

28 October 2014



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By E-lodgement

The Company Announcements Platform
ASX Limited

ROADSHOW PRESENTATION

Virax Holdings Limited is pleased to provide its shareholders with the presentation that Managing Director Robert Crombie will be presenting at the roadshows being undertaken in Melbourne, Sydney and Perth this week.

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Monsoon Communications

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Managing Director

Ph: +61 (0) 439 361 331

About Virax

Virax is a clinical stage oncology company currently engaged in the development of novel products for the treatment of cancer. It holds an exclusive worldwide license to the novel cancer compound GGTI-2418 for the treatment of multiple myeloma, breast and pancreatic cancer.

GGTI-2418 is expected to enter Phase 1b/2 clinical trials in breast cancer and multiple myeloma in early 2015.

In addition, the company has granted a license to major French biotechnology company Transgene for access to its Co-X-Gene™ technology for use in two of Transgene's immunotherapeutic products. These are TG4001 – a treatment for pathologies relating to human papilloma virus (HPV) infection that can lead to oropharyngeal (head and neck) cancer and TG4010 – a treatment for non-small cell lung cancer (NSCLC).



Aktivate Acquisition launches Virax into a multi-product, clinical stage leading ASX-listed company

28th October 2014

*Dr Rob Crombie
Managing Director
Virax Holdings Limited*

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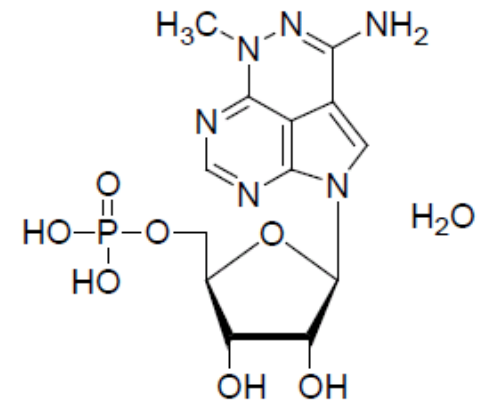
Virax Holdings is an ASX-listed clinical stage oncology company developing products that block critical RAS and AKT cancer growth pathways

Following the acquisition of AKTivate's TCN-P technology, Virax's pipeline will be one of the deepest of any ASX listed biotech



TCN-P Investment Highlights

- Two human clinical trials already underway in breast (Phase 1b/2) & ovarian cancer (Phase 1b)
- **Both trials funded by US Govt grants**
- Third clinical trial in Leukemia (Phase 1b) to commence early 2015
- GMP drug manufacturing complete
- Robust intellectual property portfolio with long patent life
- Attractive acquisition terms with deferred payments against value-creating milestones
- Impeccable scientific provenance from leading US institutions
- AKT drug target an area of intense interest by big pharma



