Biotech Daily

Tuesday June 5, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: AIRXPANDERS UP 28%; IMMUTEP DOWN 10%**

*** FEDERAL, BRANDON, UNISEED $25m FOR CERTA KIDNEY THERAPY**

*** ADALTA HIRES SELEXIS, KBI FOR AD-214 MANUFACTURE**

*** RACE: 'BISANTRENE 30-YEAR EFFICACY FOR AML'**

*** FDA PROVIDES RECCE 'CLARITY' FOR CLINICAL TRIAL**

*** CE MARK FOR COGSTATE COGNIGRAM**

*** NOXOPHARM NOX66 TRIAL: 1 PARTIAL RESPONSE**

*** IMUGENE REQUESTS 'ACQUISITION, CAPITAL RAISING' HALT**

*** BOTANIX REQUESTS RESULTS TRADING HALT**

MARKET REPORT

The Australian stock market fell 0.51 percent on Tuesday June 5, 2018 with the ASX200 down 30.6 points to 5994.9 points. Fourteen of the Biotech Daily Top 40 stocks were up, 18 fell, six traded unchanged and two were untraded. All three Big Caps fell.

Airxpanders was the best, recovering 2.5 cents or 27.8 percent to 11.5 cents with 1.9 million shares traded.

Cynata and ITL climbed four percent or more; Admedus was up 3.8 percent; Actinogen, Medical Developments, Opthea, Prana and Universal Biosensors improved two percent or more; Mesoblast, Nanosonics and Pharmaxis were up more than one percent; with Neuren and Polynovo up by less than one percent.

Immutep led the falls, down 0.4 cents or 9.8 percent to 3.7 cents with 18.2 million shares traded.

LBT lost 8.3 percent; Compumedics and Impedimed shed more than six percent; Reva and Uscom fell more than five percent; Orthocell was down 4.1 percent; Ellex, Osprey, Prescient, Starpharma and Volpara were down more than three percent; Dimerix and Genetic Signatures shed more than two percent; Clinuvel, Cochlear, Factor Therapeutics and Telix were down by more than one percent; with CSL, Resmed and Sirtex down by less than one percent.

FEDERAL GOVERNMENT, BRANDON CAPITAL PARTNERS

The Federal Government says that Brandon Capital Partners will invest $22 million in Certa Therapeutics for kidney disease.

A media release from Health Minister Greg Hunt and Innovation Minister Senator Michaelia Cash said the funding through the Biomedical Translation Fund would “help commercialize Certa’s cutting edge kidney disease treatment, providing Australian patients with direct access to this medicine through clinical trials, while giving taxpayers an opportunity to maximize their investment”.

The Federal Government that the Certa drug made it “less likely [for patients] to suffer from kidney failure and have a shorter life on dialysis”.

The media release said that the Biomedical Translation Fund consisted of equal parts of Federal Government and industry funding and was managed by private sector fund managers, who made investments in Australian biomedical ideas with great potential.

Mr Hunt said the $22 million investment in Certa was “the largest single investment to date and a terrific example of how [the Fund] was supporting late-stage clinical development of promising new therapies in Australia”.

A separate media release from Brandon Capital said that its Medical Research Commercialisation Fund would invest $22 million and Uniseed would invest $3 million in Certa.

Brandon said that Certa used genetic information to identify which patients would respond best to specific treatments, initially targeting kidney disease.

The company said that fibrosis, or scarring, of the kidney led to kidney failure and ultimately dialysis or kidney transplantation.

Brandon said that Certa’s drugs blocked a receptor that was a key driver of fibrosis and used genetic analysis to identify which patients were most likely to benefit from the therapy, addressing a market worth about $US5 billion a year.

Certa founder and chief executive officer Prof Darren Kelly said the treatment could be on the market within five years.

Brandon said that the Medical Research Commercialisation Fund and Uniseed acquired clinical development candidates from the Dublin, Ireland-based Shire PLC, which had an 18 percent equity stake in Certa and was eligible to receive royalties on future global product sales.

The company said that Australian technology being developed by Certa originated from Melbourne’s St Vincent’s Institute for Medical Research, the University of Melbourne and Bio21.

Brandon managing director and Medical Research Commercialisation Fund chief executive officer Dr Chris Nave said that “the scale of this investment has been made possible by the Biotechnology Translation Fund”.

“In many ways this investment represents the raison d’être of the [Biotechnology Translation Fund], taking great Australian medical science and providing it with access to sufficient capital to enable its continued, late stage, clinical development in Australia,” Dr Nave said.

“The [Biotechnology Translation Fund] was designed to be transformative for our local industry, providing the ability for research discoveries to be developed from concept to commercialisation right here in Australia, creating jobs and growing a sustainable industry along the way,” Dr Nave said.

ADALTA

Adalta says it has appointed Selexis SA and KBI Biopharma for the manufacture of its idiopathic pulmonary fibrosis treatment drug AD-214.

In April, Adalta said AD-214 was the renamed improved form of its previous pulmonary fibrosis drug AD-114, and that intended to begin a phase I clinical trial for AD-214 by the end of 2019 (BD: Apr 18, 2018).

Today, Adalta said Selexis SA had been appointed for cell line development, while KBI Biopharma would handle process development, analytical development, formulation development and clinical manufacturing services.

Adalta chief executive officer Sam Cobb told Biotech Daily that both Selexis and KBI were owned by the Tokyo-based JSR Life Sciences.

