Biotech Daily

Thursday December 3, 2015

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: PHARMAXIS UP 25%, PRO MEDICUS DOWN 8%**

*** FDA REQUESTS CLINUVEL SCENESSE VITILIGO PRE-CLINICAL TRIAL**

*** PROGEN MEETS $10m MINIMUM FOR MEDIGEN TBG ACQUISITION**

*** PARADIGM TREATS 1st ZILOSUL SPECIAL ACCESS PATIENT**

*** NEUREN REQUESTS TROFINETIDE FRAGILE X RESULTS TRADING HALT**

*** HEALTH CANADA APPROVES RHINOMED'S TURBINE, MUTE**

*** BLUECHIIP, GENEA FERTILITY TRACKING LICENCE**

*** CYNATA, REGIENCE CONSIDER JAPAN, ASIA PARTNERSHIP**

*** CHRIS RETZOS, ASSOCIATES TAKE 9% OF PRESCIENT**

*** PHOSPHAGENICS BEGINS SECOND TPM PIG STUDY**

MARKET REPORT

The Australian stock market fell 0.58 percent on Thursday December 3, 2015 with the ASX200 down 30.6 points to 5,227.7 points. Sixteen of the Biotech Daily Top 40 stocks were up, 16 fell, five traded unchanged and three were untraded. All three Big Caps fell.

Pharmaxis was the best for the second day in a row, up six cents or 25 percent to 30 cents with 6.1 million shares traded, followed by Optiscan up 20 percent to 3.6 cents and Biotron up 15.6 cents to 5.2 cents.

Atcor climbed 8.6 percent; Impedimed was up 5.5 percent; Avita and Compumedics rose more than four percent; Oncosil was up three percent; Ellex and IDT rose more than two percent; Anteo and Clinuvel were up more than one percent; with Admedus, Mesoblast, Psivida and Viralytics up by less than one percent.

Pro Medicus led the falls, down 26 cents or 8.3 percent to $2.86 with 179,381 shares traded. Osprey and Polynovo lost more than six percent; Cellmid, Medical Developments and Universal Biosensors fell four percent or more; Benitec, Genetic Technologies and Prana were down more than three percent; Actinogen, Living Cell and Prima shed two percent or more; Cochlear, Nanosonics, Reva and Sirtex lost more than one percent; with Acrux, CSL and Resmed down by less than one percent.

CLINUVEL PHARMACEUTICALS

Clinuvel says the US Food and Drug Administration has requested a further pre-clinical study of Scenesse (afamelanotide 16mg) in vitiligo ahead of human trials.

Separately, Clinuvel said that preliminary results from its 21-patient phase II Singapore study (CUV103) in patients with naturally darker skin were consistent with results from the previous US phase II trial (CUV102), showing combination benefit.

The company said that preliminary analyses comparing the change from baseline between the treatment groups showed “a positive trend” for Scenesse ($p = 0.052$ at day 168) and a higher decrease of the average re-pigmentation score after the second Scenesse dose for the trunk, lower and upper extremities compared to placebo.

Clinuvel said the Singapore trial showed that safety was good and no serious drug-related adverse events were reported in the preliminary analysis cohort.

The company said its 54-patient, phase II US Scenesse study (CUV102) in vitiligo in 2013 showed that Scenesse with narrowband ultraviolet B (NB-UVB) light therapy was superior for vitiligo re-pigmentation than NB-UVB alone (BD: Sep 2, 2013).

Clinuvel said at that time the trial showed that re-pigmentation following treatment with Scenesse was higher than with the narrowband ultraviolet B group at 11 months since the start of the treatment ($p = 0.032$).

Today, Clinuvel did not specify the type of pre-clinical study requested by the FDA, but said the regulator had “requested that one pre-clinical study be conducted, simulating the anticipated human dose regimen, ahead of advanced US trials … [and it was] common for the FDA to request additional preclinical evidence to further demonstrate the safety of novel combination therapies”.

The company said that there was a range of vitiligo therapies, with NB-UVB phototherapy two to three times weekly for 12 to 18 months a standard-of-care.

