Biotech Daily

Thursday July 23, 2009

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: BIOTA UP 9%, BONE DOWN 11%**

*** TISSUE THERAPIES' TROUBLE IN TORONTO; NEW IMPROVED VITROGRO**

*** PEPLIN BEGINS 2nd NON-HEAD LESION PHASE III TRIAL**

*** MESOBLAST APPLIES FOR BONE FRACTURE REPAIR APPROVAL**

*** QRX BEGINS PHASE II IV MOXDUO PAIN RELIEF STUDY**

*** GSK TRIPLES RELENZA CAPACITY, PAYS BIOTA $8.9m ROYALTY**

MARKET REPORT

The Australian stock market slipped 0.11 percent on Thursday July 23, 2009 with the S&P ASX 200 down 4.4 points to 4,064.1 points.

Eighteen of the Biotech Daily Top 40 stocks were up, nine fell, four traded unchanged and nine were untraded.

Technically, Genetic Technologies was best up half a cent or 10 percent to 5.5 cents but with just 10 shares traded, while Biota climbed 14 cents or 8.6 percent to $1.76 with 4.5 million shares traded.

Prana, Progen and Sirtex climbed more than six percent; Cytopia and Psivida were up more than five percent; Alchemia was up 4.3 percent; Mesoblast, Nanosonics, Peplin and Pharmaxis were up more that three percent; Genera and Tissue Therapies rose more than two percent; with Chemgenex, Circadian, Clinuvel and Cochlear up more than one percent.

Bone led the falls, down two cents or 11.1 percent to 16 cents with 2,000 shares traded followed by Living Cell down 10.5 percent to 17 cents.

Impedimed lost 8.9 percent; Novogen was down 6.8 percent; Compumedics and Viralytics were down more than three percent; Cathrx and Labtech shed more than two percent; Resmed was down 1.8 percent; with Acrux down by less than one percent.

TISSUE THERAPIES

Tissue Therapies has had significant problems with recruitment to its Canadian wound care trial while receiving “exceptional preclinical results” for new formulations of Vitrogro.

Tissue Therapies said it had hoped for 30 patients by June 30, 2009 in the Toronto Canadian venous, diabetes and pressure ulcer trial, which has been plagued by delays since the beginning of the regulatory approval process.

The Toronto trial was originally scheduled for December 2007 but the first patient was not treated until August 2008 (BD: Aug 11, 2008).

Tissue Therapies’ chief executive officer Dr Steven Mercer told Biotech Daily that so far the Canadian trial had produced “excellent” results for six patients of eight recruited.

He said the company would be switching its focus to the ongoing Western Australia-based trial of venous ulcers in Freemantle and taking the total data package to regulators.

“Venous ulcers are 70 percent of the advanced wound care market for the three types of ulcers,” Dr Mercer said.

Dr Mercer said the Freemantle trial expected to treat 30 patients by the end of September 2009 which would be the milestone required to continue negotiations with several wound care companies.

He said trials of the new formulation of Vitrogro with up to 100 patients should begin in early 2010 with registration of Vitrogro as a device by mid-2011.

Dr Mercer said Vitrogro had “shown excellent wound healing results in a group of patients who clinically are at the most extreme end of difficulty and for whom the best available treatments had failed”.

“Positive Vitrogro results, even in patients with chronic wounds as severe as these, make the delays in patient recruitment even more disappointing and frustrating,” Dr Mercer said.

He said Tissue Therapies was negotiating with the Australian clinical trials team headed by Prof Michael Stacey “to quickly increase patient recruitment, with the focus on venous ulcer patients”.

“We already have ethics board approval for another four venous ulcer patients and will be lodging an application shortly for an additional 20 [patients],” Dr Mercer said.

This will more than fulfill the original target of 30 patients targeted with the Canadian human trial. We already have data for 14 patients including the already announced 8 venous ulcer patients.”

Dr Mercer said the single-protein Vitrogro preclinical data was “compelling” and the company would place priority on manufacturing the new formulation Vitrogro for the final clinical trial and regulatory approval.

The regulatory classification of Vitrogro as a device for the treatment of chronic wounds means that data from only a single clinical trial is required for regulatory approval for sale.

Dr Mercer said Tissue Therapies expected the Vitrogro commercialization program would require up to an additional three months due to the slow Canadian clinical trial recruitment.

Tissue Therapies said both new formulations of Vitrogro combine into a single-protein the same wound healing biology as the original multi-protein Vitrogro.

