Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: BIOTRON UP 50%, GENETIC TECHNO DOWN 14%**

*** BIOTRON JUMPS 90% ON BIT225 'UNDETECTABLE' HEPATITIS C LEVELS**

*** ALCHEMIA PHASE III HA-IRINOTECAN CANCER TRIAL LOCKED**

*** LIVING CELL PARTNER OTSUKA LENDS JOINT VENTURE UP TO $38m**

*** ADMEDUS APPOINTS JOHN SEABERG, WAYNE PATERSON DIRECTORS**

MARKET REPORT

The Australian stock market lost 2.05 percent on Friday October 10, 2014 with the S&P ASX 200 falling 108.4 points to 5,188.3 points, apparently following the US markets.

Eight of the Biotech Daily Top 40 stocks were up, 17 fell, 10 traded unchanged and five were untraded. All three Big Caps fell.

Biotron was the best (see below), up as much as 9.5 cents or 95 percent to 19.5 cents before closing up five cents or 50 percent at 15 cents with 52.5 million shares traded.

Avita and Living Cell climbed more than nine percent; Analytica was up 4.1 percent; Cellmid was up 3.7 percent; Alchemia rose 2.4 percent; with Acrux and Nanosonics up by less than one percent.

Genetic Technologies led the falls, down 0.3 cents or 14.3 percent to 1.8 cents – believed to be its lowest closing price on record - with 2.1 million shares traded

Psivida lost 8.9 percent; Benitec was down 7.7 percent; Impedimed and Starpharma fell more than four percent; Admedus, Anteo, Bionomics, Clinuvel, Medical Developments, Phosphagenics, Resmed and Viralytics were down more than three percent; Mesoblast and Prima shed more than two percent; with Cochlear, CSL, Neuren, Sirtex and Tissue Therapies down more than one percent.

BIOTRON

Biotron jumped as much as 90 percent to 19 cents, on news that all five HIV and hepatitis C patients remaining in its phase II trial of BIT225 have “undetectable” hepatitis C levels.

Biotron chief executive officer Dr Michelle Miller told Biotech Daily that the Thailand trial of HIV patients co-infected with hepatitis C virus genotype 3 patients began with eight patients.

Dr Miller said that two patients dropped out due to the side effects of interferon and ribavirin, with one patient reaching the 12-week treatment mark with undetectable levels of hepatitis C virus, before also dropping out due to interferon and ribavirin side effects.

Dr Miller said that the five patients remaining in the trial had undetectable levels of hepatitis C virus 12 weeks after ceasing all treatment.

Dr Miller said that all patients were co-infected with HIV but had undetectable HIV levels on admission to the trial, continued on retroviral medication for HIV and had no spikes in their HIV levels throughout the trial.

In a media release to the ASX, Biotron said that the treatment endpoint was a sustained virologic response, defined as an undetectable hepatitis C RNA levels 12 weeks after completion of treatment.

Biotron said that the findings extended previous data that showed the patients had undetectable hepatitis C levels at earlier stages of treatment (BD: Mar 6, 2014).

The company said the phase II trial was an open label pilot study undertaken at a single trial site in Bangkok, Thailand, with eight patients co-infected with HIV and hepatitis C genotype 3, receiving the standard-of-care hepatitis C drugs interferon and ribavirin for seven days before beginning treatment with BIT225 and then receiving 300mg BIT225 twice daily plus interferon and ribavirin for 28 days.

Biotron said that after that time, patients continued to take interferon and ribavirin until week 48, at which time all treatment was stopped.

The company said that the primary objectives of the trial were safety and tolerability, with secondary objectives pharmacokinetics and antiviral efficacy.

Biotron said that the five patients completing the full course had undetectable virus levels from week 12 of dosing, their levels continued to be undetected through to week 48, when all treatment ceased and at week 60, 12 weeks after stopping treatment, all were clear of virus, achieving a sustained virologic response.

Biotron said that the sustained virologic response rate for interferon and ribavirin alone in hepatitis C genotype 3 patients in Thailand was 68.8 percent.

The company said that although the number of patients in the trial was small, the fact that 100 percent had no virus detected from week 12 onwards was encouraging.

Biotron said that the rate of reduction in virus levels was accelerated once BIT225 was added to the interferon and ribavirin treatment at day seven.

Dr Miller said the data “support the efficacy of BIT225 as a potential new therapy for [hepatitis C] and, in particular, for this difficult to treat group of ... co-infected patients who typically have more serious [hepatitis C] infection and fewer treatment options”.

Biotron said that in vitro assays had shown that BIT225 had pan-genotypic activity and while previous clinical trials of BIT225 focused on genotype 1 patients the most common genotype in Western populations, the new data extended the company's clinical data portfolio to include genotype 3, which is endemic in Southeast Asia.

The company said that a three-month dosing, phase II, placebo-controlled, double-blinded trial of BIT225 in combination with interferon and ribavirin in 30 genotype 1 patients and 30 genotype 3 patients was in progress, with preliminary results expected this year.

Biotron climbed as much as 9.5 cents or 95 percent to 19.5 cents before closing up five cents or 50 percent at 15 cents with 52.5 million shares traded.

