and other therapeutic areas

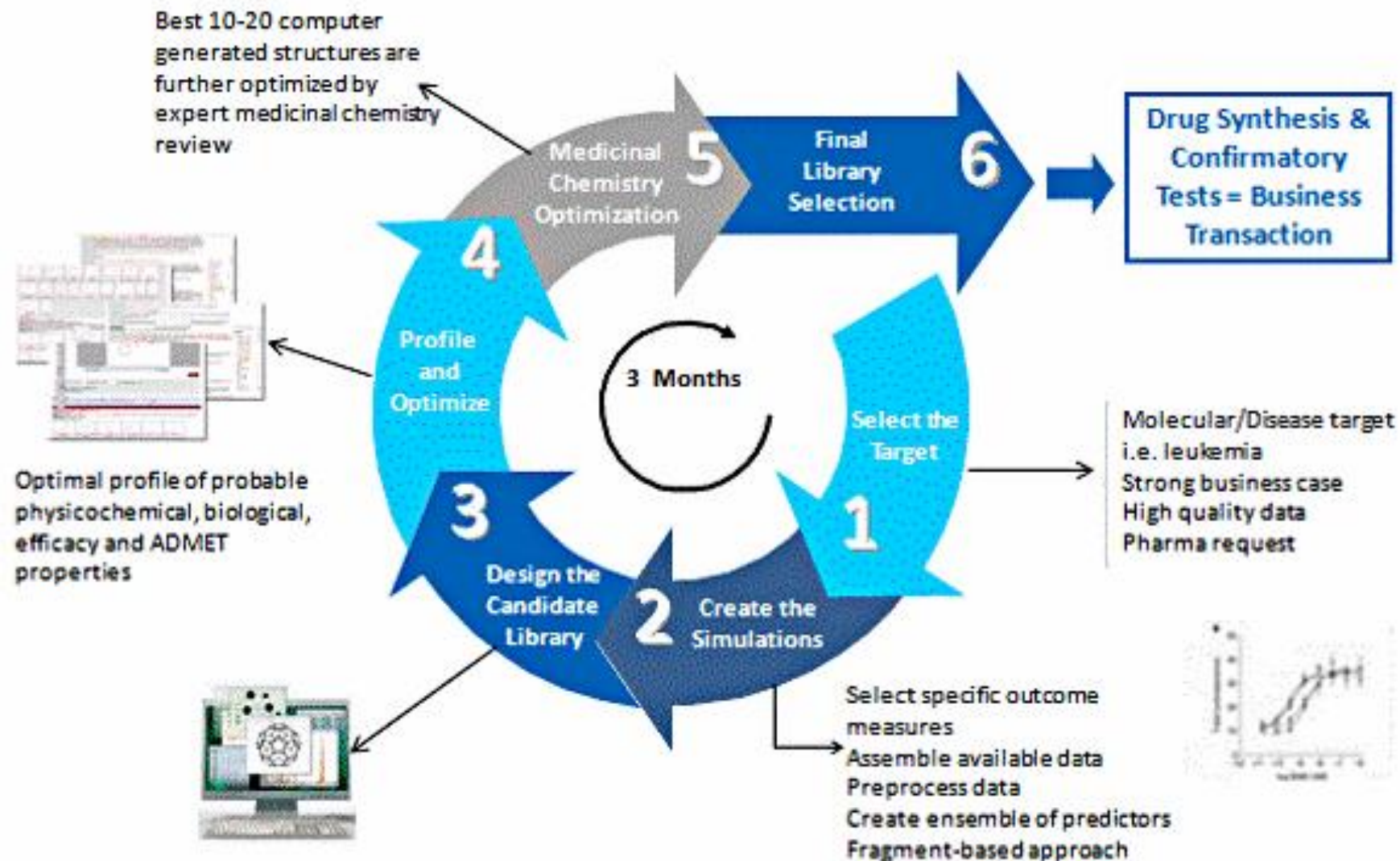
# Building a robust pipeline with CHEMSAS®

- Proprietary, machine learning (AI) based drug discovery platform technology
- Big Data analysis solutions





# CHEMSAS<sup>®</sup> technology overview

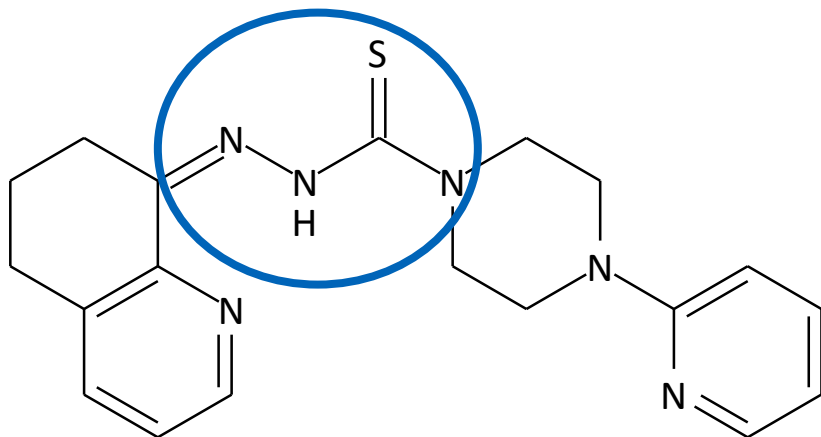


Database driven  
computational  
replication of  
traditional  
'wet lab' drug  
discovery process