TCN-P

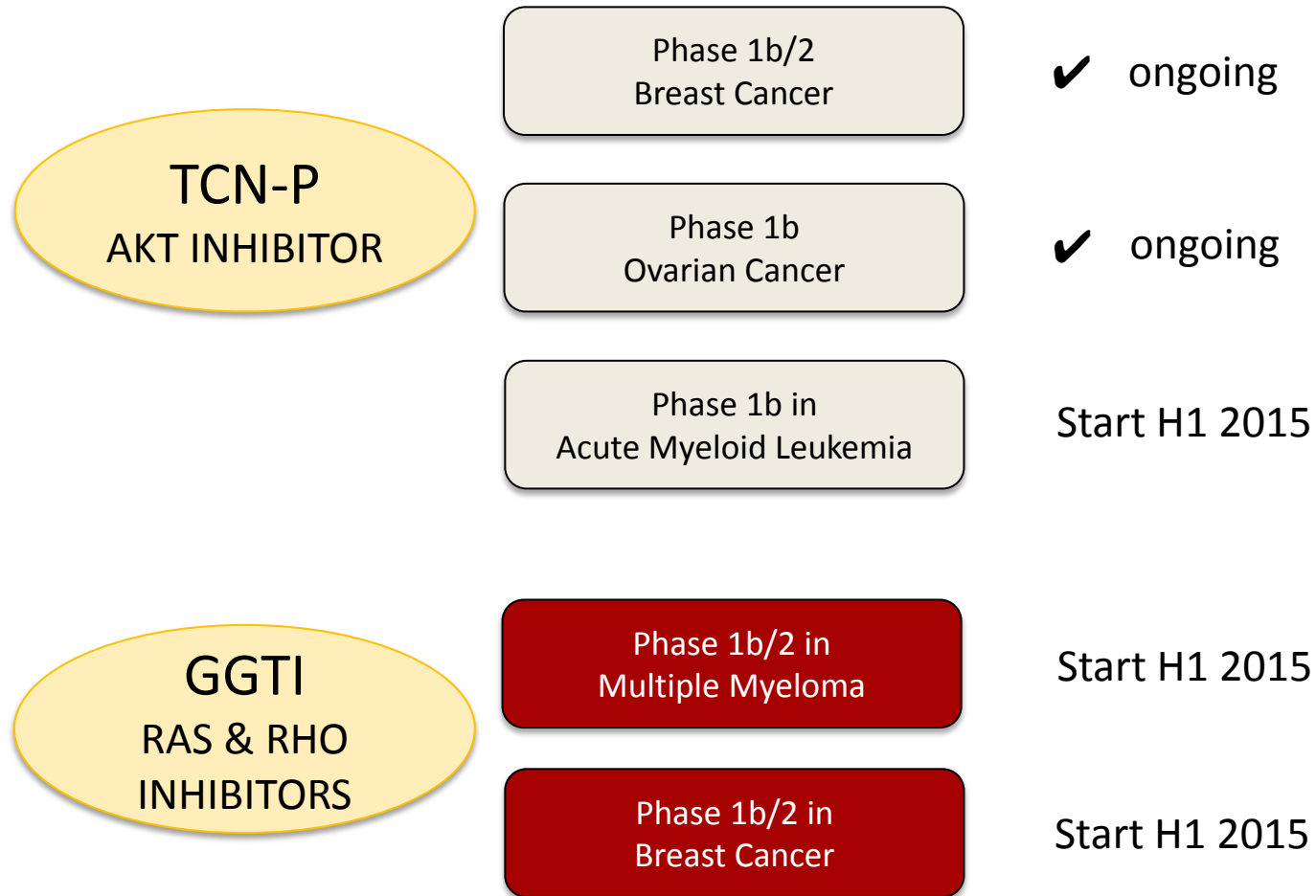
TCN-P Acquisition Metrics

- Attractive acquisition terms for Virax, with majority consideration linked to significant milestones that will ratchet up inherent value of Virax
- Cash consideration up-front – US\$300K
- 234 m shares comprising
 - 134m shares upfront
 - 100m shares on achieving clinical success milestones

(m)	Shares	Unlisted options
Securities currently on issue	920m	87m
Upfront Pathway consideration	134m	
Total	1054m	87m

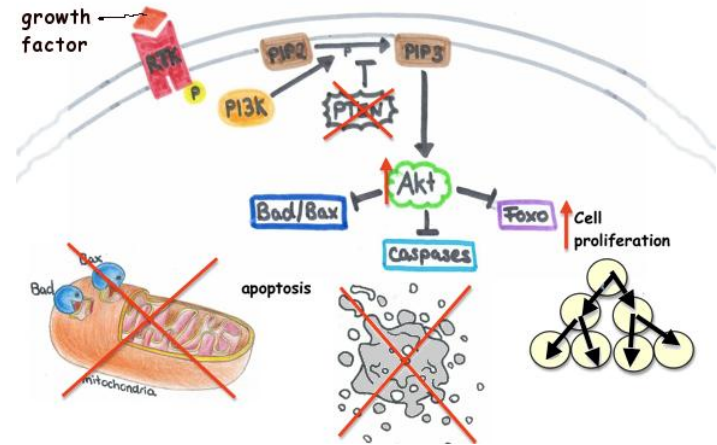


Deep Clinical Pipeline Post Acquisition



What is TCN-P & AKT?

- AKT plays key role when activated causing cancer cells to grow
- TCN-P is a small molecule that blocks the AKT growth signal inside cancer cells
- Many human cancers contain activated AKT including breast, ovary, leukemia and pancreatic cancer
- AKT associated with a resistance to chemotherapy & shortened patient survival time
- TCN-P blocks AKT and inhibits cancer growth & causes the cancer cells to die
- TCN-P overcomes resistance to chemotherapeutic agents



TCN-P Acquisition Highlights

- Acquisition transforms Virax into one of the deepest clinical stage companies on the ASX
- Funded almost entirely in Virax shares with deferred consideration back-ended against clinical milestones
- **100+ patients dosed.** Extensive clinical trials at prestigious centers such as MD Anderson, Moffitt Cancer Center and Memorial Sloan Kettering Cancer Centre
- **Two current fully funded clinical trials in breast & ovarian cancer** at prominent US cancer centers – Montefiore Medical Centre & Moffitt Cancer Centre.
- **Funding from National Cancer Institute & US Department of Defense grants**



TCN-P Acquisition Highlights cont...

