Biotech Daily

Thursday June 27, 2024

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: ACTINOGEN UP 12%; IMMUTEP DOWN 23%**

*** IMMUTEP: 'EFTI COMBO BEATS KEYTRUDA FOR HEAD, NECK CANCER'**

*** CONTROL BIONICS: 4 MILESTONES IN 3 MONTHS; RECORD TRADING**

*** LBT TO FOCUS ON 'LARGE PHARMACEUTICAL MANUFACTURERS'**

*** SOMNOMED EGM 13.5% OPPOSE CEO TERMINATION BENEFITS**

*** AUSBIOTECH CEO REBEKAH CASSIDY OPENS 'POLICY TASKFORCE'**

MARKET REPORT

The Australian stock market fell 0.3 percent on Thursday June 27, 2024, with the ASX200 down 23.4 points to 7,759.6 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 14 were down, 10 traded unchanged and one was untraded.

Actinogen was the best, for the second day in a row, following biomarker trial data, up 0.5 cents or 12.2 percent to 4.6 cents, with 31.9 million shares traded; followed by Universal Biosensors up 11.1 percent to 15 cents, with 582,008 shares traded.

Paradigm climbed 8.3 percent; Alcidion was up 6.5 percent; Atomo, Emvision and Resmed were up four percent or more; Cynata was up 3.6 percent; 4D Medical rose 2.7 percent; Impedimed, Medical Developments, Mesoblast and Proteomics were up more than one percent; with CSL, Polynovo, Pro Medicus and SDI up by less than one percent.

Immutep led the falls, down 10 cents or 23.0 percent to 33.5 cents, with 66.97 million shares traded.

Dimerix lost 6.4 percent; Imugene was down 5.3 percent; Syntara fell 4.35 percent; Orthocell, Prescient, Starpharma and Telix shed two percent or more; Cyclopharm, Neuren and Percheron were down more than one percent; with Avita, Clarity, Clinuvel and Cochlear down by less than one percent.

IMMUTEP

Immutep says its 171-patient, phase IIb trial for head-and-neck cancer showed efti with Keytruda led to “overall response rates that exceed Keytruda monotherapy”.

Last year, Immutep said it had enrolled the Tactis-003, phase IIb trial of eftilagimod alpha, or efti, with the anti-programmed cell death-1 therapy pembrolizumab, marketed as Keytruda, for head and neck squamous cell carcinoma (BD: Nov 9, 2023).

At the time, the company said the study’s cohort A enrolled 138 patients with tumors expressing programmed-cell death-ligand 1 (PD-L1) with a combine positive score of more than one, with cohort B enrolling 33 patients with PD-L1-expressing tumors with a combined positive score of less than one.

Immutep said the trial’s primary endpoint was overall response rate of evaluable patients measured by response evaluation criteria in solid tumors (Recist), with secondary endpoints including overall survival, overall response rate according to ‘immune Recist’, progression free survival, and duration of response.

Today, Immutep said the combination therapy was shown to lead to “higher overall response rates in evaluable patients … across all levels of PD-L1 expression”.

The company said 58 of the 118 evaluable patients in cohort A, with PD-L1 expression, showed a 32.8 percent overall response rate when treated with the combination compared to a 26.7 percent overall response rate in the 60 patients treated with Keytruda alone.

Immutep said that of the 58 evaluable patients treated with the combination therapy, 29 patients with a high PD-L1 expression, or a combined positive score of more than 20, had an overall response rate of 31.0 percent, compared to 18.5 percent for the 27 patients treated with Keytruda alone.

The company said that the 29 combination-dosed patients with low PD-L1 expression, or a combined positive score of between one and 19, had an overall response rate of 34.5 percent, compared to 33.3 percent for the 33 low PD-L1 expression patients receiving Keytruda alone.

Immutep said efti in combination with Keytruda continued to be “favourable with no new safety signals as expected”.

Earlier this year, the company said data from 26 cohort B patients showed a 26.9 percent overall response and a 57.7 percent disease control rate (BD: Apr 24, 2024).

Today, Immutep said that the 26 evaluable cohort B patients had shown a “substantially improved” overall response rate compared to the 26.9 percent in preliminary results reported in April, but that final topline results would be delivered in an oral presentation on July 11, 2024.

The company said it would enter regulatory discussions for this indication, with further data to be presented “at a medical conference” in the second half of 2024.

Immutep chief scientific officer Dr Frédéric Triebel said the company was “pleased with the quality of responses”.

“Once again, durability is tracking well driven by the complementary nature of these two unique immuno-therapies in fighting cancer,” Dr Triebel said.

Dr Triebel said efti’s mechanism of action and engagement with the immune system had “consistently translated into promising duration of responses in combination with immune checkpoint inhibitors across multiple oncology indications”.

Dr Triebel said statistically, “given the relatively small number of evaluable patients and the very ambitious differences required to generate significance, coupled with … unanticipated strength in the [low PD-L1 expression] control arm … we are excited to see the 68 percent differential” in the high PD-L1 expressing patients (CPS ≥ 20).

Immutep fell 10 cents or 23.0 percent to 33.5 cents with 66.97 million shares traded.

