



# Biotech Daily

Monday September 19, 2016

*Daily news on ASX-listed biotechnology companies*

- \* **ASX FLAT, BIOTECH DOWN: CYCLOPHARM UP 8%, PSIVIDA DOWN 5%**
- \* **UK APPROVES CYNATA PHASE I CYP-001 FOR GVHD TRIAL**
- \* **PHARMAUST TREATS 1<sup>st</sup> DOG IN PHASE II MONEPANTEL CANCER TRIAL**
- \* **BIONOMICS REQUESTS BNC210 ANXIETY DISORDER TRIAL HALT**
- \* **ASIA UNION DECREASES TO 50% OF GENETIC SIGNATURES**
- \* **CRYSTAL AMBER TAKES 16% OF GI DYNAMICS**
- \* **AUSBIOTECH HOSTS ADELAIDE BROKER MEETS BIOTECH**

## MARKET REPORT

The Australian stock market experienced major technical difficulties today.

In an email received at 5.47pm, ASX chief executive officer Dominic Stevens said that the ASX primary issue “arose from a hardware failure in the main database ... [which] had consequences that affected the operation of the market ... [and was] not in any way related to cyber security”.

Today's report is based on current ASX data which may not be reliable.

The ASX200 slipped 0.04 percent on Monday September 19, 2016, down 1.9 points to 5,294.8 points. Eleven of the Biotech Daily Top 40 companies were up, 16 fell, seven traded unchanged and six were untraded. All three Big Caps fell.

Cyclopharm was the best, up 8.5 cents or 8.2 percent to \$1.125 with 7,210 shares traded. Benitec recovered 5.9 percent; Prima rose 2.6 percent; Admedus, Compumedics, Orthocell and Osprey were up more than one percent; with Airxpanders, Nanosonics, Starpharma and Viralytics up by less than one percent.

Psivida led the falls, down 25 cents or 5.3 percent to \$4.50 with 2,129 shares traded. Atcor and Oncosil fell more than four percent; Cellmid, Opthea and Reva were down more than three percent; Acrux and Living Cell shed more than two percent; Avita, Clinuvel, Factor Therapeutics, Mesoblast, Polynovo, Resmed and Sirtex were down more than one percent; with Cochlear, CSL, Medical Developments and Pro Medicus down by less than one percent.

## CYNATA THERAPEUTICS

Cynata says the UK has approved its 16-patient, phase I trial of CYP-001 for steroid-resistant graft-versus-host disease.

Cynata said the UK Medicines and Healthcare Products Regulatory Agency approval was for a trial of its lead Cymerus mesenchymal stem cell product CYP-001 at centres in the UK and Australia, with additional centres in other jurisdictions being considered.

The company said it “believes that this will be the world’s first clinical trial involving a therapeutic product derived from allogeneic induced pluripotent stem cells”.

Mesoblast acquired Osiris for its mesenchymal stem cells which have been approved for graft versus host disease in Japan and is conducting a 60 patient US phase III registration paediatric trial which the company previously said was due to report its interest results within the next month (BD: Oct 11, 2013; Dec 17, 2015).

Cynata chief executive officer Dr Ross Macdonald told Biotech Daily that other stem cell companies “derived their mesenchymal stem cells and mesenchymal precursor cells from bone marrow or other tissue sources, whereas our source is induced pluripotent stem cells, originally derived from blood”.

“It’s like first generation versus second generation technology,” Dr Macdonald said.

Cynata said that its induced pluripotent stem cells had similar characteristics to embryonic stem cells, but without the ethical controversies associated with embryonic stem cells, since they were derived from adult cells rather than from embryos.

The company said that graft-versus-host disease was a potentially fatal disease that often followed a bone marrow transplant and occurred when the immune cells in the donor graft material attacked the recipient’s host tissues as foreign.

Cynata was up 3.5 cents or 6.8 percent to 55 cents.

## PHARMAUST

Pharmaust says it has treated the first dog with monepantel for cancer in a phase II study at England’s University of Cambridge, Department of Veterinary Sciences.

