Biotech Daily

Tuesday November 7, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMUGENE UP 27%; PATRYS DOWN 11%**

*** ADALTA 'OVERSUBSCRIBED' PLACEMENT RAISES $1.65m**

*** RACE 40% RESPONSE RATE IN PHASE II BISANTRENE AML TRIAL**

*** RECCE DOSES 1st UTI PATIENTS AT 15-MINUTE R327 INFUSION RATE**

*** CLARITY RECRUITS 'SABRE' CU-64 PROSTATE CANCER IMAGING TRIAL**

*** ISLAND ISLA-101 DOSE ASCENDING STUDY ETHICS APPROVAL**

*** SIO CAPITAL INCREASES, DILUTED TO 6% OF ANTERIS**

*** VISTRA TO REPLACE ATOMO CFO WILLIAM SOUTER**

MARKET REPORT

The Australian stock market fell 0.29 percent on Tuesday November 7, 2023, with the ASX200 down 20.3 points to 6,977.1 points. Twelve of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and two were untraded.

Imugene was best, on tomorrow's conference about yesterday's trial update, up 1.4 cents or 26.9 percent to 6.6 cents, with 217.7 million shares traded.

Kazia climbed 19.4 percent; Next Science was up 5.3 percent; Antisense, Nova Eye and Pro Medicus were up more than three percent; Nanosonics rose 2.5 percent; with 4D Medical, Alcidion, Clinuvel, Cochlear, Telix and Volpara up by more than one percent.

Patrys led the falls, down 0.1 cents or 11.1 percent to 0.8 cents, with 5.4 million shares traded.

Dimerix lost 8.8 percent; Compumedics and Impedimed were down more than seven percent; Paradigm and Resonance shed six percent or more; Actinogen and Opthea were down more than five percent; Genetic Signatures fell 4.3 percent; Emvision, Micro-X and Starpharma were down more than three percent; Avita, Cyclopharm and Medical Developments shed more than two percent; Orthocell and SDI were down more than one percent; with CSL, Neuren and Resmed down by less than one percent.

ADALTA

Adalta says it has raised $1.65 million of a hoped-for $1.23 million in an “oversubscribed placement” at two cents a share.
Adalta said the $450,000 in oversubscriptions would be subject to shareholder approval at an extraordinary general meeting expected to be held about December 14, 2023.
Adalta said the offer included one option for every two shares purchased, exercisable at three cents each by May 29, 2024, as well as an additional option on the same terms subject to shareholder approval.
Adalta said the funds would be used for its phase I study of AD-214 in healthy volunteers, progressing AD-214 to a phase II study, expanding its pipeline and working capital.
Adalta fell 0.2 cents or 8.7 percent to 2.1 cents.

RACE ONCOLOGY

Race says its phase II trial of bisantrene with fludarabine and clofarabine for acute myeloid leukaemia (AML) shows a clinical response in six of 15 patients, or 40 percent.
In 2021, Race said it had dosed the first of up-to 12 patients in its phase Ib/II trial of bisantrene with two other drugs for relapsed or refractory AML (BD: Aug 9, 2021).
In July, the company said the investigator-led, phase II, open label trial at Chaim Sheba in Israel had enrolled 20 heavily pre-treated patients, with two further patients required to meet the first stage of the two-stage decision point (BD: Jul 7, 2023).
Today, Race said results from the first 15 evaluable patients showed the combination led to five complete responses and one partial response, with the five complete response patients able to be bridged to a stem cell transplant within three months of treatment.
Race said of the five patients who progressed to stem cell transplants, three had since died, one from graft-versus-host disease, one who relapsed and one of infection, with the other two patients remaining disease free and in complete remission.
The company said due to the expected low probability of achieving a clinical response in the treatment resistant patient population, the primary endpoint was “any clinical response” and the secondary endpoints were “any clinical response that enabled a stem cell transplant”.
Race said five patients had died from disease progression or bacterial and, or fungal infection before they could be evaluated, but “this was not an unexpected outcome given the advanced disease state of this heavily pre-treated salvage AML patient population”.
Race said treatment-related neutropenic fever was observed in 18 patients in the study, with ten patients developing transient liver toxicity, a well-known toxicity associated with the combination drug clofarabine.
The company said “importantly, clinically relevant cardiotoxicity was not observed in any patients” even though clofarabine had been associated with rates of heart left-ventricular dysfunction of up-to 27 percent treatment regimens containing the drug.
Race said the results would be presented in an oral poster, titled ‘Bisantrene in combination with Fludarabine and Clofarabine as Salvage Therapy for Adult Patients with Relapsed or Refractory Acute Myeloid Leukemia (AML) - An Open-label, Phase II Study’ at the American Society of Hematology meeting from December 9 to 12, 2023.
Race executive director Dr Pete Smith said “these are highly positive outcomes in a heavily pre-treated patient population”.
“To see such meaningful clinical responses in a group that would typically be receiving palliative care is striking,” Dr Smith said. “It is also encouraging that the safety profile was manageable, even for this advanced patient population.”
Race was up 10 cents or 10.9 percent to $1.015.

