Biotech Daily

Tuesday December 11, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: USCOM UP 18%, GENETIC TECHNO DOWN 5%**

*** SPINIFEX STARTS PHASE II EMA401 CHEMO NEUROPATHY TRIAL**

*** THROMBOVIEW PLATFORM RETURNS AS AGENIX LEAD PRODUCT**

*** CYCLOPHARM RIGHTS ISSUE RAISES $2.1m**

*** BEARISH M&G GROUP TAKES 11% OF STARPHARMA**

*** CIRCADIAN CREATES INTERNAL VEGF SUBSIDIARIES**

MARKET REPORT

The Australian stock market was up 0.4 percent on Tuesday December 11, 2012 with the S&P ASX 200 up 18.1 points to 4,576.0 points.

Ten of the Biotech Daily Top 40 stocks were up, 13 fell, 14 traded unchanged and three were untraded.

Uscom was the best, up three cents or 17.65 percent to 20 cents with 25,000 shares traded.

Benitec climbed 7.1 percent; QRX was up 6.2 percent; Bionomics was up 5.1 percent; Phosphagenics was up 3.6 percent; Mesoblast and Neuren rose more than two percent; Heartware and Reva were up more than one percent; with Cochlear and Starpharma up by less than one percent.

Genetic Technologies led the falls, down 0.4 cents or 5.1 percent to 7.5 cents with 350,550 shares traded.

Allied Health, Patrys and Prana fell four percent or more; Anteo, GI Dynamics and Tissue Therapies lost more than three percent; Ellex and Nanosonics shed more than two percent; Impedimed and Sirtex were down one percent or more; with Alchemia, CSL and Pharmaxis down by less than one percent.

SPINIFEX PHARMACEUTICALS

Spinifex says the first of about 50 patients have been treated in its phase II study of EMA401 for chemotherapy-induced peripheral neuropathy.

Spinifex said that chemotherapy-induced peripheral neuropathy (CIPN) was “a painful and debilitating condition that develops in some patients receiving cancer chemotherapy”.

The company said the study was an open-label biomarker study being conducted at London’s Hammersmith Hospital and was designed to provide proof-of-concept of the use of EMA401, an angiotensin II type 2 receptor antagonist, in chemotherapy-induced peripheral neuropathy.

Spinifex said that the trial patients had received either taxane or platinum chemotherapy for any cancer type.

The company said that the primary endpoint was the change in mean spontaneous pain intensity score between baseline and the last week of 28 days of dosing using the numeric pain rating scale (NPRS).

Spinifex said that a number of secondary endpoints would be evaluated including changes in nerve characteristics in skin biopsies taken from the calf pre-treatment and after EMA401 treatment at day 29.

Spinifex said that in August it 183-patient, phase II clinical trial of EMA401 in post-herpetic neuralgia showed the drug met its primary endpoint of a reduction in mean daily pain score as well as key secondary endpoint, in which a significantly greater proportion of patients on active treatment reporting a more than 30 percent reduction in mean pain intensity score compared to baseline (BD: Aug 28. 2012).

The company said that EMA401 was also shown to be generally safe and well-tolerated with no serious treatment related adverse events reported.

Spinifex said that despite being a large and growing market, current therapy for chronic and neuropathic pain needed to be improved as a significant proportion of patients did not respond to therapy and the treatments had dose-limiting side effects.

The company said that EMA401 was being developed as a potential first-in-class oral treatment for chronic pain, including neuropathic pain, without central nervous system side effects.

Spinifex chief executive officer Dr Tom McCarthy said the chemotherapy-induced peripheral neuropathy phase II trial was “another significant step in the development of EMA401 and for Spinifex”.

“Our recent results for EMA401 in [post-herpetic neuralgia] served to highlight its potential as an entirely novel approach for the treatment of neuropathic pain,” Dr McCarthy said.

“We look forward to completing this study in a second key indication and to moving EMA401 further towards being an important treatment for broader chronic and neuropathic pain indications,” Dr McCarthy said.

The trial’s lead investigator Prof Praveen Anand said the pain associated with chemotherapy-induced peripheral neuropathy could be extremely debilitating and affect the quality of life of patients for years, even when the cancer was in remission, and was “a major reason for cancer treatments to be reduced or stopped early”.

“The use of an [angiotensin II type 2] receptor antagonist as a treatment for neuropathic pain is a highly innovative approach and, in addition to the strong phase II results already seen by the company, my own group has undertaken non-clinical work which is highly compelling,” Prof Anand said.

Spinifex said that the discovery that angiotensin II type 2 receptor antagonists offered an innovative approach to the treatment of neuropathic and inflammatory pain was originally made by the University of Queensland’s Prof Maree Smith.

