Biotech Daily

Tuesday December 17, 2019

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: IMMUTEP UP 15%; NEXT SCIENCE DOWN 6%**

*** ANTISENSE JUMPS 46% ON ATL1102 FOR DMD 'SAFETY, EFFICACY'**

*** MORGANS UNDERWRITES ANTISENSE OPTIONS FOR $4m, TOTAL $5.5m**

*** MESOBLAST NEARS CARDIAC STEM CELL TRIAL COMPLETION**

*** NOXOPHARM RAISES $8.5m FOR NYRADA IPO**

*** ZELIRA COMPLETES MARIJUANA INSOMNIA TRIAL DOSING**

*** RACE RECEIVES $159k FEDERAL R&D TAX INCENTIVE**

*** NEUROTECH: HOLY STONE TAIWAN MENTE AUTISM DISTRIBUTOR**

*** PERENNIAL TAKES 7% OF GENETIC SIGNATURES**

*** JEFFERY EMMANUEL TAKES 7% OF SIENNA**

*** GAYLE MCGARRY, CAPERI REDUCE TO 6% OF BOTANIX**

MARKET REPORT

The Australian stock market slipped 0.04 percent on Tuesday December 17, 2019, with the ASX200 down 2.4 points to 6,847.3 points. Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, nine traded unchanged and three were untraded.

Immutep was the best, up 3.5 cents or 15.2 percent to 26.5 cents, with 2.1 million shares traded. Antisense climbed 9.8 percent; Kazia was up 7.7 percent; Cyclopharm, Medical Developments and Oncosil were up three percent or more; Actinogen and Opthea rose two percent or more; Genetic Signatures and Pro Medicus were up more than one percent; with Avita, Mesoblast, Paradigm and Resmed up by less than one percent.

Next Science led the falls, down 11.5 cents or 6.25 percent to $1.725, with 184,228 shares traded. Alterity, Amplia and Polynovo fell more than four percent; Cynata, Dimerix and Prescient lost more than three percent; LBT, Nanosonics and Orthocell shed more than two percent; Clinuvel fell 1.5 percent; with Cochlear, CSL, Neuren, Starpharma, Telix and Volpara down by less than one percent.

ANTISENSE THERAPEUTICS

Antisense jumped 46.3 percent on news that its nine-patient phase II trial of ATL1102 for Duchenne muscular dystrophy showed safety, tolerability and efficacy.

Antisense said that the primary objective of the trial was to assess the safety and tolerability of ATL1102 at 25mg administered by subcutaneous, or under the skin, injection once weekly for 24 weeks in non-ambulatory Duchenne muscular dystrophy (DMD) patients at Melbourne's Royal Children's Hospital.

The company said the trial showed an "excellent safety profile and positive drug effects on disease progression endpoints" and planned to take ATL1102 into "a potentially pivotal phase IIb clinical trial".

Antisense said that "no serious adverse events [had] been reported and there [had] been no safety concerns expressed by the data safety monitoring board" with the most commonly reported adverse events relating to the subcutaneous administration of the drug; mainly injection site erythema, or redness, and skin discoloration.

The company said the trial assessed drug activity and efficacy by measuring functional capacity and the effects on immune cells numbers in the blood.

Antisense said that function capacity and upper limb strength was evaluated through the performance of upper limb test (PUL2.0) and the Myogrip and Myopinch tests.

The company said the PUL2.0 data showed that seven of the nine participants showed either increases or no change in their PUL2.0 scores from baseline "suggestive of an overall improvement with a positive mean change of 0.9 in this key parameter".

Antisense said that the Myogrip and Myopinch assessments showed "a distinct improvement in muscle strength based on the observed mean changes from baseline".

The company said ATL1102 was an inhibitor of CD49d expression on certain immune cells, such as T-lymphocytes, and DMD patients with a greater number of T-cells and high levels of CD49d had more severe and rapid disease progression.

Antisense said that immune cell data showed overall reductions from baseline to week 24 in the number of lymphocytes and types of lymphocytes, including lymphocytes expressing CD49d, with a return to around starting levels at week 28.

The company said the trial follow-up period was ongoing and expected the final study report to be announced by April 2020.

Antisense chief executive officer Mark Diamond said that the trial had exceeded high expectations "with respect to its efficacy signal at the lower dose tested".

"The next stage of development will be in translating what we have learned into optimizing clinical benefit for the non-ambulatory boys who comprise [about] 50 percent of the total DMD population and who have no effective treatment options," Mr Diamond said.

"The company is moving forward with all deliberate speed to advance ATL1102 through the clinic, with specific view to a blinded controlled study in the EU which, based upon recent and on-going guidance, may lead directly to early approval," Mr Diamond said.

Antisense scientific advisory board chair Dr William Goolsbee said that "seeing the "efficacy signals of this study, conducted with a low dose in a small number of boys over a relatively short time period, is both gratifying and immensely encouraging".

"DMD is a devastating disease where only a small handful of drugs have shown indications of efficacy so early in development," Dr Goolsbee said.

"In the context of DMD, we now look to have a drug," Dr Goolsbee said.

Previously, Antisense said ATL1102 had shown efficacy for multiple sclerosis, reducing active lesions and nerve fibre loss and had potential for stem cell mobilization in stem cell transplants (BD: Jun 30, 2008; Mar 24, 2010; Sep 20, 2011; May 24, Oct 30, 2017).

