Biotech Daily

Monday February 6, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PATRYS UP 14%, ALLIED HEALTH DOWN 6%**

*** SIRTEX SIR-SPHERES, SORAFENIB PHASE III COMPARISON TRIAL**

*** ALCHEMIA'S FONDAPARINUX TAKES 18% OF US MARKET**

*** CALZADA, POLYNOVO WOUND TREATMENT TRIAL BEGINS**

*** GENETIC TECHNOLOGIES SETTLES EUROFINS CASE**

*** BONE UP 186% ON EURO PATENT FOR ORAL PEPTIDE DELIVERY**

MARKET REPORT

The Australian stock market climbed 1.05 percent on Monday February 6, 2012 with the S&P ASX 200 up 44.8 points to 4296.0 points.

Fifteen of the Biotech Daily Top 40 stocks were up, nine fell, 11 traded unchanged and five were untraded.

Patrys was the best, up half a cent or 14.3 percent to four cents with 285,000 shares traded, followed by Neuren up 12 percent to 2.8 cents with 17.3 million shares traded.

Antisense and Uscom climbed more than 11 percent; Alchemia and Prana were up more than six percent; Avita was up four percent; Reva and Universal Biosensors were up more than three percent; Bionomics, QRX and Tissue Therapies rose more than two percent; Anteo, Clinuvel, Mesoblast and Resmed were up more than one percent; with Cochlear up 0.2 percent.

Allied Health led the falls, down 0.2 cents or 6.25 percent to three cents, with 465,200 shares traded.

Impedimed lost 3.6 percent; Living Cell fell two percent; Acrux, Bioniche, CSL, Nanosonics and Pharmaxis were down more than one percent; with Biota and Starpharma down by less than one percent.

SIRTEX MEDICAL

Sirtex says it will support a 400-patient, phase III trial comparing SIR-Spheres against versus sorafenib, the standard of care for inoperable liver cancer.

Sirtex said the multi-centre, prospective, randomized, open-label, controlled trial would be sponsored by France's Assistance Publique Hôpitaux de Paris, to directly compare the effectiveness of locally-targeted SIR-Spheres microspheres against the systemic drug sorafenib, marketed as Nexavar, by Bayer Healthcare.

The company said the trial expected to recruit 400 patients with advanced hepatocellular carcinoma, as defined by the Barcelona Clinic Liver Cancer 'stage C', with or without portal vein thrombosis and no extra-hepatic spread, who are ineligible for surgical resection, liver transplantation or radiofrequency ablation; or whose disease has progressed or recurred after previous therapies.

Sirtex said the study's primary aim was to assess if SIR-Spheres provided an increased survival benefit compared to sorafenib in patients with advanced liver cancer.

The company said the study would be led by the hospital's Prof ValérieVilgrain and would involve about 20 specialist cancer centres throughout France.

Sirtex said that sorafenib was associated with an increased overall survival, but 80 percent of patients experienced treatment-related adverse events and there was a growing interest in radio-embolization using yttrium-90 resin microspheres, based on a substantial number of open-label single-group studies, as well as a large multi-centre European analysis of the long-term outcomes related to survival and safety of radio-embolization using SIR-Spheres in patients with inoperable liver cancer.

Sirtex chief executive officer Gilman Wong said the study was an "important clinical trial for patients with inoperable hepatocellular carcinoma".

"Our investment in this trial is part of our long-term plan to significantly expand our business by realizing the full potential of SIR-Spheres microspheres," Mr Wong said.

Sirtex was unchanged at $4.85.

ALCHEMIA

Alchemia says its generic fondaparinux has taken 18 percent of the US prescription market with sales of more than $1.4 million a week.

Alchemia said its synthetic heparin, generic fondaparinux was launched in the US in July 2011 by Dr Reddy's Laboratories.

The company said that the non-hospital retail segment of the market was known to be relatively higher priced and profitable compared with the hospital or non-retail segment, and Dr Reddy's had achieved a dollar market share of more than 30 percent in the retail segment.

Alchemia said that the dollar value of the retail market for fondaparinux remained robust at $240 million in 2011, maintained by a sharp increase in prescription numbers after the introduction of lower price generics.

Alchemia chief executive officer Dr Pete Smith said the company was "very happy with the advances made by Dr Reddy's both in terms of the market share achieved and the increases in yields and production capacity".

"With this strong performance we believe that we are on track to meet our expectations for fondaparinux in 2012," Dr Smith said.

"With a strong balance sheet, the anticipated cash-flow from fondaparinux and the recent initiation of recruitment to our phase III colorectal cancer and phase II lung cancer trials, Alchemia is well placed for a very exciting year," Dr Smith said.

Alchemia was up two cents or 6.1 percent to 35 cents with 2.9 million shares traded.

