Biotech Daily

Thursday March 27, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: USCOM UP 18%, ATCOR DOWN 8%**

*** PATRYS PAT-SM6 MULTIPLE MYELOMA RESULTS BACK COMBINATION**

*** REVA DUMPS REZOLVE FOR FANTOM, CUTS STAFF**

*** BIOGRID, GENOMICS HEALTH ALLIANCE PILOT PROJECT**

*** PRELIMINARY DUTCH COVERAGE FOR GI DYNAMICS ENDOBARRIER**

*** NEUREN AGM FOR 30m CFO, COO LOAN SHARES, 3.3m FREE RIGHTS**

MARKET REPORT

The Australian stock market fell 0.5 percent on Thursday March 27, 2014 with the S&P ASX 200 down 26.7 points to 5,350.1 points.

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

Uscom was the best, up 4.5 cents or 17.65 percent to 30 cents with 129,047 shares traded.

Compumedics climbed 5.6 percent; Avita and Tissue Therapies were up more than four percent; Living Cell and Universal Biosensors were up more than three percent; with Acrux, Bionomics, Mesoblast and Resmed up by less than one percent.

Atcor led the falls, down one cent or 7.7 percent to 12 cents with 17,500 shares traded.

Prana lost 6.9 percent; Patrys fell 4.4 percent; Oncosil was down 3.7 percent; Clinuvel and QRX shed more than two percent; Anteo, CSL, Genetic Technologies and Starpharma were down more than one percent; with Benitec, Cochlear, Medical Developments, Nanosonics and Sirtex down by less than one percent.

PATRYS

Patrys says four of 12 patients in its phase I/IIa trial of PAT-SM6 for refractory or relapsed multiple myeloma had stable disease with two patients stable for more than 130 days

Patrys said the final results showed that one patient who received 3mg/kg of PAT-SM6 was stable for 138 days before additional therapy was needed and another patient, who received 6mg/kg, was stable for 154 days and was currently therapy free.

The company said that on average each patient received five prior lines of therapy, including proteasome inhibitors, immunomodulatory drugs or stem cell transplantation.

Three patients in each of four cohorts received four intravenous infusions of PAT-SM6 at 0.3mg/kg, 1mg/kg, 3mg/kg or 6mg/kg per dose and were assessed at 36 days.

The company said that the primary endpoint of the study was safety and tolerability and PAT-SM6 was well tolerated at all doses with no serious adverse events or dose limiting toxicities reported and no maximal tolerated dose reached.

Patrys said the data compared favorably with the antibody elotuzumab currently in phase III combination trials for multiple myeloma and when tested in a phase I single agent trial, nine of 35 patients (26.5%) treated with increasing doses of elotuzumab (0.5 - 20mg/kg) responded with stable disease.

Patrys said that patients had a mean time to next therapy of 51 days which was clinically significant and those previously treated with proteasome inhibitors responded much better to PAT-SM6 treatment than patients who had been previously treated with immunomodulatory drugs or other chemotherapeutics.

The company said this indicated that PAT-SM6 might act synergistically with proteasome inhibitors, such as carfilzomib, to induce better clinical responses, which would be tested in a clinical trial of PAT-SM6 in combination with carfilzomib.

Patrys said that 11 of 12 patients went on to additional salvage therapy after completing the trial, with seven of 11 patients responding “very positively with a partial response while three others responded with [stable disease] indicating that PAT-SM6 treatment may make cancer cells more sensitive to killing by other chemotherapeutics”.

The company said blood sample analysis showed that no patient generated a significant adverse immune response to PAT-SM6 and pharmacokinetic analysis demonstrated linear dose proportional increases in maximum serum concentration of PAT-SM6.

Patrys said that patients had apparent linear pharmacokinetics with a rapid distribution phase followed by a slower disposition phase and a half-life of about seven hours, with the parameters of half-life, volume of distribution and clearance consistent across dose levels and between cycles, indicating that higher doses did not affect the general pharmacokinetic properties of PAT-SM6.

The company said that post-treatment malignant cells showed that PAT-SM6 specifically targeted and bound to the myeloma cells and immune system analysis indicated that PAT-SM6 was capable of inducing an immune response by both stimulating and increasing the absolute number of CD8+, natural killer and regulatory T-cells, which were more significant in patients who had stable disease post-treatment with PAT-SM6, which might indicate specific crosstalk between PAT-SM6 and immune cells, a previously unreported finding that warrants further investigation.

Patrys chief executive officer Dr Marie Roskrow said the trial results were “especially exciting because they reflect single-agent activity in a difficult-to-treat population”.

“Due to very high rates of relapse, the combination of multiple agents is increasingly becoming a therapy of choice for patients with multiple myeloma,” Dr Roskrow said. “The results ... strongly support further evaluation of PAT-SM6 in combination with carfilzomib which is the basis of our planned Amgen-sponsored clinical trial.”

Patrys fell 0.2 cents or 4.4 percent to 4.3 cents with 11.8 million shares traded.

REVA MEDICAL

Reva says it will fast-track development of its Fantom thin-strut bioresorbable cardiac stent scaffold family and close its Rezolve program, cutting staff.

After the market closed, Reva said it would cease expending further resources on Rezolve, other than to follow patients in the Restore Conformité Européenne (CE) mark trial, allowing the company to focus all resources on preparing Fantom for human studies.