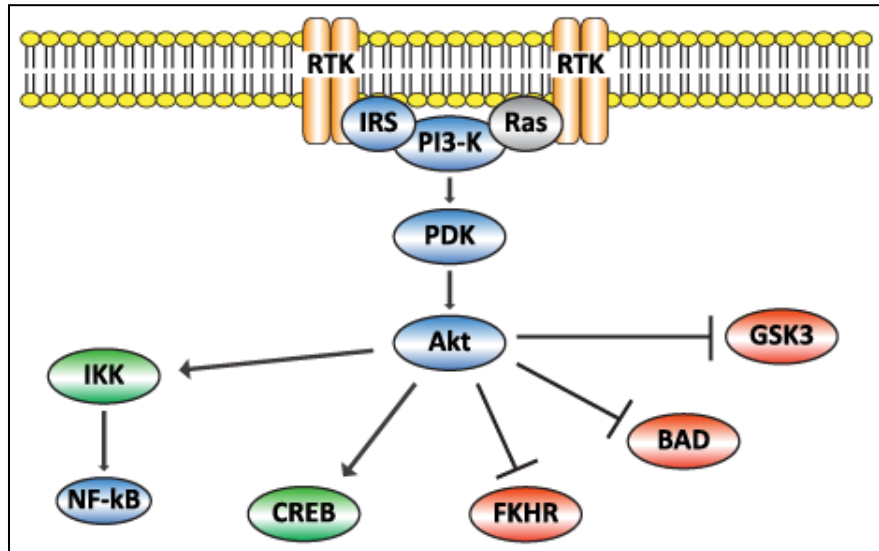
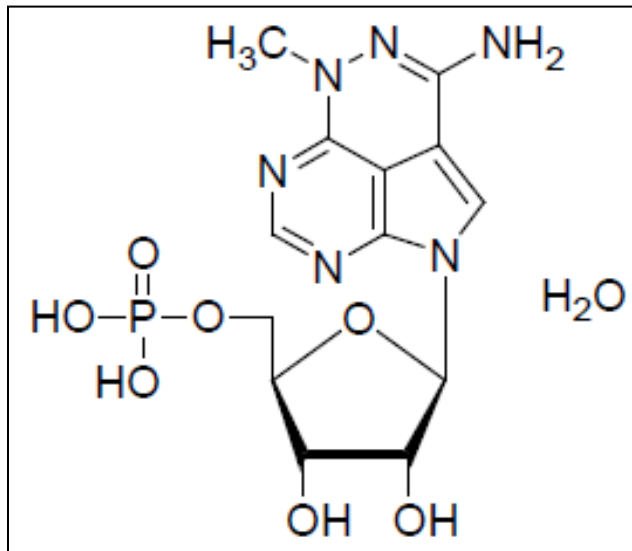


- Phase 1b/2 breast cancer trial in 36 patients well underway at Montefiore Medical Center (Albert Einstein) New York with 15 patients treated to date
- Phase 1 ovarian cancer has now commenced at Moffitt Cancer Center in Florida in 15 patients
- Phase 1 trial in Acute Myeloid Leukemia to commence early 2015
- GMP drug manufacturing complete with sufficient drug material to complete trials
- Robust intellectual property with foundational patent recently issued in 2013 – long patent life
- Significant investment in the drug to date (\$10+m)



How Does TCN-P Work?

- TCN-P is an AKT inhibitor with novel mechanism of action
 - High preferential binding to AKT – mitigates off-target toxicity
 - Binds to AKT and blocks membrane recruitment (key to activation)
- Broad therapeutic implications for cytotoxic regimens where tumor cells can use multiple resistant pathways



TCN-P: Promising Pre-clinical & Clinical Studies

- National Cancer Institute
 - Discovered as an AKT inhibitor in random screen of compound library (“NCI Diversity Set”)
- MD Anderson & H Lee Moffitt
 - Supported Pre-clinical & clinical development
 - Published significant peer reviewed papers
 - Gained successful grant applications for ongoing Phase 1/2 trials in advanced breast & ovarian cancers
- Robust proof-of-concept data compilation for use as combination agent to potentiate gold-standard chemotherapy regimens



TCN-P Highlights from Multiple Clinical Studies

- Early Phase 1/2 programs: NCI
 - Initial studies showed activity in cervical, colorectal, sarcoma & leukemia, thyroid, multiple myeloma & SCC
 - Dosing by continuous infusion caused toxicity
- Phase 1/2 programs: H Lee Moffitt & MD Anderson
 - Established drug as an AKT inhibitor with novel dosing regime to reduce toxicity issues
 - Established drug as an AKT inhibitor in synergy with chemotherapeutic agents
 - Established effective biological dose as a combination therapy
 - Leukemia: Phase 1 study demonstrated potent reduction in malignant myeloblasts & improvement in platelet/neutrophil counts (Moffitt & MD Anderson)



TCN-P: Current Phase 1b/2 Breast Clinical Program

- “TCN-P Plus Paclitaxel followed by Dose-Dense Doxorubicin and Cyclophosphamide in Patients with Metastatic and Locally Advanced Breast Cancer”
- PI: Joseph Sparano MD FACP, Albert Einstein College of Medicine Montefiore Medical Center
- Funded by National Cancer Institute R01 grant
- Phase 1
 - 15 patients already dosed (1 more for Phase 2 dose selection)
- Phase 2
 - N=36
 - Interim analysis: 18 patients
 - Planned initiation: Q1 2015



TCN-P: Current Phase 1b Ovarian Clinical Program

- Triciribine & Carboplatin in platinum resistant ovarian cancer
 - PI: Patricia L Judson MD, Moffitt Cancer Center
 - Funded by US Dept of Defense grant
 - Phase 1b - commenced
 - 3-6 patients; dose-escalation (5 levels); MTD
 - Phase 2
- N=18