ALCHEMIA

Alchemia says the database has been locked for analysis of its 415-patient pivotal phase III trial of hyaluronic acid irinotecan (HA-Irinotecan) in metastatic colorectal cancer.
Alchemia said that the trial achieved its primary endpoint analysis threshold of a minimum of 350 progression free survival events.
The company said that the validated dataset had been finalized and submitted to project statisticians for analysis and results were expected by the end of October 2014.
Alchemia chief executive officer Thomas Liquard said that the company was “excited to reach the final stage of the phase III trial process and we look forward to the results of this trial, which has the potential to substantially impact the current second and third-line treatment regimen for patients with metastatic colorectal cancer”.
“A successful trial would be transformational for Alchemia as our further validated Hyact platform could then be applied to many different chemotherapy agents used against a broad range of solid tumors,” Mr Liquard said.
Alchemia said that the randomized, double-blinded, active-controlled study of its Hyact technology formulated with chemotherapeutic drug irinotecan was compared with irinotecan when administered as part of the conventional Folfiri chemotherapy regimen, which was a combination of folinic acid, fluorouracil and irinotecan, in patients with metastatic colorectal cancer who were candidates for second or third line chemotherapy.
The company said that the primary objective was to demonstrate superiority in progression free survival of HA-irinotecan over irinotecan.
Alchemia chief scientific officer and Hyact inventor Prof Tracey Brown said that the “collection and processing of the phase III clinical trial data marks an important point in the development of the Hyact technology and we are hopeful that the results will provide strong clinical rationale for targeting CD44 on solid tumors via hyaluronic acid”.
“There is a real need for more efficacious treatments in [metastatic colorectal cancer] and we are now one step closer to potentially offering patients a new treatment to fight their disease,” Prof Brown said.
Royal Melbourne Hospital oncologist and principal trial investigator Prof Peter Gibbs said that “if the Folfiri regimen containing HA-irinotecan succeeds in demonstrating superiority when compared to Folfiri, it has the potential to become the standard of care for [metastatic colorectal cancer] and could significantly alter the treatment landscape”.
Alchemia was up 1.5 cents or 2.4 percent to 64 cents.

LIVING CELL TECHNOLOGIES

Living Cell says that Otsuka Pharmaceutical Factory will lend their 50 percent each joint venture Diatranz Otsuka up to $NZ42 million ($A38 million).
Living Cell said the loan will be repaid from Diatranz Otsuka’s cash flows.
The Diatranz Otsuka joint venture was created to develop the Diabecell encapsulated pig islets of Langerhans for type 1 diabetes (BD: Oct 19, Nov 2, 2011).
Today, Living Cell said that Diatranz Otsuka had agreed to licence Diabecell to Otsuka Pharmaceutical Factory for use in US and Japan for a fee of up to $NZ15 million.
The company said the agreements were consistent with the restructure announced on April 1, 2014, in which Diatranz Otsuka controlled the resources to realize the potential of Diabecell and Living Cell focused on developing cell therapies for neurodegenerative diseases from its intellectual property portfolio and core technologies.
Living Cell said that under a services and products agreement Diatranz Otsuka supplied it with facilities and piglets to manufacture NTCell.
Living Cell was up 0.6 cents or 9.4 percent to seven cents.

ADMEDUS

Admedus says it has appointed John Seaberg and Wayne Paterson as independent, non-executive directors.

Admedus said that Mr Seaberg had 37 years experience in the medical devices industry with a strong background in development, sales and marketing, particularly in the cardiovascular space, and that for 20 years Mr Paterson was a senior executive in the pharmaceutical industry, with managerial and marketing experience to the emerging, European and US markets.

The company said that from 2007 until May 2014, Mr Seaberg was the founder, chairman and chief executive officer of the venture capital-backed Neochord Inc, commercializing technology developed at the Mayo Clinic for the repair of the mitral valve through minimally invasive techniques.

Admedus said that Mr Seaberg was employed by Guidant Corp from 1996 until 2006 as a sales and marketing executive, in which he managed a field sales team of more than 600 people and more than $US1 billion in revenue.

The company said that in 1991, Mr Seaberg co-founded Acist Medical which manufactures and distributed power injection technologies for coronary angiography and was acquired by Bracco for $US105 million in 2001.

Admedus said that Me Seaberg was the founder and chief executive officer of Seaberg Medical, a regional distributor of implantable cardiovascular devices.

Mr Seaberg holds a Bachelor of Arts and a Masters in Business Administration from the University of Minnesota.

Admedus said that from 2007 to 2013, Mr Paterson had held senior positions at Merck Serono, most recently as president of Europe, Canada and Australia, managing more than $US3 billion in sales with an operational budget of $US500 million.

The company said that previously Mr Paterson was the head of cardio-metabolic care and general medicine, with revenue responsibility of $US1.5 billion.

Admedus said that Mr Paterson created Merck Serono Japan and managed all company divisions, launching several products.

The company said that from 1994 to 2005, Mr Paterson was employed by Roche Pharmaceuticals and as marketing director in Shanghai, China, he launched eight products, including cardiovascular products.

Admedus said that the Switzerland-based Mr Paterson held a Masters of Business Administration from the University of Southern Queensland, and a degree in business studies from the Queensland University of Technology.

Admedus fell half a cent or 3.7 percent to 13 cents with 5.3 million shares traded.