Biotech Daily

Monday November 14, 2022

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: EMVISION UP 10%; CLINUVEL DOWN 6%**

*** FEDERAL $12.6m FOR CYTIVA QUEENSLAND BIO-MANUFACTURING**

*** TELIX ACQUIRES 'NON-MATERIAL' OPTIMAL TRACERS**

*** ANTISENSE STARTS ATL1102 TOXICOLOGY STUDY**

*** IMUGENE COMBINATION 'KILLS LIVER CANCER CELLS, IN MICE'**

*** EMVISION DELIVERS 1st CLINICAL TRIAL PORTABLE BRAIN SCANNER**

*** ISLAND: ISLA-101 CAPSULES 'EXCELLENT CONTENT UNIFORMITY'**

*** EXOPHARM TRANSFERS LEAP TECHNOLOGY TO ASTELLAS**

*** IMMUTEP RECEIVES $1m FEDERAL R&D TAX INCENTIVE**

*** FIREBRICK NASODINE AUSTRALIA PATENT**

*** CSO, DIRECTOR DR DANIEL TILLETT TAKES 9.9% OF RACE**

MARKET REPORT

The Australian stock market slipped 0.16 percent on Monday November 14, with the ASX200 down 11.7 points to 7,146.3 points. Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, 11 traded unchanged and one was untraded. All three Big Caps fell.

Emvision was the best, up 17 cents or 10.4 percent to $1.81, with 119,973 shares traded. Avita and Orthocell climbed more than seven percent; Alcidion and Polynovo were up more than six percent; both Amplia and Antisense improved five percent; Starpharma was up 4.55 percent; Next Science, Oncosil and Universal Biosensors were up more than two percent; Kazia and Paradigm rose one percent or more; with Cyclopharm up 0.4 percent.

Clinuvel led the falls, down $1.18 or 5.7 percent to $19.50, with 78,129 shares traded. Cochlear, Compumedics and Genetic Signatures fell more than four percent; Dimerix, Nanosonics, Prescient and Resmed lost more than three percent; CSL and Opthea shed two percent or more; Impedimed, Medical Developments, Neuren, Nova Eye, and Pharmaxis were down more than one percent; with Pro Medicus and Telix down by less than one percent.

FEDERAL GOVERNMENT, CYTIVA LIFE SCIENCES

The Federal Government says it will provide $12.6 million to support Cytiva's Springfield Bio-Park Australia project in Ipswich, Queensland.

A media release from the Minister for Industry and Science Ed Husic said the Federal Budget allocated the funds for the project, operated by the Marlborough, Massachusetts-based Cytiva Life Sciences, formerly known as General Electric Life Sciences.

The media release said that the funds would help Cytiva "buy new equipment to expand its bio-manufacturing capabilities for high-value medicines".

"The Albanese Government was elected with a mandate to revitalize Australian manufacturing, with a strong focus on supporting regional development," Mr Husic said.

"We want Australia to be a country that makes things, now and well into the future," Mr Husic said. "That includes advanced manufacturing and the biotechnology that is at the heart of Cytiva's business."

Mr Husic said the investment "would support jobs and help industry secure domestic supply chains, clinical trials and research and development".

The Federal Representatives for Blair Shayne Neumann said he was delighted that the Government's first Budget delivered on the commitment to the Springfield Bio-Park project.

"This investment will boost advanced manufacturing of critical therapies and vaccines here in Ipswich, supporting local jobs," Mr Neumann said.

The media release said that the $12.6 million investment was "one of eight targeted industry grants the … Government delivered in the Budget to support local industry, economic growth and job creation".

The Government said that the Springfield Bio-Park Australia project would "boost Australia's sovereign capability in medical manufacturing, including mRNA vaccine production, which will support the country's future pandemic preparedness".

TELIX PHARMACEUTICALS

Telix says it has an agreement with the Northern California PET Imaging Centre to buy the Davis, California-based radio-chemistry development business Optimal Tracers.

Telix did not disclose the value of the acquisition from the Sacramento-based Northern California PET Imaging Centre, but said the price was "non-material", would be funded from its operational cashflow, and offset by Optimal Tracers' income and cost savings from bringing radiochemistry-related research and development activities in-house.

The company said the acquisition of Optimal Tracers would bolster its "in-house radiochemistry development capability, by adding a highly skilled team to Telix and establishing a US-based laboratory and production footprint for clinical trial doses" with a radiation and pharmaceutical manufacturing licence sufficient to cover its diagnostic and therapeutic isotope requirements for research purposes.

Telix said that Optimal Tracers would be available "as a strategic collaborative resource to partner organizations and [pharmaceutical company] collaborators that need access to specialist radiochemistry domain knowledge".

Telix head of business development Jonathan Barlow said that Optimal Tracers had "built a strong reputation based on their deep technical skills and ability to help clients optimize drug development, production processes and quality control".

"We are looking forward to welcoming the talented Optimal Tracers team into the Telix family, together harnessing an innovative approach to radiochemistry to further enhance Telix's pipeline and continue support of the Optimal Tracers business," Mr Barlow said.

Telix fell two cents or 0.3 percent to $6.76 with 1.1 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says it expects to begin a nine-month toxicology study of ATL1102 for Duchenne muscular dystrophy in monkeys, by the end of this year.

Antisense said it expected the study would allow the US Food and Drug Administration to lift the partial clinical hold on ATL1102 limiting dosing to 25mg weekly for six months.

Last year the company said the FDA required updated clinical and toxicology protocols to be resubmitted to lift the ATL1102 partial clinical hold and later said it planned a nine-month chronic monkey toxicology study to support the dosing of patients with ATL1102 beyond six months (BD: Aug 12, Dec 9, 2021).