Spinifex is a private company.

AGENIX

Agenix executive chairman Nick Weston says that Thromboview has returned as the company's lead product.

Mr Weston had previously emphasized the Chinese hepatitis B asset AGX-1009 as the company's lead development product.

Today, Mr Weston told a media and investor briefing at Fortrend Securities in Melbourne that he had been involved in lengthy negotiations with an unnamed major pharmaceutical company to spend the $40 million required to take the Thromboview D-dimer monoclonal antibody from the completed phase II trial to phase III and on to market.

Mr Weston said that Thromboview was not just an imaging agent able to "light up" fresh blood clots in pulmonary embolism and deep vein thromboses but was a potential platform with the ability to take positron emission tomography tags, as well as identify clots in atrial fibrillation.

"It is not an imaging agent," Mr Weston said.

"It can do things that [computed tomography] scans can't do," Mr Weston said.

He said the safety compared to the need for highly radioactive scans as well as its diverse uses made Thromboview a "blockbuster".

Mr Weston said that AGX-1009 for hepatitis B in China was progressing and most of the preclinical work had been completed.

Mr Weston said that AGX-1009 was based on Gilead's tenofovir, marketed as Viread, but could be more potent.

He said he expected AGX-1009 to begin clinical trials in 2013.

Mr Weston said the recent licencing of Tyrian Diagnostics point-of-care Diagnostiq technology for human use for $500,000 in shares was expected to return early revenues (BD: Oct 25, 2012).

Mr Weston said that instead of using the hand held diagnostic test for prostate cancer and active tuberculosis as Tyrian had attempted, Agenix would develop it as a platform diagnostic with multiple purposes.

Mr Weston said the point-of-care immuno-assay could provide rapid five minute results, backed up by a sophisticated reader computer.

He said it could be set-up to run HIV, hepatitis B and syphilis tests on the one sample, or a range of sexually transmitted infections on the one test, or be used to detect vitamin D levels.

Mr Weston said the diagnostic could potentially run up to 50 separate tests on the one unit and he hoped to finalize the model and platform applications by July 2013.

"In 12 months we expect to have partners and preferably for all applications," Mr Weston said.

Agenix was up half a cent or 16.1 percent to 3.6 cents.

CYCLOPHARM

Cyclopharm has raised its expected $2.1 million through a fully underwritten one-for-four pro-rata renounceable rights issue at 18 cents a share (BD: Nov 9, 2012).

Cyclopharm said that it received acceptances for 7,166,861 shares raising $1,290,035 and the underwriters, CVC Managers, would take up the shortfall of 4,458,945 shares.

In November the company said the funds were for the operating costs of Cyclopet, support the legal proceedings Cyclopet had begun against the Australian Nuclear Science and Technology Organisation and to fund the commencement of the phase III Technegas clinical trial in the US (BD: Dec 13, 2011, Jun 28, 2012).

Cyclopharm was unchanged at 15 cents.

STARPHARMA

M&G Investment Funds has increased its substantial shareholding in Starpharma from 28,534,809 shares (10.06%) to 31,234,957 shares (11.01%).
The London-based M&G companies first acquired 18,604,651 shares (6.70%) shares In November 2011 month for $19,999,999 or $1.075 a share and has continued increasing its holding (BD: Nov 24, Dec 13, 2011; Mar 22, Jul 3, Nov 23, 2012).
Today the M&G Group said it bought 2,700,148 shares between November 22 and December 7, 2012, buying more than 1.5 million shares for prices between $1.02 and $1.14 following the November 29, 2012 share price fall on the news of the failed Vivagel phase III bacterial vaginosis trial (BD Nov 29, 2012).
Starpharma was up half a cent or 0.5 percent to $1.08.

CIRCADIAN TECHNOLOGIES

Circadian says it has created two 100-percent owned subsidiaries, Ceres Oncology Pty Ltd and Opthea Pty Ltd for its vascular endothelial growth factor (VEGF) applications.
Circadian managing director Robert Klupacs told Biotech Daily that the division would enable “specialized investments or licences as well as a potential spin-off”.
Mr Klupacs said that the company had divided its VEGF assets into the Ceres Oncology and Opthea divisions for oncology and ophthalmology respectively.
Mr Klupacs said that the company first announced the re-organization at the annual general meeting in November, but believed it needed restating.
Mr Klupacs said that Circadian owned other divisions including Vegenics Pty Ltd, Precision Diagnostics Pty Ltd, Polychip Pharmaceuticals which owns part of Antisense, Syngene and a listed investment in Optiscan.
Circadian was unchanged at 36.5 cents.