Costly failed attempts  
occur **quickly & cheaply**  
in computer simulations,  
not the 'wet lab'

**Increased probability** of  
clinical & commercial  
success

- 3rd generation  
Thiosemicarbazone



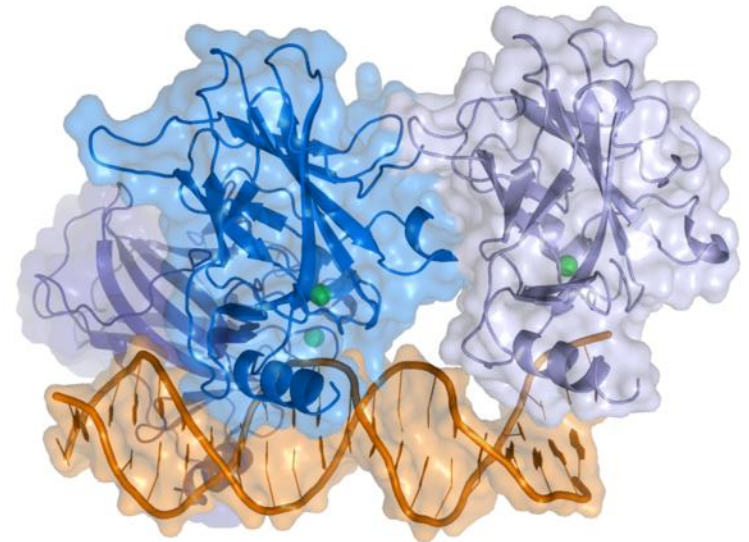
- A small molecule discovered by our CHEMSAS<sup>®</sup> process
- Engineered for low toxicity and easily synthesized in 3 steps
- Demonstrates strong *in vitro* and *in vivo* activity



# COTI-2: Potential breakthrough for many cancers

- Novel Mechanism of Action reactivates p53 function
- Effective against many common cancers with a p53 gene mutation
- > 50% of all human cancers have at least one p53 gene mutation

**“a promising advance” for many cancers with p53 mutations.”** – Dr. G.B. Mills, MDACC



# What is p53?

- p53 is a tumor suppressor gene
  - meaning that it normally helps control the growth and division of cells
- Mutations in this gene can allow cells to divide in an uncontrolled way and form tumors
- p53 mutations are also associated with permitting other genetic and environmental factors to affect the risk of cancer

# COTI-2: the pathway to the clinic

- Granted orphan drug status for ovarian cancer by FDA in June 2014
- Completed final pre-clinical studies required by the FDA
- Signed LOI with MD Anderson for Phase 1 clinical development
- IND approved by FDA on May 22, 2015
- Initiating Phase 1 clinical trial in second half of 2015
- Phase 1 completed early 2017



