Biotech Daily

Tuesday September 13, 2011

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: PHOSPHAGENICS UP 7%; USCOM DOWN 12.5%**

*** SPINIFEX EMA401 CORRECTS RAT DIABETIC NEUROPATHY SYMPTOMS**

*** CIRCADIAN'S VGX-100 EFFECTIVE FOR DRY EYE DISEASE IN MICE**

*** PSIVIDA READY FOR PHASE I/II ILUVIEN TRIAL FOR POSTERIOR UVEITIS**

*** PSIVIDA REVENUE DOWN 79%, PROFIT TURNS TO $US9m LOSS**

*** SEPTEMBER BIO-BEERS**

MARKET REPORT

The Australian stock market was up 0.85 percent on Tuesday September 13, 2011 with the S&P ASX200 up 34.2 points to 4,072.7 points.

Twelve of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and eight were untraded. All three Big Caps were up.

Phosphagenics was the best, up one cent or 7.1 percent to 15 cents with 479,510 shares traded, followed by Living Cell up 5.3 percent to six cents with 590,457 shares traded and Cochlear recovering 4.5 percent to $60.10 with 2.2 million shares traded.

Benitec and Starpharma climbed more than four percent; Prana was up three percent; Alchemia, Anteo, Resmed and Viralytics rose more than two percent; with Acrux, CSL, Mesoblast, Pharmaxis and Psivida up by less than one percent.

Uscom led the falls, down 2.5 cents or 12.5 percent to 17.5 cents with 93,809 shares traded, followed by Antisense down 10 percent to 0.9 cents with 12 million shares traded.

Bionomics lost 7.4 percent; Universal Biosensors fell six percent; Genetic Technologies and Reva fell four percent or more; Circadian and Tissue Therapies were down more than three percent; Allied Health and Biota shed more than two percent; with QRX and Sirtex down by less than one percent.

SPINIFEX PHARMACEUTICALS

Spinifex says its compound EMA401 corrected nerve conduction velocity and sciatic nerve blood-flow, and reduced pain and heat sensitivity in a rat model of diabetic neuropathy.

Spinifex said the pre-clinical data on the angiotensin II type 2 receptor antagonist EMA401 was presented at the Diabetic Neuropathy Study Group of the European Association for the Study of Diabetes meeting in Porto, Portugal on September 11, 2011 by the University of Aberdeen's Prof Norman Cameron and Prof Mary Cotter.

The company said that EMA401 was in development for a number of neuropathic pain indications and the study showed that it corrected motor and sensory nerve conduction velocity in the rat model of diabetes, as well as reducing pain and heat sensitivity and correcting sciatic nerve nutritive blood flow.

Spinifex said EMA401 was effective at a dose of 1mg/kg/day and no central nervous system side effects were observed, consistent with earlier studies at this and higher doses.

Spinifex said diabetic neuropathy was a side effect of diabetes characterized by the peripheral nerves not functioning properly.

The company said patients presented with symptoms that included pain but could also include sensory loss and reduced reflex.

Spinifex said diminished nerve conduction velocities resulting from damage to the peripheral nervous system had also been linked to other serious side effects of diabetes such as ulcers of the feet and legs which could lead to amputation.

Spinifex chief executive officer Dr Tom McCarthy said the discovery that angiotensin II type 2 (AT2) 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 "and we have good earlier data on the impact of EMA401 on neuropathic pain in pre-clinical models".

"This new study we initiated with Prof Cameron and Prof Cotter not only reinforces our earlier data on the impact of EMA401 on neuropathic pain but also confirms our hypothesis that EMA401 may treat the underlying nerve conduction velocity deficits that are the hallmark of diabetic neuropathy," Dr McCarthy said.

"This expands the range of potential indications for the compound and, importantly, provides a new therapeutic target for what is a particularly devastating form of neuropathy," Dr McCarthy said.

Prof Cameron said that inhibition of the renin-angiotensin system "can reduce the development of diabetic complications including neuropathy but most attention has focused on AT1 receptor-mediated mechanisms".

"This is the first study of the effect of an AT2 receptor antagonist on nerve function in an appropriate diabetes model," Prof Cameron said.

"In showing EMA401 corrects aspects of neurovascular dysfunction the data suggests the AT2 receptor is a valuable new potential therapeutic target in diabetic neuropathy," Prof Cameron said.

Spinifex said it acquired the initial technology underpinning EMA401 from the University of Queensland and had conducted a comprehensive pre-clinical and early clinical development program, showing efficacy in a number of relevant models, good human safety and pharmacokinetics in phase I studies and the first of three phase II clinical trials would begin soon.

The company said the EMA401 clinical program was focused on neuropathic pain as a potential first-in-class oral treatment, for a market expected to reach $US6.2 billion by 2017.

Spinifex is a private company.

CIRCADIAN TECHNOLOGIES

Circadian says its human antibody, VGX-100 can reduce inflammation and corneal tissue damage associated with dry eye disease in a mouse model of the disease.

Circadian said VGX-100 was an antibody against the angiogenic and lymphangiogenic molecule vascular endothelial growth factor C (VEGF-C).

The company said that data published in the journal Archives of Ophthalmology showing that VGX-100 could significantly reduce inflammation and corneal tissue damage indicated “a major new therapeutic opportunity for VGX-100”.

The article entitled ‘Blockade of Prolymphangiogenic Vascular Endothelial Growth Factor C in Dry Eye Disease’ concluded that “treatment with anti–VEGF-C led to significant improvement in dry eye disease, reflected by a decrease in inflammation at the clinical, molecular, and cellular levels”.