Dr Patricia Judson, Principal Investigator –
Center for Women's Oncology Moffitt



TCN-P: Proposed Phase 1b Leukemia Clinical Program

- Phase 1b TCN-P plus cytarabine in refractory or relapsed acute leukemia
- PI: Jeffrey E Lancet MD, Moffitt Cancer Center
- Protocol approved; ready to initiate
 - Refractory patients in combination with cytarabine
 - 6 patients; dose-escalation (5 levels); MTD
 - Up to 10 additional patients enrolled at the MTD
 - Phase 2 studies to follow



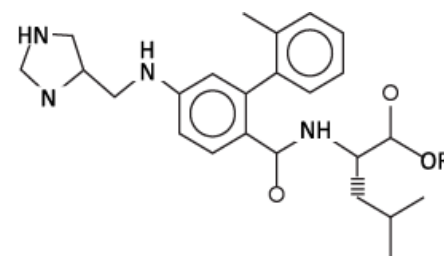
TCN-P: Low Risk Acquisition

- **Minimal financing/capital risk** – if Virax chooses not to recruit additional centres, both trials are funded through US Govt grants
- **No manufacturing risk** – the drug is made, is at drug storage depot, being administered to patients in breast trial & shortly be dosed in ovarian patients
- **Minimal regulatory risk** – IND is active/FDA approved
- **Minimal clinical trial execution risk** – Principal Investigators in place at Moffitt & Albert Einstein, protocols approved, trial sites committed & underway



What is GGTI-2418?

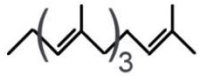
- Aberrant Ras growth signaling plays a crucial role in cancer
- GGTI-2418 is a novel small molecule drug that blocks a key enzyme GGTI that activates the Ras (Rho) pathway
- GGTI-2418 blocks uncontrolled cell growth and kills the cancer cell
- Technology is the invention of Prof Andrew Hamilton at Yale University and Prof Said Sebtì of Moffitt Cancer Center
- Technology licensed from Yale University early 2014
- Yale is 3rd largest shareholder in Virax



GGTI-2418

How Does GGTI Work?

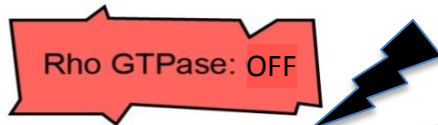
Geranylgeranyl
Or 'GG', is a type of
'lipid' (a fat or oil)



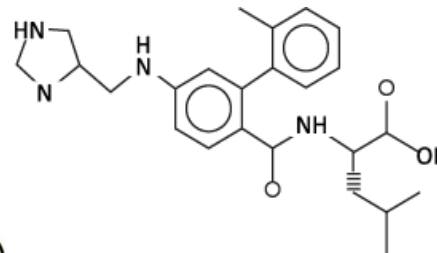
'Active' Rho GTPase
needs an attached GG
lipid to signal correctly



Rho is activated causing
uncontrolled cell growth -
cancer



Rho is switched off
and cancer cell dies



GGTI-2418

GGTI-2418 blocks GGTI
from activating Rho

GGTI : Phase 1 Clinical Trial Completed

Patients	13
Trial Centres	Indiana University & University of Pennsylvania
Patient Inclusion	Advanced solid tumors for which standard treatments failed – “refractory”
Methods	GGTI-2418 as a 30-min IV infusion on Days 1-5 every 21 days.
Study Objectives	<ul style="list-style-type: none">• Determine dose limiting toxicity (DLT) & maximum tolerated dose (MTD)• Assess safety, tolerability & pharmacokinetics• Observe clinical response & explore biomarkers predictive of GGTI-2418
Summary	<ul style="list-style-type: none">• GGTI-2418 well tolerated with nausea as main adverse event• Elevation in Liver Function Test identified as the dose limiting toxicity, with the LFTs returning to baseline upon discontinuation of GGTI-2418• GGTI-2418 plasma concentrations were dose proportional & far exceeded concentrations required for in-vitro inhibition of geranylgeranyl transferase I• Stable disease achieved in 4 cancer patients



INDIANA UNIVERSITY



GGTI: Future Studies: Phase 1b/2 in Myeloma & Phase 1b/2 in Breast

Multiple Myeloma

- Bone marrow cancer arising from plasma cells
- 24,000 new cases each year in US, 1500 in Australia
- High mortality rate, large unmet medical need
- Phase 1b dose escalation in >18 patients to determine safe & effective dose for Phase 2
- Phase 2 – GGTI-2418 in combination with Velcade™ standard of care in >36 patients
- To be conducted at Moffitt Cancer Center



Dr Melissa **Alsina** is associate professor & head of multiple myeloma program at the H Lee Moffitt Cancer Center