Today, Antisense said that a long-term shortage of monkeys of the appropriate type and age had delayed the study, but an opportunity had presented for the study to begin.

The company said it expected to complete the toxicology study by July 2024, about the same time as its six-month dosing results from its phase IIb ATL1102 for Duchenne muscular dystrophy trial.

Antisense chair Dr Charmaine Gittleson said the toxicology study was “an important advancement for the ATL1102 program and a key value adding catalyst”.

“It provides the company the prospect of sharing with FDA a compelling data package encompassing the clinical results from the placebo controlled six-month study along with the outcome of the nine-month toxicology study,” Dr Gittleson said.

“The company expects that this investment in the chronic toxicology study should remove a key hurdle to lifting the partial clinical hold and in initiating clinical DMD studies under an [investigational new drug application] and in turn provides more certainty on the path forward in the US,” Dr Gittleson said.

Dr Gittleson said the toxicology and clinical data “could provide an opportunity for more than one regulatory pathway to registration”.

Antisense was up half a cent or five percent to 10.5 cents.

IMUGENE

Imugene says combining its Oncarlytics (CF33-CD19) oncolytic virus with Estrella Biopharma’s CD19-redirected Artemis T-cells kills liver tumor cells, in mice.

Imugene said that a poster titled ‘CF33-CD19t oncolytic virus (Oncarlytics) targets hepatocellular carcinoma (HCC) and in combination with CD19- Redirected Artemis T cells results in significant tumor killing’ was presented at Society for Immunotherapy of Cancer meeting in Boston on November 8 to 12, 2022.

The company said that CF33-CD19 could target triple negative breast cancer cell line MDA-MB-468 to express CD19t as a target for engineered T-cells and could target hepatocellular carcinoma, or liver cancer, cell lines HepG2 and Hep3B to express CD19t as a target for engineered T-cells.

Imugene said using its CF33-CD19 in combination with the Emeryville, California-based Estrella’s CD19-redirected Artemis T-cells showed “greater in-vitro efficacy against MDA-MB-468, HepG2 and Hep3B tumor cell lines compared to Oncarlytics alone”.

Imugene said that CD19t expression was detected in tumors following Oncarlytics infection in mice and CD19-redirected Artemis T-cells and CF33-CD19 combination therapy efficacy would be tested in multiple in-vivo models.

Imugene managing-director Leslie Chong said the goal of the collaboration with Estrella was “to see if combining our Oncarlytics technology with its CD19-redirected Artemis T-cells could drive improved efficacy and safety, and the outcomes from this research to date are very positive on numerous fronts”.

Imugene was unchanged at 19.5 cents with 19.8 million shares traded.

EMVISION

Emvision says it has delivered the first of its portable brain scanners to Sydney's Liverpool Hospital, in preparation for a multi-centre trial.
In October, Emvision said it would enrol at least 180 participants, including acute stroke and stroke mimic patients in the trial of the scanner (BD: Oct 4, 2022).
Today, Emvision said Liverpool Hospital's biomedical engineering department had completed essential testing and would begin operator training, with the first participant expected to be scanned this month.
Emvision chief executive officer Dr Ron Weinberger said it was "a pivotal moment for our company" and the multi-site trial across pre-validation and subsequent validation phase "will provide crucial clinical evidence for the safety and efficacy of our product".
Emvision was up 17 cents or 10.4 percent to $1.81.

ISLAND PHARMACEUTICALS

Island says batch testing of its ISLA-101 capsules has shown them to have "excellent content uniformity".
Island said the test results further validated the viability of use of ISLA-101 in its planned phase IIa trial for Dengue fever.
The company said ISLA-101 would undergo stability studies expected to conclude by early December, allowing filing of its investigational new drug application to the US Food and Drug Administration later that month, and an anticipated commencement of the trial in January 2023.
Island chief executive officer Dr David Foster said the company was "very pleased to receive confirmation that our manufactured clinical material has achieved this successful analysis and content uniformity milestone".
"This is the final step required prior to submission of the ethics application for the study, which is expected to take place imminently," Dr Foster said.
Island was up two cents or 11.8 percent to 19 cents.

EXOPHARM

Exopharm says it has begun transfer of three of its technologies to the Marlborough Massachusetts-based Astellas Institute for Regenerative Medicine.
In January, Exopharm said the Astellas Institute would pay $US481,000 ($A686,000) to collaborate on exosomes with the first phase being a demonstration of its ligand-based exosome affinity purification (Leap) platform (BD: Jan 31, 2022).
Today, the company said the collaboration had progressed to stage two, which involved the transfer of Leap, as well as its extracellular vesical positioning system (EVPS) and load technologies, for the addition of engineered surface proteins and specialized cargo, respectively, into extracellular vesicles.
Exopharm was up half a cent or 6.1 percent to 8.7 cents.

IMMUTEP

Immutep says it has received $986,286 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Immutep said the rebate related to research and development expenditure for the year to June 30, 2021.
Immutep was unchanged at 31.5 cents with 2.1 million shares traded.

FIREBRICK

Firebrick says that IP (intellectual property) Australia has accepted a patent protecting its Nasodine virucidal nasal spray.
Firebrick said that once granted, the patent, titled 'Virucidal Formulations Containing Povidone-Iodine', would protect its technology until June 2041.
Firebrick was up 3.5 cents or 14.9 percent to 27 cents.

RACE ONCOLOGY

Race director and chief scientific officer Dr Daniel Tillett says he has increased his holding from 13,480,000 shares (8.35%) to 15,920,920 shares (9.88%).
The Sydney-based Mr Tillett said that between March 2, and November 14, 2022, he acquired shares on-market and through option exercises, with the largest single acquisition 83,954 shares for $165,442, or $1.97 a share.
Race was up two cents or 0.9 percent to $2.22.