Clinuvel said that Scenesse was being evaluated as a combination therapy with NB-UVB with the aim of reducing both the cumulative irradiation dose and overall treatment time.

The company said it was currently conducting a six-month, placebo-controlled pre-clinical study combining six monthly doses of Scenesse with NB-UVB administered three times per week, and the total accumulated irradiation and dose per session simulated the treatment regimen in humans.

Clinuvel said that when the study report was completed it would request a meeting with the FDA to discuss the results and the protocol for evaluating Scenesse in vitiligo patients.

Clinuvel said it expected two or three concurrent advanced clinical trials would be required prior to submitting a new drug application to the FDA.

The company said that its scientific hypothesis was that Scenesse in combination with NB-UVB would elicit a positive response in vitiligo patients and that Scenesse accelerates the follicular re-pigmentation response.

Clinuvel said it had “worked closely with a group of leading global academics and clinicians specialising in vitiligo and pigmentation [the Global Vitiligo Consortium] to design its vitiligo program” and the group’s clinical feedback from trials had added value to the analyses.

The company said that the Consortium would assist in developing and reviewing the final clinical protocols for the North American vitiligo program.

Clinuvel said that consensus had been reached to focus development on patients with darker skin complexions due to the high disease burden and impact in this group and pending the final results of CUV103 in Singapore, expected by July 2016, the definitive vitiligo patient population would be decided (BD: May 6, 2014).

Clinuvel climbed five cents or 1.75 percent to $2.90.

PROGEN PHARMACEUTICALS

Progen says it reached the minimum subscription of $10 million within one week of the share offer opening.
In November, Progen filed a prospectus to raise up to $14.5 million at 21 cents a share to acquire TBG Inc from Taiwan's Medigen Biotechnology Corp (BD: Nov 11, 2015).
In October, Progen said that it would acquire TBG, which had research and development, manufacturing and sales operations and was "one of the leading providers of quality human leukocyte antigen typing kits for immune matching of bone marrow, cord blood and solid organ transplants" (BD: Oct 16, 2015).
Today, Progen executive chairman Jitto Arulampalam said the company was "delighted with the support … we are now another step closer towards achieving our strategy of repositioning the company from a drug development business to a global molecular diagnostic business".
Progen said the offer was scheduled to close on December 9, 2015.
Progen was untraded at 19.5 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has treated its first Zilosul bone marrow oedema or bone bruising patient under Australia's Therapeutic Goods Administration's special access scheme.
Paradigm said that the Melbourne-treated unnamed "elite athlete" had un-resolving bone marrow lesion, refractory to multiple therapeutic and surgical interventions.
The company said that the treatment involved six intramuscular injections of Zilosul, from early November 2015, with no adverse events observed, the product was well tolerated and the prescribing doctor advised that the initial clinical response was "very positive [and] encouraging particularly given the refractory nature of symptoms in this patient".
The company expects to begin a 40-patient, open-label, pilot trial investigating the safety and tolerabilityof Zilosul in patients with bone marrow lesions from an anterior cruciate ligament injury early in 2016 (BD: Nov 23, 2015).
In November, Paradigm said that Zilosul was an injectable form of pentosan polysulphate and the trial would be conducted at Adelaide's Southern Orthopaedics and Melbourne's Southern Orthopaedics.
The company said that pentosan polysulphate was a sulphated extract of a polysaccharide obtained from the bark of the European beech tree and had been approved by US Food and Drug Administration for oral treatment of bladder pain associated with interstitial cystitis for more than 30 years.
Paradigm chief executive officer Paul Rennie said that bone marrow oedema was "a serious and painful condition which can hamper the ability of sportspeople to return to training and competitive sports".
"The upcoming clinical trial will explore the effects of Zilosul treatment in more detail, but the early result in the TGA-approved special access treatment is very encouraging," Mr Rennie said.
Paradigm said the patient had not recently ruptured his anterior cruciate ligament, was not eligible to enter the clinical trial and was being treated under the special access scheme because the drug in its injectable form was not registered for human use in Australia, the patient did not meet the eligibility criteria for the trial and current therapies had not been effective.
The company said that the patient's governing sports body had determined Zilosul was not a performance enhancing drug.
Paradigm fell one cent or 3.1 percent to 31 cents.