The company said New Formulation Vitrogro 1 was more efficient than both the original multi-protein formulation and New Formulation Vitrogro 2.

Healing or re-epithelialization was faster for New Formulation Vitrogro 1, which will be the formulation to be manufactured for clinical trial and regulatory approval for sale. The company said.

Tissue Therapies said a single-protein formulation reduced cost and time of manufacture, preparation, clinical trial approval, regulatory approval, incorporation into wound dressings, reduced patient costs and improved margins.

Tissue Therapies was up half a cent or 2.7 cents to 19 cents.

PEPLIN

Peplin has begun its second pivotal non-head phase III clinical trial to confirm the efficacy and safety of PEP005 (ingenol mebutate) gel for actinic or solar keratoses.

Peplin said the Region-Ib trial would include the trunk and extremities and was designed to replicate the recently completed Region-I trial and confirm the results of PEP005 gel, which showed a total clearance rate across all anatomical non-head locations of 27.4 percent ($p<0.0001$), a median lesion reduction of 66.7 percent ($p<0.0001$) and statistical significance when compared to vehicle for clearance of actinic keratoses on the chest and the especially difficult-to-treat locations, the arm and back of hand (BD: May 18, 2009).

Peplin chief executive officer Tom Wiggans said that "achieving this additional milestone immediately following the rapid enrolment in our phase III head trials, demonstrates our commitment to progressing PEP005 gel through the final phase of our clinical development process".

"Based on the data we generated in the Region-I trial, we believe PEP005 gel with its short course of therapy represents a significant advance in the treatment of a common skin condition, which if left untreated can progress to squamous cell carcinoma," he said.

Last month (BD: Jun 9, 2009) the US Food and Drug Administration told Peplin that required a further trial.

Peplin said the 200 patient, randomized, double-blind, vehicle-controlled clinical trial would be conducted at multiple sites in the US and patients would apply the medication or vehicle gel for two consecutive days to a $25cm^2$ treatment area containing four to eight actinic keratosis lesions.

The company said the primary efficacy endpoint would be the complete clearance rate of actinic keratosis lesions and the secondary efficacy endpoint would be the partial clearance rate of lesions within the treatment area, the company said.

Peplin will also measure the overall median reduction of AK lesions.

Peplin said it would complete its phase III clinical trials for actinic keratosis by the end of this year and plans to file a new drug application in mid-2010.

Peplin climbed two cents or 3.4 percent to 61.5 cents.

MESOBLAST

Mesoblast says it has begun the process for Australian Therapeutic Goods Administration approval to commercially manufacture and distribute its adult stem cell products.

Mesoblast said it would seek TGA approval for its cell manufacturing process that would be provided and managed by TGA-licenced manufacturer, Cell Therapies Pty Ltd, a 51 percent subsidiary of the Peter MacCallum Cancer Clinic in Melbourne.

Mesoblast's executive director Prof Silviu Itescu said TGA approval of its first product would result in earlier revenues by making a fracture repair product available to hospitals and clinicians throughout Australia.

Mesoblast said it had completed an Australian trial of its autologous stem cell therapy for the repair of non-healing long bone fractures of the legs and the bone repair product for the trial was manufactured by Cell Therapies.

Mesoblast said non-healing long bone fractures affected millions of people worldwide, were usually a complication of road accident trauma, were very debilitating, and in some cases resulted in limb amputation.

Prof Itescu said the company was "excited at the prospect of making our bone repair product available for those patients who have poorly-healing fractures of their long bones and for whom no satisfactory alternatives are available".

Mesoblast was up three cents or 3.1 percent to $1.00.

QRX PHARMA

QRX says it has begun a phase II comparative proof-of-concept study to evaluate the efficacy and safety of intravenous Moxduo compared to morphine alone for pain.

QRX said that Moxduo was a combination of morphine and oxycodone and the study would evaluate its ability to treat severe post-operative pain in patients following hip replacement surgery.

The company said data from the study would "serve as a significant predictor" of intravenous Moxduo's clinical benefits and provide guidance for the design of further clinical trials leading to the submission of a new drug application to the US Food and Drug Administration within the next three years.

QTX chief executive officer Dr John Holaday said the company's goal was "to bring to market complementary analgesic options for pain specialists, delivering greater patient tolerability and efficacy than current standards of care".

He said Moxduo IV was one of three dual-opioid products that included immediate-release and controlled release oral formulations.

