Biotech Daily

Tuesday December 12, 2023

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: COMPUMEDICS UP 12.5%;**
- GENETIC SIGNATURES DOWN 12%

*** EYEPOINT UP 200% ON EYP-1901 PHASE II AMD SUCCESS; RAISES $350m**

*** COMPUMEDICS: $9m CHINA MEG ORDERS**

*** TELIX DOSES 1st US TLX250-CDx EAP PATIENT**

*** ISLAND DOSES 2nd ISLA-101 COHORT**

*** IMUGENE NEOIMMUNETECH NT-I7 TO 'BOOST' AZER-CEL**

MARKET REPORT

The Australian stock market was up 0.5 percent on Tuesday December 12, 2023, with the ASX200 up 36.3 points to 7,235.3 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 21 fell, four traded unchanged and two were untraded. All three Big Caps were up.

Compumedics was the best, up three cents or 12.5 percent to 27 cents, with 286,572 shares traded.

Amplia climbed 7.25 percent; Mesoblast was up 5.6 percent; Telix improved 4.7 percent; Medical Developments was up 3.5 percent; Cochlear, Nanosonics and Universal Biosensors rose more than two percent; 4D Medical, Antisense, Curvebeam, Neuren, Pro Medicus, Resmed and Volpara were up more than one percent; with CSL up by 0.65 percent.

Genetic Signatures led the falls, down six cents or 11.8 percent to 45 cents, with 203,408 shares traded.

Alcidion, Avita, Imugene, Opthea and Prescient lost more than seven percent; Impedimed was down 6.7 percent; Actinogen, Micro-X, Paradigm and Syntara (Pharmaxis) fell four percent or more; Immutep, Proteomics and Starpharma were down more than three percent; Clarity and SDI shed more than two percent; Clinuvel, Cyclopharm, Orthocell and Polynovo were down one percent or more; with Emvision down by 0.7 percent.

EYEPOINT PHARMACEUTICALS (FORMERLY PSIVIDA CORP)

Eyepoint climbed 200.5 percent on its 160-patient phase II trial of EYP-1901 for wet age-related macular degeneration results and raised $US230 million ($A350.1 million).

Eyepoint said EYP-1901 was the administration of the tyrosine kinase inhibitor, vorolanib, into the eye using its approved Durasert intra-vitreal, micro-insert drug delivery device, and led to a statistical change in visual acuity and was safe.

In 2018, the then Psivida said the US Food and Drug Administration had accepted its new drug application for its Durasert device for posterior segment uveitis and it would rebrand to Eyepoint Pharmaceuticals and delist from the ASX (BD: Mar 29, 2018).

In 2019, having redomiciled to the US, Eyepoint said it had launched the FDA approved Yutiq, or Durasert and Medidur, for posterior segment uveitis (BD: Feb 5, 2019).

Last week, the company said the randomized, controlled phase II trial dosed patients with two milligrams or three milligrams of EYP-1901 compared with a control.

The company closed up 200.5 percent from $US6.62 to $US19.89 and then raised $US250 million at $US17.00 a share.

Eyepoint said the trial's primary endpoint was the change in 'best corrected visual acuity', or the best vision possible with the use of glasses or contact lenses, compared to control about six months after EYP-1901 injection.

The company said that both EYP-1901 cohorts showed a statistically non-inferior change in BCVA versus aflibercept control with a numerical difference of only -0.3 and -0.4 letters, respectively for the 2mg and 3mg dose at the blended six-month endpoint.

Eyepoint said that the positive safety profile continued "with no EYP-1901-related ocular or systemic [serious adverse events]".

The company said secondary endpoints included reduction in treatment burden, supplement use at six-months, and anatomical control.

Eyepoint said the trial showed that EYP-1901 had an 89 percent reduction in treatment burden at a 2.0mg dose and an 85 percent reduction at 3.0mg, with 65 percent and 64 percent of patient eyes supplement-free for up-to six-months, respectively.

The company said patient discontinuation in the trial at week 32 was four percent, the results showed a continued positive safety and tolerability profile with no EYP-19801-related ocular or systemic serious adverse events.

Eyepoint said both EYP-1901 cohorts had "strong anatomical control" with optical coherence tomography difference below 10 microns at week 32 compared to controls.

The company said it was on-track to reach additional EYP-1901 clinical milestones with the start of its phase II trial in diabetic macular oedema expected by April 2024, and data from its phase II trial in non-proliferative diabetic retinopathy expected by July 2024.

Eyepoint chief executive officer Dr Jay Duker said the company was "incredibly pleased by these highly positive phase II results which underscore EYP-1901's potential as a paradigm-altering maintenance treatment for patients with wet AMD".

"Since EYP-1901 achieved statistical non-inferiority to the aflibercept control in this trial there is potential for meaningfully lower-sized and lower cost … phase III trials," he said.

"The 32-week topline Davio 2 data strongly supports our planned phase III non-inferiority design, consistent with the FDA's recent guidance for wet AMD clinical trials," Dr Duker said.

Eyepoint executive vice chair and former chief executive officer Nancy Lurker said the "highly positive phase II results are the result of years of hard work by the dedicated Eyepoint team, coupled with our proven Durasert technology which continues to demonstrate the benefit of zero order kinetics drug delivery".