Montefiore

Breast cancer

- Most common cancer in American & Australian women
- >200,000 new cases in US & >13,000 new cases in Australia each year
- High unmet medical need for advanced disease
- Phase 1b dose escalation stage to determine safe & effective dose for Phase 2
- Phase 2 – GGTI-2418 in combination with paclitaxel Taxol™ in HER2/ER/PR negative cancer
- Design to include p27 diagnostic to identify patients most likely to respond
- To be conducted at Albert Einstein Montefiore Medical Center




virax

Minimal Manufacturing Risk

TCN-P

- Manufactured by KP Pharmaceuticals
Bloomington, Indiana
- GMP drug is complete and held at drug depot
- Sufficient supplies for clinical trials



GGTI

- 5 kgs of GMP grade Active Pharmaceutical Ingredient already manufactured for conversion to final formulation
- API manufactured by Syntagon
- API, bulk & patient ready drug, stored at Catalent



Robust Intellectual Property Portfolio

TCN-P

- IP estate anchored by “foundational” patent issued Jan 2013
- Established TCN-P as a targeted therapy by specifying cancer patients with AKT over-expression
- Sets stage for approval of >8 pending related applications in 2013-14 to use TCN-P in combination with current standard-of-care regimens
- Multiple existing combination-use patents across several tumour types
- Pending applications in EU, Canada, Japan, Hong Kong, Australia

GGTI

- Strong Composition of Matter patent covering “Piperazinone compounds as anti-tumour and anti-cancer agents & methods of treatment”
- Patent Life: 2025 with possibility to extend to 2030
- Methods of Use patent for “Inducing tumour regression, inhibiting tumour growth & inducing apoptosis in breast tumours with geranylgeranyltransferase inhibitors”
- Publication Date: August 5, 2010
- Opportunities to establish new IP rights



Regulatory Risk Minimised

TCN-P

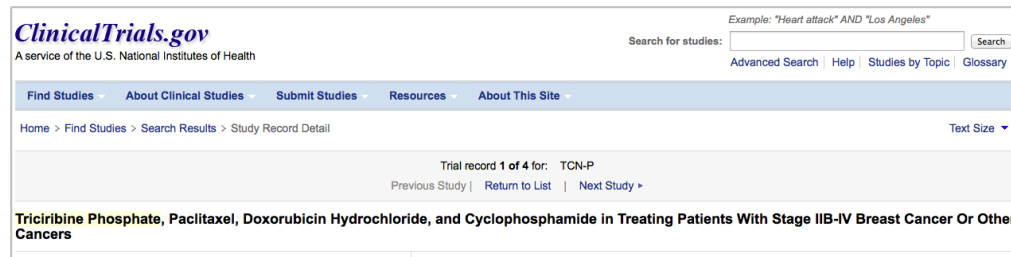
- Active IND
- Currently recruiting Phase 1b/2 breast cancer trial at Albert Einstein College of Medicine
- Currently recruiting Phase 1b ovarian cancer trial at Lee

