Biotech Daily

Wednesday September 21, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PARADIGM UP 10%; IMUGENE DOWN 13%**

*** TELIX: TLX101 FOR GLIOBLASTOMA 'SAFE, WELL-TOLERATED'**

*** IMUGENE DOSES 1st I-V VAXINIA PATIENT**

*** RESPIRI RAISES $1.6m FOR US EXPANSION**

*** CRONOS TO COMPLETE CANVIEW 2.0 'BY MID-2023'**

*** LBT 1.7m DIRECTORS' SHARES IN LIEU AGM**

*** MONTGOMERY BELOW 5% IN AVITA**

*** ADHERIUM APPOINTS DANIEL KAPLON CFO**

MARKET REPORT

The Australian stock market fell 1.56 percent on Wednesday September 21, 2022, with the ASX200 down 106.2 points to 6,700.2 points. Eleven of the Biotech Daily Top 40 were up, 16 fell, eight traded unchanged and five were untraded. All three Big Caps fell.

Paradigm was the best, up 11.5 cents or 10.1 percent to $1.25, with 648,985 shares traded.

Resonance and Starpharma climbed more than six percent; Next Science improved 5.4 percent; Polynovo was up 3.5 percent; Kazia rose 2.4 percent; Pharmaxis was up 1.2 percent; with Avita, Clinuvel, Emvision and Proteomics up by less than one percent.

Yesterday's 4.55 percent best, Imugene, led the falls, down three cents or 13.0 percent to 20 cents, with 50.6 million shares traded.

Patrys fell eight percent; Mesoblast and Volpara lost more than three percent; Actinogen, Cochlear, Medical Developments and Pro Medicus shed more than two percent; Antisense, Cynata, Immutep, Nanosonics, Orthocell, Resmed and Universal Biosensors were down more than one percent; with CSL, Neuren, Opthea and Telix down by less than one percent.

TELIX PHARMACEUTICALS

Telix says final results from its 10-patient trial of TLX101 for recurrent glioblastoma multiforme confirm safety and tolerability, as well as preliminary efficacy data.

Last year, Telix said the 10-patient, phase I/II trial of TLX101 combined with external beam radiation therapy for glioblastoma met its primary objective of safety and tolerability, and showed overall survival of 15.97 months for the nine of 10 evaluable patients, with one patient dying from Covid-19 (BD: Oct 20, 2021).

The company said at that time that six of the 10 patients in the study were still alive and would be followed until one year after dosing for the final overall survival calculation expected in May 2022.

Today, Telix said the trial of TLX101, or 131-iodine-iodo-phenylalanine (131-I-IPA), for recurrent glioblastoma "delivered encouraging preliminary efficacy data for further evaluation, demonstrating a median overall survival of 13 months from the initiation of treatment in the recurring setting or 23 months from initial diagnosis".

"Given that [glioblastoma multiforme] has a median survival from initial diagnosis of 12-15 months, the overall survival improvement trend seen in this patient population clearly warrants further evaluation in a larger patient population," the company said.

Telix chief medical officer Dr Colin Hayward said that "TLX101 has demonstrated safety and tolerability profile and encouraging early efficacy data".

"The median overall survival of 13 months from initial treatment in the recurrent second line setting reinforces the validity of further investigation and dose escalation of TLX101 in patients with [glioblastoma]," Dr Hayward said.

"Due to the aggressive nature of this cancer and limited treatment options, we are experiencing a high level of interest in the follow-on study that Telix is now undertaking in newly diagnosed patients, as a front-line therapy in combination with standard of care treatment," Dr Hayward said.

"In parallel we will continue to study TLX101 in the recurrent setting," Dr Hayward said.

The trial's principal investigator Dr Josef Pichler of the Linz, Austria-based Kepler University Hospital said that considering that glioblastoma multiforme had a median survival from initial diagnosis of 12 to 15 months "the potential benefit demonstrated in relapsed patients, in a second-line setting is encouraging".

"We are very motivated to continue to investigate TLX101 in a larger patient population in the planned phase II IPAX-L (Linz) study underway at Kepler University Hospital, with the goal of collecting additional safety and efficacy data for TLX101 in combination with [external beam radiation therapy] in patients with relapsed glioblastoma," Dr Pichler said.

Telix fell one cent or 0.2 percent to $5.52 with 1.4 million shares traded.

IMUGENE

Imugene says it has dosed the first patient in the intra-venous dosing cohort of its phase I trial of CF33-hNIS, or Vaxinia, virotherapy in metastatic advanced solid tumors.

