cynata therapeutics

ANNUAL GENERAL MEETING ADDRESS

16 November 2016

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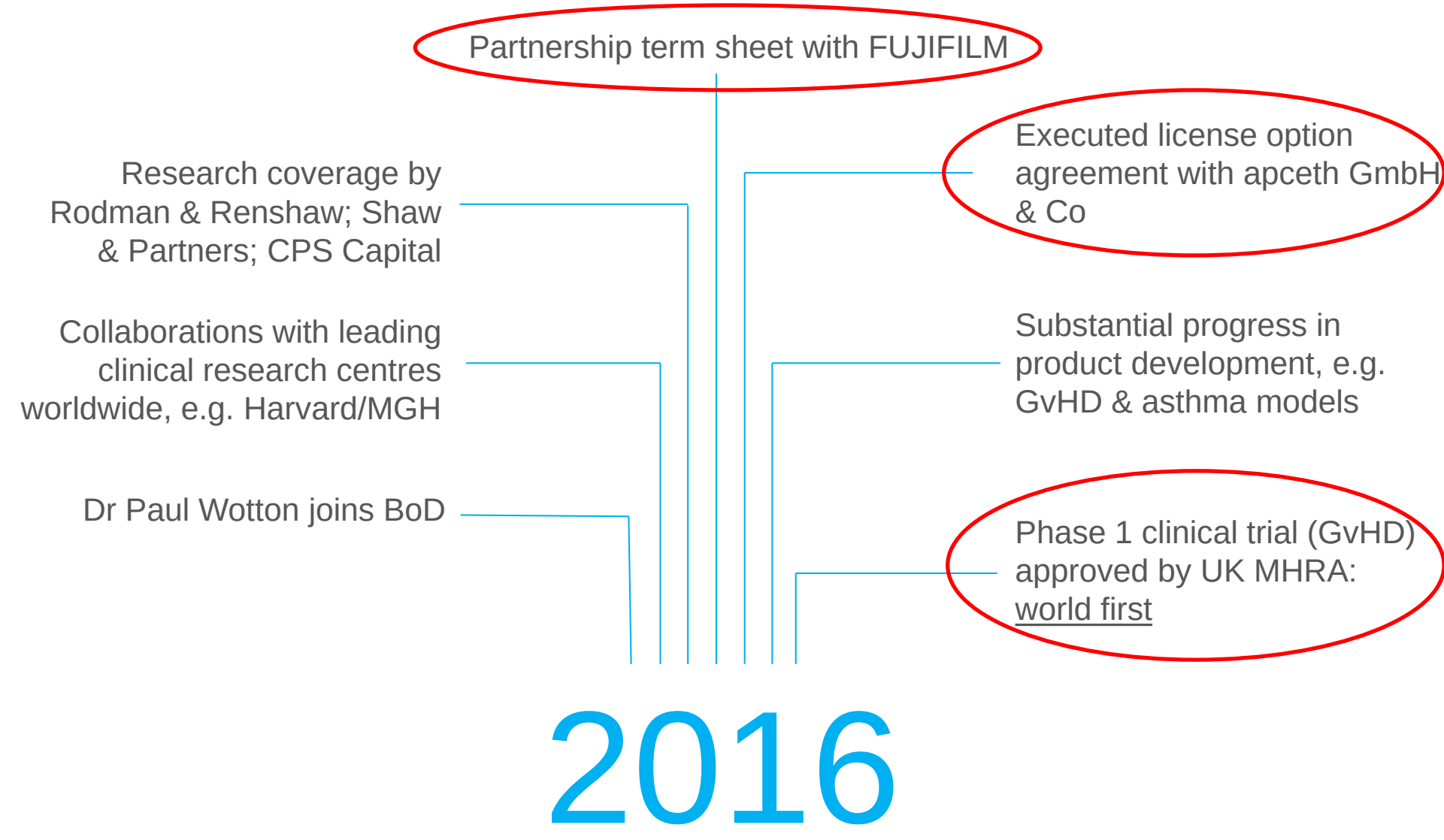
About Cynata

Cynata Therapeutics Ltd is an Australian stem cell and regenerative medicine company.