Moffitt

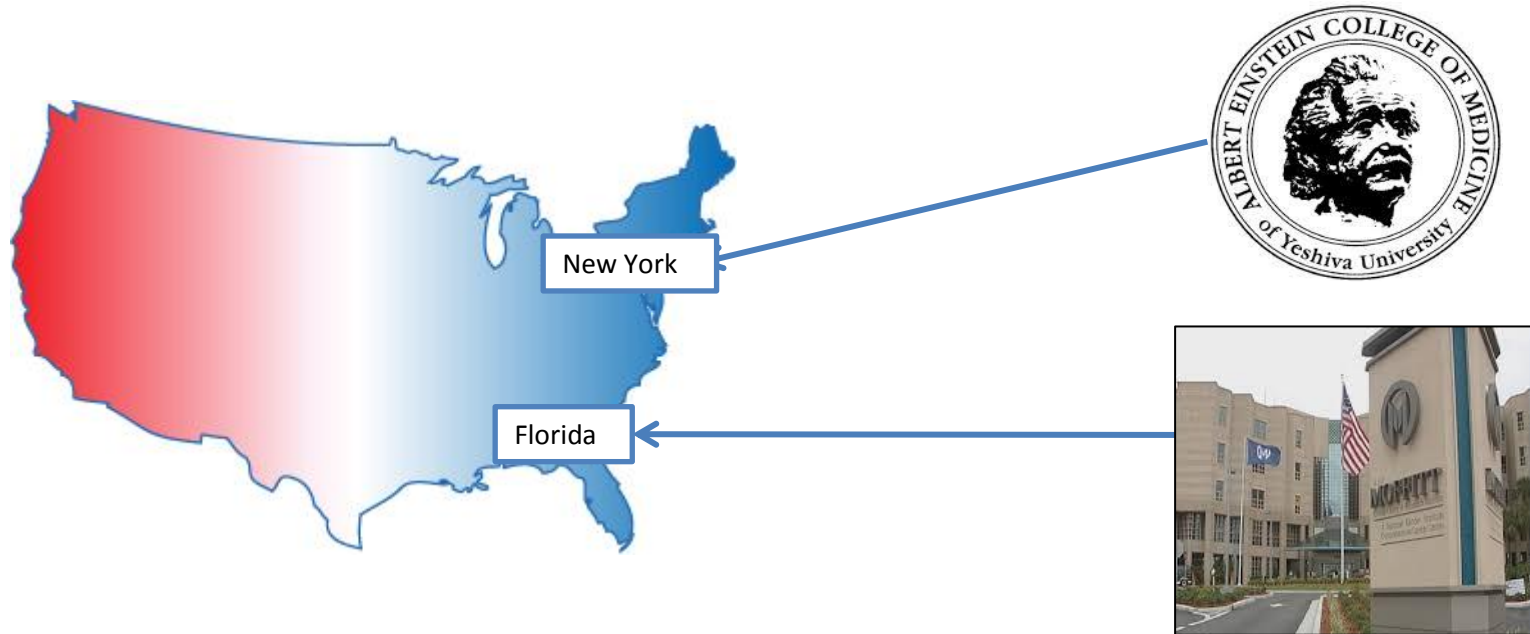


GGTI-2418

- IND inactive
- CRO (Ground Zero Pharma) engaged to reactivate IND for multiple myeloma trial at Moffitt & breast cancer trial at Montefiore Medical Center in NY



Outstanding Scientific Provenance, World Class Centres & Collaborations



PREVIOUS CLINICAL TRIALS

THE UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER
Making Cancer History®



MEMORIAL SLOAN-KETTERING
CANCER CENTER



virax

Extensive Peer Review Publications

2013



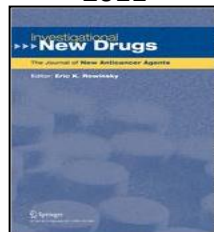
Leuk Res.
2013 Nov;37(11):
1461-7
PMID: 23993427

2013



Cell Cycle.
2013 Jul 1;12(13):
2024-32.
PMID: 23777806

2011



Invest New Drugs.
2011 Dec;29(6):
1381-9
PMID: 20644979

2011



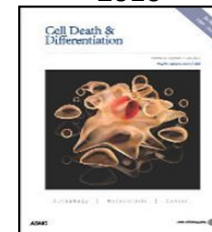
Nat Protoc.
2011 Oct 27;
6(11):1775-91.
PMID:
22036881
2007

2011



Clin Cancer Res.
May 1, 2011;
17(9):
2852-2862.
PMID: 21536547
2006

2010



Cell Death Differ.
2010 Nov;17(11):
1795-804.
PMID: 20489726

2009



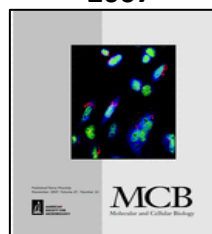
Mol Cell Biol.
2009 Apr;29(8):
2254-63.
PMID: 19204084

2008



Chemistry.
2008; 14(5):
1392-401.
PMID: 18200641

2007



Mol Cell Biol.
2007 Nov;27(22):
8003-14.
PMID: 17875936



Oncogene.
2007 Feb 1; 26(5):
633-40.
PMID:16909123

2006



Life Sci.
2006 Sep 5; 79(15):
1484-92.
PMID: 16740276

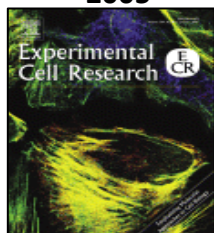


Org Biomol Chem.
2006 May 7; 4(9):
1768-84.
PMID: 16633570

Note: The slide contains only key publications out of 43 publications by Prof Saïd M. Sebti on GGT1

Extensive Peer Review Publications – cont.

2005



Exp Cell Res.

2005 Apr 1;
304(2):
354-64.

PMID: 15748883

2005



J Surg Res.

2005 Apr; 124(2):
256-63.

PMID: 15820256

2005



Bioorg Med Chem.

2005 Feb 1;
13(3):677-88.

PMID: 15653335

2005



Biochem Pharmacol.

2005 Jan 1; 69(1):
87-95.

PMID: 15588717

2004



Oncogene.

2004 Jan 22; 23(3):
706-15.

PMID:14737105

2004



Cancer Res.

2004 Jul 1;64(13):
4394-9.

PMID:15231645

2003

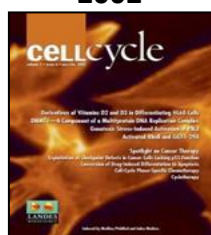


Cancer Res.

2003 Dec 15;
63(24): 8922-9.

PMID:14695209

2002

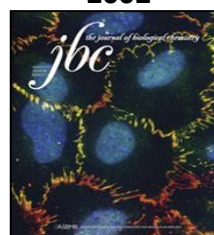


Cell Cycle.

2002 Nov-Dec;
1(6):
430-7.

PMID:12548020

2002

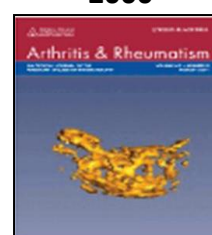


J Biol Chem.