NEUREN PHARMACEUTICALS

Neuren has requested a trading halt “pending an announcement regarding [its] phase II clinical trial of trofinetide [NNZ-2566] in Fragile X syndrome”.
Trading will resume on December 7, 2015 or on an earlier announcement.
Neuren last traded at nine cents.

RHINOMED

Rhinomed says that Health Canada has approved the distribution of its Turbine sports and Mute snoring and sleep technology as class I medical devices in Canada.
Rhinomed said that the Health Canada approval was through the provision of a Medical Device Establishment Licence enabling the import into, and sale of, both products in Canada.
The company said that the licence also supported continued dialogue with distributors.
Rhinomed said that it would seek to distribute the Turbine through Canadian cycling, triathlon and sporting store outlets and major sporting retailers, with Mute distribution through pharmacies.
Rhinomed fell 0.3 cents or 8.6 percent to 3.2 cents with 2.9 million shares traded.

BLUECHIIP

Bluechiip says that Genea Biomedx has a licence to incorporate its sample tracking technology into Genea’s assisted reproductive technology instruments.
Bluechiip said that the Sydney-based Genea Biomedx would licence the wireless tracking technology designed for -196oC cryogenic temperatures for assisted reproductive technology and the licence and supply would progress through staged development phases including concept due diligence, product development and subsequent commercial release.
The company said that the licence included milestone payments with minimum quantities on commercial release.
Bluechiip chief executive officer Andrew McLellan said the agreement was “a major step forward for Bluechiip providing validation of our … strategy to partner with global leaders to incorporate Bluechiip technology into their products”.
Bluechiip was up 1.5 cents or 38.5 percent to 5.4 cents with 2.1 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has a letter-of-intent for a stem cell development and commercialization alliance with Japan’s Regience KK for Japan and certain other Asian countries.
Cynata said the two companies had identified “a mutually beneficial business opportunity” to enter a partnership in which Regience would licence, develop and commercialise its Cymerus mesenchymal stem cell technology.
The company said the two companies would evaluate and define a commercial relationship and, if appropriate, enter a strategic alliance agreement.
Cynata fell half a cent or 1.25 percent to 39.5 cents.

PRESCIENT THERAPEUTICS

The Shepparton, Victoria-based Chris Retzos has directly and indirectly become a substantial shareholder in Prescient with 8,305,131 shares (8.86%).
Mr Retzos said the holding included shares held with Susie Retzos through the Retzos Family Superannuation Fund, Jaclyn Stojanovski through the Retzos Executive Superannuation Fund, Stephen Retzos and Melissa Martin.
Mr Retzos said the shares were acquired between August 24 and December 1, 2015 in a placement and share plan at 5.4 cents a share and on-market.
Prescient fell 0.1 cents or 1.35 percent to 7.3 cents.

PHOSPHAGENICS

Phosphagenics says it will begin a second swine study in its feed efficiency program, targeting older pigs and completing the initial pig treatment program.
Phosphagenics said it expected to report results from its completed weaner, or young, pig study later this month.
In September, Phosphagenics said the first trial of its tocopheryl phosphate mixture (TPM) for piglet nutrition was “a key milestone” for its animal health and nutrition business and the trial would assess the phosphorylated vitamin E feed additive for weaner pigs, measuring weight gain, feed efficiency and other production endpoints (BD: Sep 28, 2015).
The company said that the weaner study targeted feed efficiency and the grower-finisher pig study would assess meat quality and feed efficiency, with headline results for the older pig study expected by July 2016.
Phosphagenics chief executive officer Dr Ross Murdoch said that “assuming positive results across the pig program, planning is already underway to expand our animal trials into other species”.
Phosphagenics was up 0.1 cents or 7.1 percent to 1.5 cents.