Competitive Strengths

- Disruptive allogeneic MSC platform technology: Cymerus™
- Economical production of clinical grade product
- Strong IP cover
- Strategic collaborations with commercial and academic partners
- Experienced Team
- Ethically non-controversial
- Low development risk
- Phase 1 Clinical Trial

Recent Cynata Milestones



Partnership with FUJIFILM

- Non-binding term sheet executed 5 September 2016
- Definitive agreement: option to an exclusive, w/w licence to market and sell CYP-001 for graft-versus-host disease (GvHD) + certain additional rights; on track to complete by end of year
- Strategic acquisition of CYP shares: US$3m @ 35% premium to 6 month VWAP
- Upfront + milestone payments + royalties on product sales
- Major multinational with activities in healthcare, graphic systems, functional materials, optical devices, digital imaging and document products
- Significant and growing business in regenerative medicine: acquired Cellular Dynamics International, Inc in 2015 for $US307m (also UW spinout)
- Group revenue in 15-16: $US22b; 79,000 employees; market cap ~$US21b

Partnership with apceth BIOPHARMA

- License Option Agreement with apceth GmbH & Co. KG executed 9 May 2016
- Proposes apceth development of Cynata's Cymerus™ MSCs engineered with apceth's proprietary genetic modification technology
- Therapeutic target is cancer as well as several other devastating diseases
- Upfront and milestone payments potentially exceed A$40m in addition to royalties on product sales
- Evaluation of Cynata's Cymerus technology is underway at apceth and progressing well: decision expected within the next few months.
- Pioneering clinical stage biopharmaceutical company with HQ in Munich; established in 2007; privately owned primarily by private investors Santo Holding GmbH and FCP Biotech Holding GmbH.

Therapeutic Product Pipeline

Therapeutic Area	Indication	Preclinical	Phase 1	Phase 2
Immunological Disorders	Graft versus host disease	→		
	Organ transplant rejection	→		
Pulmonary Disorders	Pulmonary fibrosis	→		
	Asthma	→		
Circulatory Disorders	Critical limb ischaemia	→		
	Myocardial infarction (heart attack)	→		
Cancer	Glioblastoma (brain tumour)	→		

The Future Is Bright

What's Next?

- FUJIFILM definitive agreement: substantial revenue injection
- 1st patient in Phase 1 clinical trial; Formal interaction with FDA
- Licence option agreement with apceth
- Continued success of MSC-based therapeutics
- Develop opportunities in engineered MSCs

Now is the Right Time to Invest

EXISTING MARKET ISSUES

- Traditional production methods for MSCs limit their usage as effective therapies
- Competitors using existing, 1st generation production methods
- Growing demand for new therapies to cure disease
- Regulatory hurdles for current production methods

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THE FUTURE OF MEDICINE

- Global demand for stem cell therapeutics (ageing population)
- Unique, innovative technology from prestigious centre
- Cymerus™ overcomes critical hurdle in industrialising stem cell production
- Licensing-driven business strategy with near term revenue
- Experienced management team
- Value-accretive news flow expected in near term

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Graft Versus Host Disease Program

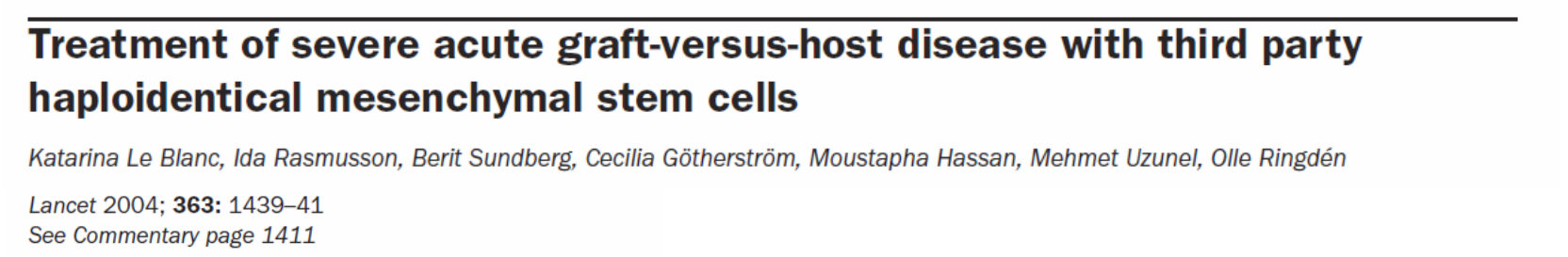
Kilian Kelly
VP, Product Development

Graft vs Host Disease

- Bone marrow transplant (BMT) is effective for certain blood cancers (e.g. leukaemia, lymphoma, myeloma)
- However, graft versus host disease (GvHD) is a potentially fatal complication of BMT
- GvHD occurs when immune cells from the donor bone marrow (the graft) attack the patient (the host), causing potentially severe damage to various organs, including the skin, gut and liver
- The only approved treatments are steroids, which are effective in only ~50% of patients
- When steroids fail, the prognosis is very poor – 70-90% mortality within 1 year