2002 May 3;
277(18): 15309-
16.

PMID:11839765

2000



Arthritis Rheum.

2000 Jul; 43(7):
1624-32.

PMID:10902768

2000

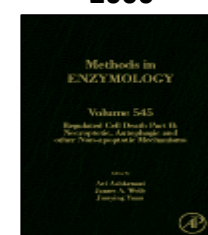


J Bone Miner Res.

2000 Aug; 15(8):
1467-76.

PMID:10934645

2000



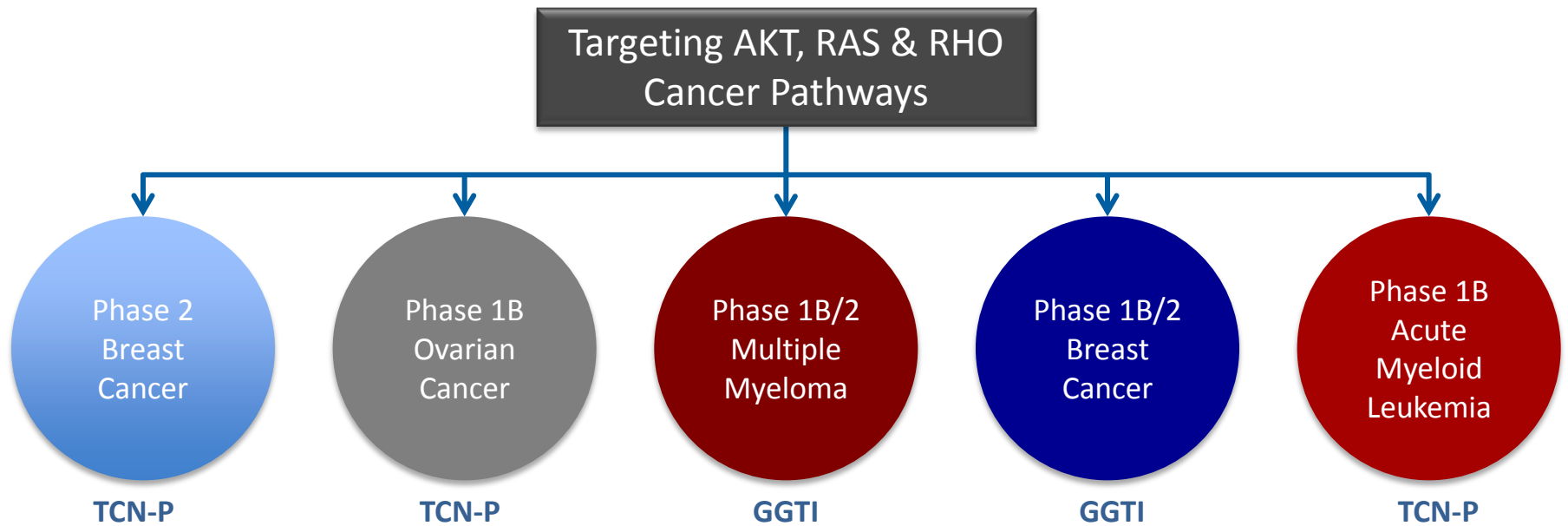
Methods Enzymol.

2000; 325:
381-8.

PMID:11036620

Note: The slide contains only key publications out of 43 publications by Prof Saïd M Sebt on GGT1

Post Completion of AKTivate Acquisition
2 Drugs in 5 Clinical Trials Under 2 INDs



Pronounced Valuation Anomaly

2 novel cancer pathways
+
5 clinical trials
+
2 INDs
+
2 leading US cancer centres



Market Cap = \$6m?

ASX		
Company	No. of Clinical Trials	Market Cap
Mesoblast	5	\$1.4 b
Starpharma	1	\$188m
Bionomics	2	\$177m
Alchemia	3	\$165m
Prana	1	\$67m
Clinuvel	3	\$55m
Prima	1	\$57m
Viralytics	1	\$50m
Innate Immuno	1	\$29m
Phosphagenics	4	\$82m
Benitec	1	\$130m

TCN-P: Near Term Value Inflection 2014-2016

Milestone TCN-P	2014	2015	2016-17
Initiate Phase 1b (Ovarian) ²			
Complete Phase 1b (Breast) ¹			
Initiate Phase 2(Breast) ¹			
Complete Phase 1b (Ovarian)			
Complete Phase 2 (Breast) ¹			
Initiate Phase 3 (Breast) ¹ Phase 2 (Ovarian) ²			

1. Funded by National Cancer Institute RO1 Grant

2. Funded by US Dept of Defense Grant



GGTI: Near Term Value Inflection 2014-2016

Milestone GGTI	2014	2015	2016-17
Reactivate Breast IND			
File IND for Multiple Myeloma			
Open Multiple Myeloma Trial			
Open Breast Trial			
Close Multiple Myeloma Trial			