QRX said its products were the only combination opioids in commercial development and clinical studies had shown dual-opioids provided better pain relief with significantly fewer side effects.

The company said the double-blind, controlled study would determine whether Moxduo IV had fewer opioid-related adverse events than morphine alone at equi-analgesic doses and whether the maximum analgesic effect of Moxduo IV was superior to morphine alone.

In April Dr Holaday told Biotech Daily that Moxduo reduced side effects "because oxycodone effectively blocked pathways that trigger those responses, reducing the impact of the morphine side effects, while allowing the pain relief" (BD: Apr 29, 2009).

"Kappa agonists like oxycodone block the effect of µ-agonists like morphine," Dr Holaday said in April. "The analgesia shines through but the side effects are dramatically reduced."

"Using equivalent doses of Moxduo with its components of morphine or oxycodone alone, one finds a significant reduction in side effects such as nausea and vomiting and respiratory depression," Dr Holaday said in April.

QRX said the study was being conducted at Germany's Cologne-Merheim Medical Center, a part of Witten/Herdecke University and Cologne University Hospital.

The company said that following hip replacement surgery, 40 subjects would be randomized into Moxduo or morphine groups over a two-part, 48-hour treatment period.

QRX said that in the first part, rapid dosing would be used by to achieve maximal reductions in pain.

In the second part, patients will manage their own pain relief on an "as needed" basis using self-administered patient-controlled analgesia.

The company said the Moxduo IV and morphine groups would be compared for clinically significant differences in analgesia and/or side effects.

"Preliminary phase III data demonstrate that the company's Moxduo [immediate release] oral formulation consistently yield superior pain relief with a lower frequency of side effects than morphine and oxycodone alone," Dr Holaday said.

"We believe our intravenous formulation will demonstrate similar benefits as seen with orally administered Moxduo IR," Dr Holaday said.

"Specifically, the absence of sedation as well as reduced nausea and vomiting may permit accelerated patient recovery while providing superior pain relief," Dr Holaday said.

"This will enable physical therapy to begin sooner, saving time and money for both patient and payer," he said.

QRX said the study was expected to be completed before the end of 2009.

QRX was untraded at 46 cents.

BIOTA, GLAXOSMITHKLINE

Biota expects to receive a royalty payment of $8.9 million from Glaxosmithkline for $122.5 million sales of Relenza in the three months to June 30, 2009.

The royalty payment follows the previous quarter indicative royalty of $32.3 million taking the total financial year to June 30, 2009 royalties to $45.0 million compared to the previous year's royalties of $20.5 million, the company said.

Biota said Glaxosmithkline's Relenza sales were worth $638.7 million for the year to june 30, 2009, compared to $304.4 million for the previous year.

Biota said Glaxosmithkline had issued an H1N1 influenza (swine 'flu) pandemic update on "its plans to assist governments and health authorities" respond to new influenza strain.

Biota said Glaxosmithkline had committed to increase its annual Relenza production capacity to 190 million courses by the end of 2009 compared to its previous capacity of 60 million courses.

Production capacity of Relenza in its standard Diskhaler format will be increased from 60 to 90 million courses and a further 100 million courses a year will be available as Relenza Rotacaps/Rotahaler.

Biota said the alternative Relenza treatment had been granted temporary approval by Swedish regulators and hence within the EU, for distribution during a pandemic.

The company said the Glaxosmithkline Rotacaps/Rotahaler was a simple, easy to use device manufactured by Glaxosmithkline for other inhaled products and offers a rapid increase in capacity for Relenza.

Biota said Glaxosmithkline was in discussion with a number of regulatory authorities to secure further approvals.

Biota said Glaxosmithkline intended to donate two million courses of Relenza to the World Health Organisation (WHO) and Biota agreed to waive royalties for this donation.

Biota said it received a minimum seven percent royalty on global sales of Relenza by Glaxosmithkline and held patent coverage until December 2014.

Biota said Glaxosmithkline had contracts to supply Relenza to more than 60 countries, but the announcement is about increased manufacturing capacity for Relenza, not orders or sales.

Biota said additional regulatory approvals would be required and the capacity increases were planned for the end of calendar 2009.

The company said the expansion of Relenza capacity and any increase in resultant royalty payments, would not effect its cash position until June 2010, at the earliest.

Biota climbed 14 cents or 8.6 percent to $1.76 with 4.5 million shares traded.