In a media release to the ASX, Adalta chief operating officer Dallas Hartman said that Selexis and KBI Biopharma had "extensive experience and expertize in the development of manufacturing processes for marketed and late clinical stage biological compounds".

"We evaluated 12 proposals as part of the manufacturing tender process and liked the fact that Selexis and KBI have a strong track record of working together in an integrated manner to develop Fc-fusion protein-based drugs," Mr Hartman said.

Ms Cobb said the company expected to have materials for a four-week non-human primate toxicology study in mid-2019, followed by a 78 healthy volunteer phase I trial to begin in January 2020, with results expected by July 2020.

Adalta fell two cents or 5.7 percent to 33 cents.

RACE ONCOLOGY

Race says two French patients with relapsed acute myeloid leukaemia treated with Bisantrene in 1984 and 1991 are both alive today.

Race chief executive officer Peter Molloy said the 1984 patient was a seven-year-old girl, who had "relapsed after multiple lines of standard chemotherapy and was treated with one seven-day course of Bisantrene, followed by other chemotherapy".

"She had a complete response to the treatment, which allowed her to receive a bone marrow transplant … [and] as a result, she's alive today and the mother of three children," Mr Molloy said.

The company said the 1991 patient was a 13-year-old girl who received Bisantrene in combination with two standard chemotherapy agents.

Race said both patients had complete responses to the treatment, which allowed them to receive bone marrow grafts.

The company said Bisantrene had been in more than 40 phase II clinical studies before it was "lost in a series of pharmaceutical mergers in the 1990s" and it had been approved in France for acute myeloid leukaemia in 1990 but not marketed (BD: Mar 16, 2017).

Race said a report on the two cases, by the Paris-based Armand Trousseau Children's Hospital haematology-oncologist Prof Guy Leverger and the Lyon-based Institute of Paediatric Haemato-Oncology Prof Yves Bertrand, would be presented at the International Conference on Leukaemia and Haematologic Oncology in Paris on June 21, 2018.

Prof Leverger said the findings supported renewed investigation of Bisantrene in acute myeloid leukaemia.

"The long-term follow-up with these two salvage paediatric patients I treated decades ago provides interesting insight into a novel chemotherapy lost to development, and with potential benefits over classical anthracyclines," Prof Leverger said.

Race was untraded at 26 cents.

RECCE PHARMACEUTICALS

Recce says it the US Food and Drug Administration has provided “clear guidance around the design of a planned phase I trial … of the Recce-327 compound”.

Earlier this year, Reece said it would meet with the FDA in May to discuss its synthetic antibiotic compound Recce-327, with the meeting to discuss proposed clinical and regulatory pathways for the drug (BD: Mar 8, 2018).

Today, the company said it had received guidance from the 13-member FDA panel regarding chemistry, manufacturing, toxicology, pharmacology and design of proposed clinical trials.

Recce chief executive officer Dr Graham Melrose said the company was “greatly encouraged by the FDA’s response to our new class of synthetic antibiotic”.

“Recce 327’s unique claim to overcome superbugs is certainly of urgent and global medical need and we now have a clear pathway to achieve development of this drug accordingly,” Dr Melrose said.

Recce was up 2.5 cents or 14.3 percent to 20 cents.

COGSTATE

Cogstate says it has been granted Conformité Européenne (CE) mark approval for its Cognigram digital cognitive assessment system.

Cogstate said Cognigram was a self-administered “digital cognitive assessment tool” that could be completed at either clinic or at home and was being used to help manage brain health for the elderly.

The company said that prior to Cognigram’s CE mark approval, it had been authorized in the US, Canada and Australia.

Cogstate healthcare president Frank Cheng said that his company was “excited about this significant regulatory milestone and we look forward to joining the fight against brain health challenges in European markets”.

Cogstate fell half a cent or 0.7 percent to 73.5 cents.

NOXOPHARM

Noxopharm says that one of 14 patients in its phase Ib trial of NOX66 had a partial response.

Noxopharm said that 14 patients completed three cycles of treatment, with two patients having disease progression.

The company said that of the 12 patients who began the next three cycles of treatment withdrew voluntarily and one died suddenly, with 10 completing the total of six cycles.

The company said that of the 10 completing the trial, one had a partial response, five had stable disease and four had disease progression.

In March, the company said results from the first three cycles of treatment showed 11 of the 14 patients with stable disease and one with partial response (BD: Mar 6, 2018).

Today, Noxopharm said it planned to conduct a larger phase II study with more patients, expected to begin in mid-2019, and would likely use an 800mg dose of NOX66, due to it resulting in “a better response rate than the 400mg dosage”.

Noxopharm fell 3.5 cents or 4.4 percent to 76 cents.

IMUGENE

Imugene has requested a trading halt “pending an announcement about a material acquisition and associated capital raising”.
Trading will resume on June 7, 2018 or on an earlier announcement.
Imugene last traded at three cents.

BOTANIX

Botanix has requested a trading halt pending an announcement regarding “results for its BTX1204 atopic dermatitis patient study”.
Last year, Botanix said it begun enrolment for the 36-patient phase Ib trial of its synthetic cannabidiol BTX1204, for atopic dermatitis, or eczema, with results expected by July 2018 (BD: Nov 23, 2017).
In April, the company said the trial had been completed and that it was on track to begin a phase II study by July 2018 in the US and Australia (BD: Apr 9, 2018).
Trading will resume on June 7, 2018 or on an earlier announcement.
Botanix last traded at 18 cents.