The company said it had made “a significant reduction of personnel”, eliminated Rezolve manufacturing overheads and reduced other non-essential costs.

Reva said that the Fantom scaffold was made from a single piece of its desaminotyrosine polycarbonate polymer, was less complex to manufacture and resulted in coronary scaffolds that half the thickness and stronger than its existing Rezolve platform.

Reva said that thinner scaffold dimensions improved deliverability and the healing response, each of which could help to ensure broader adoption.

The company said that the Fantom scaffold had x-ray visibility and a single inflation to expand the device, like the Rezolve platform, which were features competitive polymer scaffolds did not offer.

Reva said that early bench tests and preclinical results of Fantom demonstrated the substantial performance benefits of this product and the first human implants were planned by the end of 2014, with commercialization targeted for mid-2016.

Reva chief executive officer Bob Stockman said there was a “conversion in an annual $US4 billion market from metallic stents to the use of fully bioresorbable scaffolds, because these new devices help to restore blood flow in diseased heart vessels, then disappear when their jobs are complete.”

“The coronary stent market is now demanding that bioresorbable scaffolds emulate the deliverability, scaffolding mechanics and ease of use of today’s best metallic stents,” Mr Stockman said. “We believe that our new thin-strut technology family of Fantom scaffolds will best address these requirements.”

“Despite the promising results we have seen with Rezolve in its CE mark trial, a streamlined organization entirely focused on what we believe to be the product that will catalyze widespread clinical adoption is the best strategy,” Mr Stockman said.

Reva was unchanged at 39 cents.

BIOGRID AUSTRALIA, MELBOURNE GENOMICS HEALTH ALLIANCE

Biogrid says the Melbourne Genomics Health Alliance will use its systems to carry out a pilot project to assess how genomic sequencing can be applied in hospitals.

The Alliance, composed of seven Victorian health services, was created last month to link genetic and clinical data (BD: Feb 11, 2014).

Biogrid’s website said that it was an independent not-for-profit company owned by 27 collaborators representing 43 hospitals and research organizations across five states and territories and operated a federated data sharing platform for collaborative translational health and medical research.

Biogrid said the project would use the Health and Biomedical Informatics Centre which was a collaborative effort between a number of University of Melbourne departments.

A Biogrid media release said that during the next six months, more than 200 patients would have their exome, or instructions for genes, sequenced to test approaches to providing genomic testing as part of usual health care practice.

The media release said that the diseases being tested were the childhood syndromes, focal epilepsy, muscle weakening disorder Charcot-Marie Tooth, hereditary colorectal cancer and acute myeloid leukaemia.

GI DYNAMICS

GI Dynamics says that the Nederlandse Zorgautoriteit (Dutch Healthcare Authority) has designated a preliminary reimbursement code for its Endobarrier therapy.
GI Dynamics said at the designation was part of a policy rule for new and innovative health care treatments and would cover Endobarrier therapy for obesity and type 2 diabetes.
The company said that under the ruling, a defined number of Endobarrier procedures performed between July 2013 and July 2016 at Rijnstate Hospital in Arnhem would be covered by a major regional health insurance fund in the Arnhem area.
GI Dynamics said the designation allowed authorities to capture sufficient clinical and economic data for Endobarrier therapy over a three-year period, which would be evaluated to determine whether Endobarrier was eligible to receive permanent reimbursement codes with funding commiserate to the cost of the therapy.
GI Dynamics chief executive officer Stuart Randle said that following reimbursement in Germany and Switzerland, the Netherlands announcement "marks another achievement in our efforts to secure national reimbursement for Endobarrier therapy in key markets".
"We believe there is an opportunity for other hospitals in the Netherlands to secure similar coverage with their regional health insurance funds," Mr Randle said.
GI Dynamics was unchanged at 55 cents.

NEUREN

Neuren will vote to grant chief financial officer Jon Pilcher and chief operating officer James Shaw 30 million loan shares and 3,309,892 free rights.
Neuren said it had issued 20 million loan shares to Jon Pilcher and 10 million loan shares to James Shaw at 9.2 cents a share, the closing price on September 18, 2013, when the board resolved to issue the shares.
The company said that 50 percent of the loan shares were conditional on the total shareholder return equaling or exceeding 75 percent (16.1 cents) over the three year vesting period and 50 percent were conditional on the company either taking a product candidate to a phase IIb or phase III trial following a positive phase II trial outcome and a national regulatory authority approves the trial, or a material partnering or licencing transaction is concluded.
Neuren said that the loan must be repaid in full, and the conditions satisfied, before the shares could be transferred to the holder.
The company said that it proposed to issue 2,666,667 free options worth $100,000 to Mr Pilcher, vesting on August 18, 2016 and exercisable at no cost within five years.
Neuren said that it proposed to issue 643,225 free options worth $75,000 to Mr Shaw, vesting on August 25, 2016 and exercisable at no cost within five years.
The company's notice of meeting said it would seek shareholder approval to re-elect director Bruce Hancox and a special resolution requiring a 75 percent majority to remove the constitutional requirement for two New Zealand-based directors.
The meeting will be held at PWC Melbourne, Freshwater Place, Level 19, 2 Southbank Boulevard, Southbank, Melbourne on April 30, 2014 at 10.30am (AEST).
Neuren was unchanged at 9.1 cents with 1.4 million shares traded.