On the Nasdaq, Eyepoint was up 82 US cents or 4.28 percent to $US19.97 ($A30.41) with 835,731 shares traded.

COMPUMEDICS

Compumedics says it has two contracts worth a total $US6 million ($A9.14 million), for its magneto-encephalo-graphy (MEG) system for brain mapping, from China.
Compumedics said the orders with Beijing's Tsinghua University and Tianjin University were for two single-helmet MEG systems, and one dual-helmet MEG system.
The company said MEG was a neuro-imaging device for mapping brain activity through recording the magnetic fields produced by electronic currents in the brain.
Compumedics said both orders of its Orion Lifespan MEG system included electro-encephalo-grams, simulators, computers and its Curry neuro-imaging software.
The company said the sales were organized through its Chinese distributor and followed a technical review of all available MEG systems by the two Chinese universities.
Compumedics said it continued "to achieve significant milestones in its continual development of the Orion Lifespan MEG … [including] include high-quality paediatric recordings, simulated hyper-scanning from both MEG sensor arrays and powerful analysis capability via the newly released Curry 9".
The company said it expected to receive deposits this week, with funds tied to shipment and installation, due in instalments by July 2025.
Compumedics chair Prof David Burton said the company was "very pleased to receive these two additional MEG orders from China, which we regard as very important early adopters of our unique MEG technology offering".
"Whilst the business opportunity has taken longer than expected, we are now firmly on the path to commercialization of our innovative MEG offering," Prof Burton said.
Compumedics was up three cents or 12.5 percent to 27 cents.

TELIX PHARMACEUTICALS

Telix says it has dosed the first US expanded access program patient with TLX250-CDx imaging agent for clear cell renal cell carcinoma.
In an email announcement not released to the ASX, Telix said it had US Food and Drug Administration approval to proceed with an expanded access program following the completion of a phase III study.
Last year, the company said its 300-patient, phase III trial of TLX250-CDx for imaging clear-cell renal cancer met its primary endpoints, with 86 percent sensitivity and 87 percent specificity (BD: Nov 7, 2022).
Telix said at that time that TLX250-CDx had breakthrough designation from the FDA and it intended to file a biologics licence application for approval as a positron emission tomography/computed tomography (PET/CT) imaging agent to characterize indeterminate renal masses previously identified on CT or magnetic resonance imaging as clear-cell renal cancer or non-clear-cell renal cancer.
Today, the company said that the first expanded access patient was dosed with its positron emission tomography imaging agent at the Austin Radiological Association Diagnostic Imaging, in Texas.
Telix said that under an expanded access program the FDA worked with companies to allow access to investigational products outside of clinical trials to patients with no access to comparable or satisfactory alternatives.
Telix head of medical affairs Mary Jessel said that "ahead of regulatory approval, this [extended access program] provides continued access to TLX250-CDx to address a clear unmet patient need".
Telix was up 45 cents or 4.7 percent to $10.01 with 855,129 shares traded.

ISLAND PHARMACEUTICALS

Island says it has dosed the second cohort of eight-participants in its single-ascending dose study of ISLA-101 for dengue virus and other mosquito-borne diseases.
Last month, Island said it had dosed the first of 24 healthy volunteers in its study of ISLA-101 (BD: Nov 24, 2023).
Today, the company said the second cohort followed safety committee confirmation that the first cohort of healthy subjects showed "good tolerability" to ISLA-101.
Island said the study results were expected in "early 2024".
Island chief executive officer Dr David Foster said the company was "pleased that ISLA-101 demonstrated good tolerability in the first dose escalation phase and we are now excited to have progressed the dosing of the whole second cohort of subjects".
"We are on track to complete the third and final cohort and have data read-outs in early 2024, which will then inform our planned phase IIa 'Peach' clinical trial," Dr Foster said.
Island was unchanged at 8.5 cents.

IMUGENE

Imugene says it has signed a two-year deal to research the effect of the US-based Neoimmunetech's NT-I7 in the manufacturing of its 'azer-cel' technology for cancers.
In August, Imugene said it would pay Precision Biosciences up to $US227 million ($A346 million) for its off-the-shelf 'azer-cel', or azercabtagene zapreleucel, CD19 chimeric antigen receptor T-cell therapy for blood cancers (BD: Aug 16, 2023).
Today, the company said Neoimmunetech's NT-I7, or efineptakin alfa, played "a key role in T-cell development and survival, boosts cancer fighting T-cell numbers, their health, and functionality to enhance immune function and potentially provides improved cancer fighting benefits to patients".
Imugene said NT-I7 was the "only-long-acting human [interleukin-7] cytokine in clinical stage development".
The company said NT-I7 exhibited "favorable stability, activity and safety profiles on patient dosing compared with naturally occurring IL-7, making it an ideal combination partner for cell therapy drugs like azer-cel".
Imugene said the research would test the ability of NT-I7 to increase the number of azer-cel allogeneic Car T-cells produced in a manufacturing batch.
The company said it would fund its component of the agreement, which was effective immediately, and that no additional funding was required for the initial activities.
Imugene said the funding required for the research activities was material and was allowed for in its existing research budget.
Imugene said the research would be conducted in the US, and that it retained the intellectual property rights to its 'azer-cel' technology, with any further intellectual property developed through the research to be discussed "in good faith".
Imugene fell 0.7 cents or 7.5 percent to 8.6 cents with 57.5 million shares traded.