CALZADA

Calzada says that recruitment has begun in wholly-owned subsidiary Polynovo's first human clinical trial of Novosorb polymer foam dressings for pressure sores.

Calzada said the 20-patient randomized, controlled trial followed proof-of-concept studies of Novosorb in a biodegradable temporizing matrix which showed "excellent biocompatibility and efficacy".

The company said the method of wound treatment would be vacuum assisted closure of pressure sores using Novosorb dressings for topical negative pressure and would be conducted by the Royal Adelaide Hospital's adult burns unit director Prof John Greenwood and Polynovo, through their joint venture Novowound.

The company said that it expected treatment would begin by March, with results by October 2012 and the trial was budgeted to cost less than $150,000.

Calzada said the primary outcome would be the ability to transmit topical negative pressure to the wound bed, assessed by odor, reduction of oedema, development of vascular granulations and cleanliness of wound area, with the secondary outcome safety measured by the absence of local or systemic effects attributable to Novosorb.

The company said that 10 patients in the open label trial would be treated with the Novosorb dressing and 10 with the control dressing, Granufoam, for eight weeks before final closure of the wound.

Calzada said that following surgical removal of dead skin from patients wounds at the Royal Adelaide Hospital, patients would be treated at home, having wound quality assessment and dressing by a specialist nurse three times each week.

Calzada said topical negative pressure, vacuum assisted closure concept was introduced by the Wake Forest University and approved by the US Food and Drug Administration for wounds including partial thickness burns, diabetic ulcers, bedsores, dehisced surgical incisions, flaps, grafts, traumatic wounds and other non-healing wounds.

The company said a dressing was fitted to the wound and sealed with a transparent film with a drainage tube connected to a vacuum source, turning an open wound into a controlled, closed wound while removing excess fluid.

Calzada said that foam dressings were used to fill open cavity wounds and a film applied to create a seal around the dressing, with a vacuum tube connected to a pump.

The company said that the topical negative pressure consumables market was worth more than $US400 million a year.

Calzada said that in 2010, a US court ruled in favor of Smith and Nephew invalidating certain patents licenced to Kinetic Concepts, allowing competitors to use foam dressings for topical negative pressure, creating "an opportunity for Polynovo to develop its own Novosorb foam dressing" which it said was superior in terms of safety and efficacy.

Calzada said that in February 2011 the FDA issued a warning on topical negative pressure therapy, noting complications with wound infection, but Prof Greenwood and Polynovo believed that Novosorb would ameliorate those issues.

Prof Greenwood said that "in 11 animal studies and countless in-vitro cellular studies, the Novosorb material has been very well tolerated, quick to integrate and has yielded excellent outcomes".

Calzada said the trial was intended to provide safety and efficacy data on Novosorb to support regulatory approval in jurisdictions including the European Union and US, with a rapid approval process due to the nature and classification of the dressing.

The data would also provide preliminary information for Polynovo's second trial, a free flap donor site trial, affording the opportunity to gather data in human wounds without permanently implanting Novosorb.

Calzada was up 0.3 cents or six percent to 5.3 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has executed a settlement and licence agreement with the Longmont, Colorado-based Eurofins STA Laboratories.

Genetic Technologies said that Eurofins STA had been granted non-exclusive rights to a number of its patents relating to its non-coding DNA technology.

The company said that as with other similar agreements, the precise commercial terms of the agreement were covered by formal confidentiality provisions and cannot be disclosed.

Genetic Technologies said that Eurofins STA was a counter-party to the third formal patent assertion suit it had filed against 10 companies in the US District Court for the District of Colorado and was the third counterparty to settle (BD: May 26, 2011).

The company said that discussions with other parties both internal and external to the formal assertion program were ongoing and progressing.

Genetic Technologies was unchanged at 13 cents.

BONE MEDICAL

Bone says that the European Patent Office has accepted its licenced Axcess III patent application for grant.

Bone said that Axcess III extended and strengthened the proprietary position of its oral peptide delivery technology, which it licenced from Proxima Concepts.

The company said that the Axcess III patent had been granted or approved for grant in Australia, China, India, New Zealand and other markets.

Bone said that its Axcess II patent, which provided additional proprietary protection of the oral peptide technology based on a separate set of claims, had been granted or approved for grant in the US, Russia and other countries.

Bone chairman and chief scientific officer Dr Roger New is the inventor of the Axcess technology as well as co-founder and research director of Proxima Concepts.

Dr New said the patent acceptance was “confirmation of the robust and innovative character of our Axcess oral peptide formulation platform”.

“Oral delivery of peptides has been an important but elusive therapeutic goal of the life science industry for many years and Axcess provides a highly promising means of achieving it with potentially profound benefits for the treatment of chronic diseases like osteoporosis and arthritis,” Dr New said.

Bone was up 1.3 cents or 185.7 percent to two cents with 93.9 million shares traded.