# COTI-2: strong & broad market opportunity

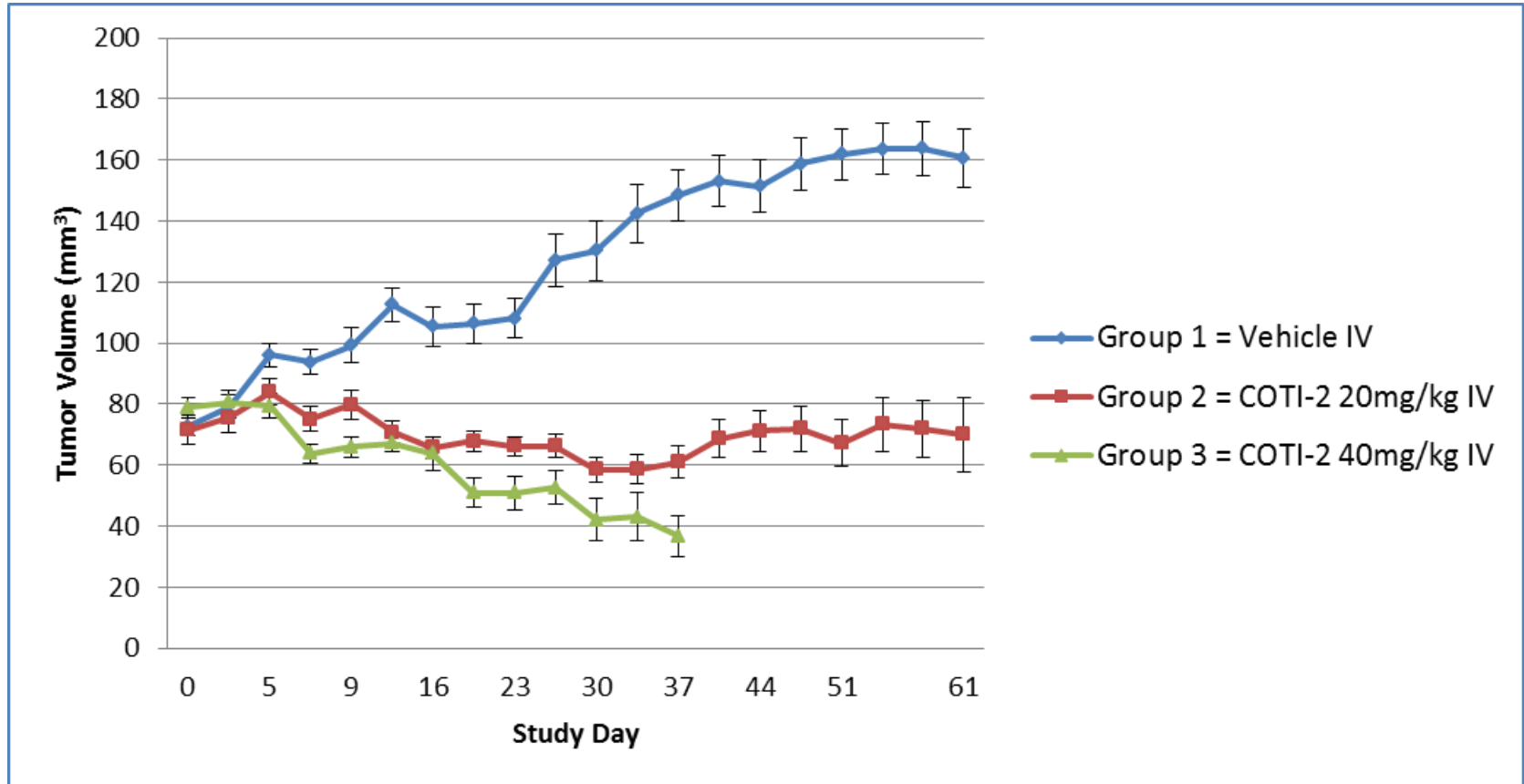
- ~ 95% of ovarian cancer patients have a p53 gene mutation
- Many other cancers with p53 mutations
- Exploring clinical studies for other indications:
  - Head and neck (orphan)
  - AML (orphan)
  - NSCLC
  - Li-Fraumeni syndrome (orphan)
- Combination treatment: COTI-2 effective when combined with many first line therapies:
  - Chemotherapy
  - Immunotherapy

Expanding the Market Potential for COTI-2

# COTI-2: first- and best-in-class potential

- Novel p53-dependent mechanism of action confirmed by Dr. Gordon Mills at MD Anderson Cancer Center
- Orally bio-available and effective at low dose
- Low toxicity in preclinical development
- Opportunity for single agent and combination therapy
- Strong IP protection in place
  - 6 U.S. patents issued
  - 1 Japanese, 1 Canadian and 1 EU patent issued
  - Additional patents pending

# COTI-2 and tumor volumes



Tumors significantly reduced by COTI-2 in all treatment groups relative to vehicle control



# MD Anderson relationship

- “Key Opinion Leader” independently confirmed COTI-2’s novel p53-dependent MOA
- Confirmed COTI-2’s selective & potent anti-cancer activity
- Identified effective dosage 60% lower than in prior animal experiments

# COTI-2 Scientific Advisory Board

Dr. Gordon Mills from the University of Texas MD Anderson Cancer Center, Houston, TX, Chairman

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Dr. Douglas Levine from the Memorial Sloan-Kettering Cancer Center in New York City, NY

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Dr. David Parkinson from New Enterprise Associates in Menlo Park, CA

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Dr. Marshall Strome from the Center for Head and Neck Oncology at Roosevelt St. Luke's Hospital in New York City, NY

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Dr Wayne R Danter, Chief Scientific Officer, Critical Outcome Technologies, London, Canada



# COTI-2: next steps

Complete Phase 1: up to 46 women with gynecologic cancers

Expand the cancer indications and combination therapies

Develop early collaborations or Phase 2 partnership(s)



# Next Clinical Candidate(s)

Options are:

- 1 - COTI-219, a unique oncology drug candidate for CRC and melanoma
- 2 - COTI-AML -01, a multi-kinase inhibitor for Acute Myelogenous Leukemia (AML)
- 3 - COTI - HIV-II, second generation dual HIV Integrase inhibitor
- 4 - COTI - MRSA1 - highly novel antibiotic

All potential candidates discovered by our CHEMSAS platform

# Strategic milestones for 2015

- 1 Advance COTI-2 into the clinic – Q2 – **IND granted**
- 2 Appoint SAB with key oncology experts – Q2 **✓**
- 3 Develop additional collaborations and partnerships with COTI-2 and CHEMSAS<sup>®</sup> - **In progress**
- 4 Increase value of COTI-2 by identifying new indications and combination therapies – **HNSCC ✓**
- 5 Build pipeline by leveraging opportunities through CHEMSAS<sup>®</sup>
- 6 Select next pre-clinical candidate for development



# Critical Outcome

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