Pharmaust said the dog had metastatic mammary cancer and had been dosed with a reformulated monepantel, previously known as PPL-1 and now known as “MPL”.

Monepantel was originally used in sheep and goats for gastro-intestinal roundworm.

Pharmaust previously said the taste of PPL-1 was an issue for both its canine and human cancer trials and it was reformulated (BD: Apr 15, 2015).

Today, the company said the primary objective was to examine the effects of the reformulated capsules in different canine cancers, in dogs that failed standard-of-care, with few or no therapeutic options available, with the aim of determining which cancers should be targeted in a phase III trial.

Pharmaust said that its phase I dog trial in 2014 and 2015 “showed excellent safety with suppression of tumor markers” and the phase II trial was intended to build on those results by including determinations of regression, stable disease or progression by measurement of tumor size (BD: Jun 17, 2015).

Pharmaust chairman Dr Roger Aston said that “having initially demonstrated activity against cancer in man and canines, this phase II study in dogs is a critical step as it is intended to show clinically relevant endpoints such as tumour size and growth or regression”.

“Furthermore, a positive effect in canines will be a strong indication as to what can be expected in man,” Dr Aston said. “It is also noteworthy that most canine cancer drugs are essentially the same as those used in man with a modified dose.”

Pharmaust was untraded at 8.2 cents.

## BIONOMICS

Bionomics has requested a trading halt “regarding results from its [24-patient] BNC210 phase II clinical trial in patients with generalised anxiety disorder”

Bionomics began the trial last year to assess the effect of BNC210 on brain activity in patients with untreated generalized anxiety disorder (BD: Apr 20, 2015; Jun 24, 2016).

Trading will resume on September 21, 2016 or on an earlier announcement.

Bionomics last traded at 26.5 cents.

## GENETIC SIGNATURES

Asia Union Investments says it has decreased in Genetic Signatures from 42,785,545 shares to 41,370,962 shares and has been diluted from 57.29 percent to 49.50 percent.

The Sydney-based Asia Union substantial shareholder notice said that the shares were held by Genetic Signatures, Asia Union and Christopher Abbott and the change related to the issue of shares under the employee share plan and escrow arrangements.

Genetic Signatures was unchanged at 51 cents.

## GI DYNAMICS

The Crystal Amber Fund says it has increased its substantial shareholding in GI Dynamics from 68,843,661 shares (14.48%) to 77,355,813 shares (16.27%).

The London and St Peter Port, Guernsey Island-based Crystal Amber Fund said that between August 23 and September 16, 2016 it acquired 8,512,152 shares for \$209,005 or an average price of 2.5 cents a share.

The company's website said it was listed on London's Alternative Investment Market.

The Crystal Amber Fund substantial shareholder notice was signed by Kevin Smith and Danny Felbabel as company secretary.

GI Dynamics was untraded at two cents.

## AUSBIOTECH

Ausbiotech says it will host a 'Broker Meets Biotech' event in Adelaide on Thursday, September 22, 2016.

Ausbiotech said that the Broker Meets Biotech series was an opportunity “to gain insight into the current investment landscape with brokers, investors and innovative companies working in the life sciences”.

The industry organization said that biotechnology and medical technology companies, including Opthea, LBT Innovations and Volpara Health Technologies would present their business cases, with a keynote address from NDF Research founder and senior analyst Stuart Roberts and an introduction from event partner Grant Thornton Adelaide's managing partner Iain Kemp.

Ausbiotech said that the event would be held at Crowne Plaza, 16 Hindmarsh Square, Adelaide on September 22, 2016 from 4:45pm to 7:30pm.

The event is free but registration is required and for more details email Ausbiotech business development manager Mel Nelson at: [mnelson@ausbiotech.org](mailto:mnelson@ausbiotech.org) or call +613 9828 1400 or go to: [www.ausbiotech.org/events](http://www.ausbiotech.org/events).