Antisense climbed as much as 3.8 cents or 46.3 percent to 12 cents before closing up 0.8 cents or 9.8 percent at nine cents with 13.5 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says that Morgans Corporate will underwrite $4.1 million of options, exercisable at 8.0 cents each, expiring on December 19, 2019.
Antisense said that it expected to raise a total of $5.5 million, including commitments from management and advisors to exercise options.
The company said Morgans would receive a management fee of $115,000 and an underwriting fee of $112,900.
Antisense said the funds would be to advance plans for its phase IIb clinical trial of ATL1102 in Duchenne muscular dystrophy and for general working capital.

MESOBLAST

Mesoblast says it is conducting final visits in its 566-patient, phase III trial of Revascor for advanced chronic heart failure, having met more than 531 primary endpoint events.
Mesoblast said the double-blind, randomized, sham procedure-controlled phase III trial evaluated Revascor alongside standard-of-care treatment for the reduction of recurrent non-fatal heart failure-related major adverse cardiac events (HF-MACE) and terminal cardiac events (TCEs) in patients with advanced chronic heart failure and reduced ejection fraction.
The company said that the trial was designed to accrue more than 531 total primary endpoint events based on expected rates of HF-MACE in similarly advanced populations of heart failure patients and on treatment benefits seen with Revascor in earlier phase II trials.
Mesoblast said the predominant patient population in the trial had advanced chronic heart failure and were at high-risk for recurrent major adverse cardiac events and terminal cardiac events.
Mesoblast said it expected completion of the final visits by February 2020, with the results expected “by mid-2020”.
The company said all surviving patients had been followed for at least 12 months, with an average follow up period of about 30 months.
Mesoblast chief executive Prof Silviu Itescu said the completion of the trial was an “important milestone in the largest trial of [a] cell-based therapy for patients with advanced heart failure”.
“These patients have exhausted other treatment alternatives, and have the highest burden of disease, recurrent hospitalizations and mortality,” Prof Itescu said.
Mesoblast was up 1.5 cents or 0.8 percent to $1.92 with 2.8 million shares traded.

NOXOPHARM

Noxopharm says it has commitments to raise $8,500,000 in an initial public offering to list its US subsidiary Nyrada on the ASX, but did not state the share price.
In August, Noxopharm said it hoped to raise $8 million through the issue of Chess depositary interests (CDIs), and would use the funds to develop three of its drug programs NYX-330, NYX-104 and NYX-205 (BD: Aug 15, 2019).
Today, the company said that lead manager, Alto Capital, confirmed that the offer had been “fully allocated” and expected the formal closure of the offer “before Christmas”.
Noxopharm said that Nyrada’s ASX listing was “expected in January 2020”.
Noxopharm was up 3.5 cents or 13.7 percent to 29 cents.

ZELIRA (FORMERLY ZELDA) THERAPEUTICS

Zelira says it has completed patient dosing in its 24-patient trial of marijuana for insomnia and “expects to provide interim results … by February 2020”.
Zelira that no serious adverse events had been reported to-date.
The company said the trial, led by the Centre for Sleep Science at Perth’s University of Western Australia would evaluate the safety and efficacy of a cannabinoid extract containing tetrahydrocannabinol and cannabidiol in patients with symptoms of clinically diagnosed chronic insomnia.
Zelira said that the primary endpoint of the trial was “to assess the impact of a full-spectrum cannabis extract on sleep”.
Zelira was up 0.2 cents or 3.6 percent to 5.7 cents.

RACE ONCOLOGY

Race says it has received $159,371 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Race said the rebate related to research and development expenditure for the year to June 30, 2019.
Race was unchanged at 18.5 cents.

NEUROTECH INTERNATIONAL

Neurotech said it has an exclusive three-year agreement with Holy Stone Healthcare for the distribution of its Mente autism spectrum disorder product in Taiwan.
The Malta-based Neurotech said the deal with the Taipei-based Holy Stone was subject to approval from the Taiwan Food and Drug Administration, expected by April 2020.
Neurotech was unchanged at 1.4 cents.

GENETIC SIGNATURES

The Sydney-based Perennial Value Management says it has become a substantial shareholder in Genetic Signatures with 10,436,415 shares or 7.33 percent.
Perennial said that between November 1 and December 12, 2019 it bought shares in 14 transactions with the single largest purchase on December 12 of 3,912,977 shares for $3,952,127 or $1.01 a share.
Genetic Signatures was up one cent or one percent to 97 cents.

SIENNA CANCER DIAGNOSTICS

The Hong Kong-based Jeffery Emmanuel says he has become a substantial shareholder in Sienna, with 25,000,000 shares or 7.43 percent of the company.
Mr Emmanuel said that on December 6, 2019 he bought the 25,000,000 shares for $875,000 or 3.5 cents a share.
Earlier this month, Sienna said it had raised $1,657,186 in a placement to institutional and sophisticated investors at 3.5 cents a share (BD: Dec 6, 2019).
Sienna was up half a cent or 16.7 percent to 3.5 cents.

BOTANIX PHARMACEUTICALS

Gayle McGarry and Caperi Pty Ltd say they have decreased their shareholding and been diluted in Botanix from 69,143,448 shares (7.17%) to 59,573,874 shares (6.12%).

The Perth-based Ms McGarry and Caperi said that between October 16 and 25 they sold 9,569,574 shares in four transactions for $1,542,048 or an average of 16.1 cents a share and on December 10, 2019, were diluted following an issue of shares.

Botanix was up 0.2 cents or 2.2 percent to 9.2 cents with 2.5 million shares traded.