MSCs as a Treatment for GvHD

- MSCs may alleviate or even eliminate GvHD by suppressing immune cells from donor bone marrow, and stimulating tissue repair
- The first GvHD patient treated with MSCs was a 9 year old boy in Sweden, with a profoundly positive outcome. One year later, the investigators commented in *The Lancet*:
  "*In our experience …… 25 patients developed grade IV acute GVHD. This is the only patient with such severe disease who is still alive. The other 24 patients died [after] a median of 2 months*"



Treatment of severe acute graft-versus-host disease with third party haploidentical mesenchymal stem cells

Katarina Le Blanc, Ida Rasmusson, Berit Sundberg, Cecilia Götherström, Moustapha Hassan, Mehmet Uzunel, Olle Ringdén

Lancet 2004; **363:** 1439–41
See Commentary page 1411

- Since then, numerous clinical trials of MSCs for GvHD have been conducted, generally with very positive results

Cynata's Initial Clinical Trial – Why GvHD?

- MSCs have shown promise for a huge range of conditions – over 70 different indications
- Decision was taken to focus on GvHD initially, because:
  - Devastating condition with very limited treatment options → unmet need; smoother regulatory pathway
  - Strong evidence that MSCs can have a beneficial effect
  - GvHD trials have a quick readout (28-100 days), unlike some other potential options (2-3 years+)
  - Successful Phase 1 trial (in any indication) can serve as foundation for Phase 2 trials in other indications

Preclinical Proof of Concept Study

- Humanised mouse model of severe acute GvHD
- Study conducted at University of Massachusetts, Amherst
- Initial results – announced April 2016:
  - Control animals (GvHD, treated with saline): median survival time of just 25.5 days (range 24-31 days)
  - CYP-001 treated animals: median survival time of at least 54 days (range 31-68 days, with three animals still alive)
  - Statistically significant difference (p=0.0011).
- Importantly, the compelling interim results, in combination with *in vitro* studies, were sufficient to support the approval of the clinical trial in the UK

Preclinical Proof of Concept Study

- Additional studies still ongoing – survival of treated animals has been unexpectedly long
- Latest data:
  - Survival of additional control animals has been no longer than in initial cohort
  - CYP-001 treated animals have survived for up to 81 days
  - Survival benefit with CYP-001 remains highly statistically significant
  - Cellular analyses suggests CYP-001 downregulates certain biomarkers known to play a key role in GvHD
- Final report now expected by Jan 17

Phase 1 Clinical Trial Overview

Protocol Number	CYP-GVHD-P1-01
Patient Population	16 adults with steroid-resistant acute GvHD
Locations	UK, Australia (+ potentially other countries)
Treatment	All subjects: 2 infusions of CYP-001 (Day 0 & Day 7) Cohort A: Dose = 1 million cells/kg (max 100 million) Cohort B: Dose = 2 million cells/kg (max 200 million)
Primary Endpoint	Safety at Day 28

Secondary Endpoints	• Response by Day 28/Day 100
	  • Complete Response = no GvHD
	  • Partial Response = improvement in GvHD grade
	• Overall survival at Day 28/Day 100

Clinical Trial – Current Status

Product manufacture complete; product has passed QC testing and been released for clinical use	✓
7 clinical sites in the UK and Australia selected (All major bone marrow transplant centres)	✓
Approved by UK Regulatory Authority (MHRA)	✓
Approved by UK Ethics Committee	✓
CTN notification submitted to Australian Regulatory Authority (TGA); TGA acknowledgement received	✓
Australian Ethics Committee: initial review complete – expect all comments/questions can be addressed satisfactorily; response will be submitted ASAP	

Estimated Timelines

- Enrolment open – Q4 2016
- Cohort A enrolment complete – Q1-2 2017
- Cohort A results – Q2 2017
- Cohort B enrolment complete – Q3 2017
- Cohort B results – Q4 2017

Notes:

- Timelines are heavily dependent on enrolment rates at site
- Progress to Cohort B is dependent on favourable DSMB review of safety data from Cohort A
- All patients will also be followed up for up to 2 years for long-term safety, GvHD/malignancy status and survival

Thank you for your attention

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