RECCE PHARMACEUTICALS

Recce says it has dosed the first male and female subjects at a faster infusion rate of 15 minutes in its phase I/II clinical trial of R327 for urinary tract infection and urosepsis.

Last month, the company said an independent safety committee had unanimously agreed R327 was safe and well tolerated at the previous dose and had approved a faster infusion rate of 3,000mg administered in 15 minutes in its phase I/II trial for urinary tract infections and urosepsis (BD: Oct 24, 2023).

Today, Recce chief executive officer James Graham said "to be dosing at twice the speed of the last cohort to 3,000mg over 15-minutes via intravenous administration is a testament to the safety and tolerability profile of R327".

"Another important clinical milestone for the company, as we push towards achieving R327's potential as a first-line treatment for the millions of patients suffering from [urinary tract infection and, or] urosepsis each year," Mr Graham said.

Recce was up one cent or 2.3 percent to 44 cents.

CLARITY PHARMACEUTICALS

Clarity says it has imaged all 50 patients in its 'Sabre' phase II trial, of 64-copper Sar-Bombesin with positron emission tomography for detecting prostate cancer.

Clarity said the multi-centre, single-arm, non-randomized, open-label trial of copper-64 Sar-Bombesin studied safety and tolerability, as well as its ability to correctly detect the recurrence of prostate specific membrane antigen (PSMA)-negative prostate cancer.

Clarity chair Dr Alan Taylor said that subject to results the company would move the product into a registrational phase III trial, but did not say it expected the trial results.

Clarity fell one cent or 0.9 percent to $1.12.

ISLAND PHARMACEUTICALS

Island says it has ethics approval for its single ascending-dose study of ISLA-101 for mosquito borne diseases, with recruitment and dosing to "commence imminently".

In February, Island said the US Food and Drug Administration had placed a "clinical hold" on its ISLA-101 investigational new drug application, requiring a further "small" trial and protocol amendments, and in April filed a response (BD: Feb 1, Apr 17, 2023).

Earlier this year, the company said it had FDA approval for the single-ascending dose study of ISLA-101 for dengue fever and other mosquito borne diseases trial with a "data read out expected in early 2024" (BD: May 16, Sep 25, 2023).

Today, Island said the study included three cohorts of healthy subjects receiving escalating doses of ISLA-101, to ensure administered doses could safely achieve blood concentrations of ISLA-101 that were predicted to be effective against the dengue virus.

The company said the study would "pave the way for optimizing protocols" for its planned phase IIa clinical trial.

Island chief executive officer Dr David Foster said "ethics approval was the final step in being able to commence our single ascending dose study for ISLA-101 and we now look forward to recruiting and dosing our first subject shortly".

"If all runs smoothly, our aim is to have final data by early 2024 and then rapidly transition to the phase II 'Peach' study soon thereafter," Dr Foster said.

"The need for dengue fever preventative and treatment options is more urgent than ever, with the disease now endemic in more than 100 countries, including record cases in Europe and recent major outbreaks in [several] countries," Dr Foster said.

Island was up 0.7 cents or 9.6 percent to eight cents.

ANTERIS TECHNOLOGIES

Sio Capital Management LLC says it has increased and been diluted in Anteris from 974,966 shares (7.02%) to 1,032,505 shares (6.00%).
The New York-based Sio Capital said that between February 15 and November 1, 2023 it bought shares at prices ranging from $11.50 to $24.00 a share.
In October, Anteris said that it had raised $40 million in a placement at $20.00 a share (BD: Oct 26, 2023).
Anteris fell 20 cents or 1.1 percent to $19.10.

ATOMO DIAGNOSTICS

Atomo says chief financial officer William Souter will leave the company from December 13, 2023 and be replaced by financial services company Vistra Australia.
Atomo said Mr Souter had been with the company for four years, playing a “pivotal role in seeing the company complete its capital raising and listing on the ASX” as well as supporting the board.
The company said it had engaged Vistra Australia to provide corporate financial services while its finance team continued to oversee the accounts and reporting and ensure ongoing financial control.
Atomo chief executive officer John Kelly thanked Mr Souter “for his considerable efforts in the role, and … [wished] him the very best in his future endeavors”.
Atomo was unchanged at 2.2 cents.