Earlier this month, Imugene said that it would begin a second cohort in its up to-100-patients, phase I trial of intra-tumoral and intra-venous Vaxinia and pembrolizumab for advanced solid tumors (BD: Sep 1, 2022).

Today, Imugene said the trial had delivered a low dose to patients with metastatic or advanced solid tumors who had at least two prior lines of standard of care treatment.

Imugene managing-director Leslie Chong said the company was "eager to see the results from this new route of administration for the drug, in addition to that of the [intra-tumoral] arm of the study".

Imugene fell three cents or 13.0 percent to 20 cents with 50.6 million shares traded.

RESPIRI

Respiri says it has raised $1.6 million in a placement at four cents a share to sophisticated investors, with management providing $100,000 of the funds.
Respiri did not disclose the placement share price in the placement announcement but in a separate proposed issue of securities filing, said it raised the funds through the issue of 40,000,000 shares at four cents a share.
The company said it had raised the money to fund expansion in the US.
Respiri said that the issue of $50,000 shares each to chair Nicholas Smedley and managing-director Marjan Mikel were subject to shareholder approval.
Respiri was up 0.6 cents or 14.3 percent to 4.8 cents with 1.1 million shares traded.

CRONOS AUSTRALIA

Cronos says it expects to complete the final stages of rollout for its Canview 2.0 on-line medical marijuana marketplace no later than mid-2023.
Cronos said it had delivered the distribution and pharmacy stages of the six-stage rollout, and was currently in a pilot program for the prescriber and patient mobile application.
The company said it expected to complete stages four, five, and six, which included supplier relationships, introducing doctors and patients to the platform, and the patient treatment tracker “in the coming months”.
A Cronos executive told Biotech Daily that the company expected the Canview 2.0 platform to be completed “no later than mid-2023”.
Cronos said Canview 2.0 would allow prescriptions and Australian Therapeutic Goods Administration approvals to be received directly from doctors and prescribers “enabling patients to order their prescription repeats directly through the platform”.
Cronos chief executive officer Rodney Cocks said the company was “very pleased to be delivering such a wide range of important new features to our large and growing number of Canview users.”
“The network effect on the platform is clear which will drive further patient, prescriber and pharmacist onboarding,” Mr Cocks said. “We are confident that the improved functionality of the Canview 2.0 platform will not only provide a superior user experience but help Cronos Australia to maintain its current market-leading position.”
Cronos was up four cents or 7.1 percent to 60 cents.

LBT INNOVATIONS

LBT Innovations says shareholders will vote on the issue of 1,741,147 shares to directors and its managing-director in lieu of fees and an annual bonus, respectively.
LBT said it would seek to issue 280,674 shares to Brian O’Dwyer, 156,574 shares to Simon Arkell, 189,943 shares to Damian Lismore and 281,423 shares to Joanne Moss, worth a total of $75,256, in lieu of directors’ fees otherwise payable in cash.
The company said its annual general meeting would vote to issue 832,533 shares, worth $59,942, to managing-director Brenton Barnes, in lieu of his annual bonus.
LBT said shareholders would vote on the remuneration report, the re-election of director Simon Arkell, the ratification of 30,660,377 shares to Hettich AG, approval of a 10 percent placement facility, and an amendment to the constitution to allow future annual general meetings to be held virtually.
The meeting will be held on at Thomson Geer Lawyers, Level 7, 19 Gouger Street, Adelaide, on October 26, 2022 at 11.30am (ACDT).
LBT fell 0.8 cents or 9.1 percent to eight cents.

AVITA MEDICAL

Sydney's Montgomery Investment Management says it has ceased its substantial share-holding in Avita.

In December, Montgomery said it had become a substantial shareholder in Avita with 6,147,402 shares, or 5.03 percent (BD: Dec 2, 2022).

Today, Montgomery said that it sold shares in Avita between August 12 and September 16, 2022, with the largest single sale 152,640 shares for $301,198, or $1.97 a share.

Avita was up one cent or 0.6 percent to $1.75.

ADHERIUM

Adherium says it has appointed Daniel Kaplon as its chief financial officer, effective from October 10, 2022.

Adherium said Mr Kaplon was previously Medisecure's chief financial officer and chief operations officer, and had worked for Ramsay Healthcare.

According to his Linkedin page Mr Kaplon held a Bachelor of Commerce from Melbourne's La Trobe University, a Bachelor of Business from the Royal Melbourne Institute of Technology and a Master of Entrepreneurship and Innovation from Swinburne University of Technology.

Adherium was unchanged at 0.7 cents.