CONTROL BIONICS

Control Bionics says it has achieved “four key milestones” in the three months to June 30, 2024, including commercial approval for its Drove wheelchair module.

Last week, Control Bionics said the Therapeutics Goods Administration had approved its Neuronode thought-to-computer-based Drove autonomous wheelchair module as a class one medical device, allowing it to sell the device in Australia (BD: Jun 20, 2024).

Today, in its maiden ‘Investor Newsletter’, Control Bionics said that following the TGA approval its share price reached a high of 6.9 cents, more than a 60 percent increase on the recent placement price of 4.3 cents a share, with a record 17 million shares traded (BD: May 17, 2024).

In 2020, Control Bionics opened on the ASX at $1.12, 86.7 percent above its initial public offer of 60 cents, and reached a high of $1.24 before closing the day up 96.7 percent at $1.18 with 4.9 million shares traded (BD: Dec 8, 2020).

The company said the three other milestones included first customer trials of its Neurostrip wearable electro-myography diagnostic device, the release of the Neurostrip application and chief executive officer Jeremy Steele’s presentation of the product at a United Nations’ summit on artificial intelligence in Geneva, Switzerland.

Control Bionics said it expected first sales of Drove, partnerships for Neuronode in Japan and Europe, a prototype for a reusable Neurostrip, US clinical trials and the first sales of Neurostrip in sports and rehabilitation businesses by “Q1 2025”, but did not specify whether it meant financial year of calendar year.

Control Bionics was not available at the time of publication.

Control Bionics was up 0.2 cents or four percent to 5.2 cents.

LBT INNOVATIONS

LBT says it is focused on engaging “pharmaceutical companies operating multiple manufacturing sites globally” with two companies to evaluate its Apas technology.

Earlier this year, LBT’s share price climbed as much as 2.4 cents or 171.4 percent to 3.8 cents on news it had validated its automated plate assessment system (Apas) Pharma QC, which was ready for commercialization (BD: Mar 13, 2024).

Today, the company said that “focusing on large global companies has the potential to create multiple instrument sales opportunities with a single customer, whereby the Apas technology was first evaluated and then may progress to a formal validation, clearing the path for potential sales to multiple manufacturing sites”.

LBT said two companies would evaluate its Apas system this year, completing “over a number of months following installation, training and ongoing support”.

The company said its Astrazeneca validation study expected to be completed by October 31, 2024, with validation expected to “clear the path for a sale of multiple instruments and will also provide credibility for the progression of other sales”.

Last year, LBT said it had a $1 million partnership with Astrazeneca to develop an automated plate assessment system ‘pharma analysis module’ into its APAS instrument (BD: Jan 22, 2023).

Today, the company said there was “no guarantee” the validation would be successful.

LBT managing-director Brent Barnes said the company’s strategy focused its “resources on potential customers with global scale, who could benefit from multiple Apas Independence instruments following their evaluation and formal validation”.

“In the upcoming evaluations, we are collaborating with two multinational pharmaceutical companies, in support of this go-to market strategy,” Mr Barnes said.

LBT fell 0.1 cents or 5.9 percent to 1.6 cents with 1.3 million shares traded.

SOMNOMED

Somnomed says its extraordinary general meeting passed all four resolutions but with up-to 13.48 percent against its joint chief executive officers' termination benefits.

Last month, Somnomed said the meeting would vote to issue directors and joint chief executive officers Amrita Blickstead and Karen Borg 1,925,000 zero exercise price options (Zepos), each, and approve potential termination benefits (BD: May 20, 2024).

Today, Somnomed said the two resolutions to approve Ms Blickstead and Ms Borg's termination benefits were both opposed by 17,483,861 votes (13.48%), with 112,188,876 votes (86.52%) in favor.

The company said the issue of the Zepos to the joint chief executive officers were both passed more easily with 98.25 percent support.

According to its most recent filing, Somnomed had 216,108,253 shares on issue, meaning the 17,483,861 votes against the potential termination benefits amounted to 8.1 percent of the company, sufficient to requisition extraordinary general meetings.

Somnomed was unchanged at 25 cents.

AUSBIOTECH

Ausbiotech says it is seeking expressions of interest for its members to join a 'Policy Taskforce' to inform its policies on various aspects of the biotechnology sector.

In a media release, Ausbiotech chief executive officer Rebekah Cassidy said the taskforce would meet three-to-four times in the "coming months with the goal of bringing a precision lens to a refresh of Ausbiotech's policies across a number of key areas".

The industry organization said these areas included investment and funding, taxation, clinical trial capacity, regulatory and market access, workforce skills and talent and sovereign manufacturing capability.

Ms Cassidy said there was "an immediate window for more collaborative and focused discussion".

In relation to the Federal Government's Future Made in Australia proposal and the term 'key industries', Ms Cassidy said it was "important that we bring clarity not only to the challenges and opportunities before us, but also to the role that industry can collaboratively play in addressing [policy] and the role that we see government playing".

Ausbiotech said places would be limited, with expressions of interest to be sent to Kate Donnellan at kdonnellan@ausbiotech.org by July 4, 2024.