An abstract is at http://archopht.ama-assn.org/cgi/content/short/archophthalmol.2011.266.

Circadian said that dry eye disease was a complex, immune-mediated disorder of the ocular surface with multiple causes.

Circadian said the collaborative study was led by Harvard Medical School’s Prof Reza Dana and Dr Sunali Goyal at the Schepens Eye Research Institute.

Prof Dana said that dry eye disease was suffered by millions of people but treatments had limitations and effective treatments were not available for many patients.

“This current study builds on our previous findings demonstrating that VEGF-C, VEGF-D and VEGFR-3 are up-regulated in [dry eye disease] corneas and demonstrates for the first time that an anti-lymphatic effect, caused by the blockade of VEGF-C, has significant beneficial effects in treating the condition,” Prof Dana said.

“We strongly believe that blocking lymphangiogenic molecules could become a major new paradigm for the treatment of [dry eye disease],” Prof Dana said.

Circadian chief executive officer Robert Klupacs said the company “always believed that blockade of VEGF-C will have clinical utility in a variety of conditions, in addition to treating solid tumors”.

“This very exciting data generated by our collaborators at Schepens offers significant opportunities for us to leverage our investment in the VGX-100 oncology program and undertake additional preclinical and clinical development activities for VGX-100 in [dry eye disease], a disease which still remains extremely difficult to treat”.

Circadian said its subsidiary Vegenics owned worldwide rights to an extensive portfolio covering the angiogenesis and lymphangiogenesis targets VEGF- C, VEGF-D and the receptor protein VEGFR-3 and had been granted exclusive worldwide rights to intellectual property filed by Schepens Eye Research Institute covering the use of anti-lymphangiogenc molecules for the treatment of dry eye disease.

Circadian said dry eye disease affected about five million Americans above the age of 50 years and about 10 percent of Australians would suffer from the condition at some point in their lives.

Circadian said dry eye disease severely impacted the vision-related quality of life and the symptoms, including persistent dryness, burning, light sensitivity, pain and blurred vision, could be both psychologically and physically debilitating.

The company said that therapeutic options were limited and mostly palliative, with topical cyclosporine-A the only approved treatment.

Circadian fell two cents or 3.5 percent to 55 cents.

PSIVIDA

Psivida says it has filed an investigational new drug application for a phase I/II clinical trial of Iluvien for the treatment of uveitis affecting the posterior segment of the eye.

Psivida said that an injectable, sustained release insert delivering the corticosteroid fluocinolone acetonide of the same design was being developed for the treatment of diabetic macular oedema by licensee Alimera Sciences, using its Iluvien brand name.

The company said the posterior uveitis study was an investigator-sponsored, dose-ranging study designed to assess safety and efficacy of inserts that deliver the high and low dose of fluocinolone acetonide studied in Alimera's phase III trials of Iluvien for diabetic macular oedema (DME).

Psivida said that if the phase I/II trial was successful it would advance the posterior uveitis product into pivotal multi-center phase III trials.

The company said it would use a new inserter with a smaller gauge needle than that used in the DME studies in any future posterior uveitis phase III trials.

In May, Alimera resubmitted a new drug application to the US Food and Drug Administration for Iluvien for diabetic macular oedema addressing questions raised in the complete response letter of December 2010 (BD: May 16, 2011).

On December 24, 2010, Psivida said the FDA rejected the Iluvien application, asking for analyses of safety and efficacy data through to month 36 of the study, to further assess the relative benefits and risks of Iluvien (BD: Jan 16, 2011).

Psivida said at that time the application contained data to month 24 of its phase III trial and Alimera was preparing the 36 month analyses that the FDA has requested

Psivida expects the review date to be November 12, 2011.

Today, Psivida said the phase I/II trial of the injected insert was for the new indication of posterior uveitis, an inflammatory condition affecting the back of the eye, estimated to be responsible for up to 30,000 cases, or about 15 percent of blindness in the US and the third leading cause of blindness worldwide.

The company said the insert was a third-generation product based on its Durasert technology system, following the surgically implanted Retisert technology.

Psivida said it had licenced the insert to Alimera for the treatment and prevention of eye diseases in humans other than uveitis.

Psivida said it intended to reference Alimera's new drug application for Iluvien for diabetic macular oedma, including the clinical data from the trials and the manufacturing and stability data, in support of any posterior uveitis regulatory filings.

Psivida was up two cents or 0.5 percent to $4.29.

PSIVIDA

Psivida says its revenue fell 78.5 percent to $US4,965,000 in the 12 months to June 30, 2011, taking last year's maiden net profit after tax to a loss of $US8,628,000.

Last year, Psivida investor relations executive Brian Leedman told Biotech Daily the company received a one-off $US15 million licence payment from Alimera, along with royalty revenue of $US342,000 for its Retisert device (BD: Sep 23, 2010).

Psivida said its diluted loss per share was 0.44 US cents compared to the previous year's earnings of 0.46 US cents.

The company said it had $US24,128,000 in cash and equivalents at June 30, 2011 compared to $US17,565,000 for the previous corresponding period.

Psivida said that royalty income increased from $US483,000 to $US1,353,000 but revenue from collaborative research and development fell from $US22,570,000 to $US3,612,000.

BIO-BEERS

Dr Chris Booth of Thomson Reuters and Ian Dixon of Genscreen have organized a Bio-Beers gathering at the Sebel Treasury Bar, on the corner of Collins Street and Queen Street, Melbourne, for Thursday September 15, 2011 at 6-8pm.
RSVP to christopher.booth@thomsonreuters.com.