Rich News Flow Over Next 18 Months

- Dose first patient in ovarian trial at Moffitt with TCN-P drug
- Complete Phase 1b breast cancer trial for TCN-P at Albert Einstein Medical Center
- Pre-IND meeting with FDA
- Re-opening of breast cancer IND
- Allowance of multiple myeloma IND
- Stability testing complete on GGTI drug completed
- Appoint CRO to recruit additional centres for GGTI
- Appoint CRO to recruit additional centres for TCN-P
- Dose first patient in Phase 1b multiple myeloma trial at Moffitt with GGTI drug
- Dose first patient in Phase 1b breast cancer at Montefiore Cancer Centre with GGTI drug
- Initiate Phase 2 breast cancer trial for TCN-P at Albert Einstein Medical Center
- Interim analysis of Phase 2 breast cancer trial for TCN-P at Albert Einstein Medical Center



Executive Leadership



Rob Crombie – Managing Director

18 years background in private & public markets in the UK & Australia with a strong business development track record in closing significant deals between biotechnology & pharmaceutical companies

Formerly head of Melbourne operations at Arana Therapeutics & was instrumental in driving from start-up phase as EvoGenix through IPO to a \$318m cash sale to Cephalon (Teva Pharmaceuticals)



Paul Hopper – Executive Director

20 years experience in international public company markets with a focus on start-ups. Served as either CEO, chairman, non-executive director of 14 public companies in the US, Australia & Asia

Advisor at Los Angeles-based Cappello Group where he is Head of the Life Sciences and Biotechnology Group responsible for mergers & acquisitions & capital raisings focusing on the biotech/life sciences sectors

Executive Chairman of Imugene Ltd & Viralytics Ltd



Scientific Advisory Board

Professor Joseph Sparano



- Professor of Medicine and Professor of Obstetrics, Gynecology and Women's Health at the Albert Einstein College of Medicine, New York
- Associate Director for Clinical Research at the Einstein Cancer Center, NY
- Associate Chair for Disease Oriented Research in the Eastern Cooperative Oncology Group
- Chair of the ECOG-ACRIN Breast Cancer Committee
- Member of Breast Cancer Steering Committee
- Authored or coauthored ~200 original publications

Professor Douglas Joshua

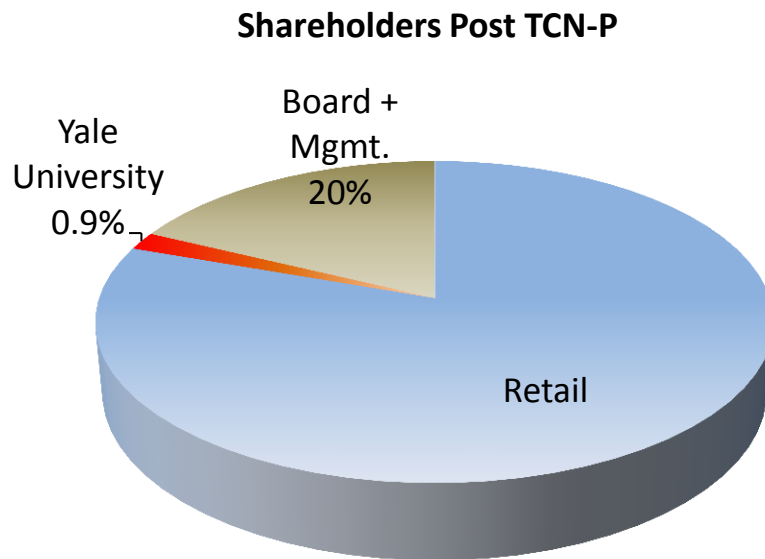


- Emeritus Professor of Haematology at the Sydney University Medical School
- Consultant Haematologist, Royal Prince Alfred Hospital
- Member of the International Myeloma Foundation
- Head of Clinical and Laboratory Haematology at Sydney Cancer Centre
- Head of Sydney South Western Area Health Service Haematology
- Former Director of the Institute of Hematology, Royal Prince Alfred Hospital
- Chairman of the Blood Clinical and Scientific Advisory Committee (BCSAC)



Corporate Summary

- Ticker Code: VHL
- Share Price: 0.05 cents
- Market Cap: A\$4.6m
- Cash Position: \$3.8m as at 30/6/14
- Total Issued Capital: 920m shares
- Options: 87m @ 0.05 cents
- Top 20 Own: 33%



Total issued capital post TCN-P acquisition = 1054 m

Why Invest?

Compelling Low Valuation	Pronounced valuation discount compared to other ASX biotechs & international peers in Phase 2. Re-rating highly likely from low market cap
Significant Investment to Date	~\$20m invested to date
News Flow	Numerous milestone announcements & valuation inflexion points over next 12 months for investors
Strong Scientific Provenance	Compelling science from leading US cancer institutes
Proven Leadership & Management	The right, experienced, successful team on board to aggressively drive TCN-P & GGTI development
Robust IP	Long-life patents to 2030 granted in all major jurisdictions
Multiple Drug Candidates	Deep pipeline with 2 technologies under two INDs, 5 clinical trials within 12 months with 2 funded by US grants



Contact

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