Biotech Daily

Tuesday June 27, 2023

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: IMPEDIMED UP 12%; STARPHARMA DOWN 11%**

*** US BENITEC JUMPS 167% ON FDA BB-301 OPMD TRIAL**

*** IMMUTEP RETAIL RIGHTS RAISE $6.5m; $80m TOTAL**

*** WEHI: OPTINEURIN PROTEIN PARKINSON'S CONNECTION**

*** NORTH STAR PRODUCES CLARITY COPPER-67**

*** INOVIQ 'EXCELLENT RESULTS' IN BREAST CANCER TEST STUDY**

*** PHARMAUST DOSES MONEPANTEL MND COHORT 3**

*** STARPHARMA: ASTRAZENECA VOLUNTARY PARTIAL CLINICAL HOLD**

*** STARPHARMA: INOVA BUYS DISTRIBUTOR MUNDIPHARMA**

*** MICROBA FEDERAL $2.9m GRANT FOR BIOBANK**

*** OSTEOPORE TO DISPOSE 200k ASX BREACH SHARES, OPTIONS**

*** IMMUTEP 3rd US EFTI, PD-1 COMBINATION PATENT**

*** CANN TO LOSE CHAIR ALLAN MCCALLUM; JULIAN CHICK DEPUTY**

MARKET REPORT

The Australian stock market was up 0.56 percent on Tuesday June 27, 2023, with the ASX200 up 39.5 points to 7,118.2 points. Nine of the Biotech Daily Top 40 stocks were up, 20 fell, 10 traded unchanged and one was untraded. All three Big Caps fell.

Impedimed was the best, up two cents or 12.1 percent to 18.5 cents, with 23.3 million shares traded. Antisense climbed 6.7 percent; Cyclopharm and Emvision improved more than three percent; Actinogen rose 2.4 percent; Neuren, Polynovo and Volpara were up more than one percent; with Nanosonics up by 0.2 percent.

Starpharma led the falls, down 3.5 cents or 10.8 percent to 29 cents, with 1.9 million shares traded. Patrys lost 9.1 percent; Amplia shed 7.95 percent; Resonance retreated 6.7 percent; Medical Developments and Nova Eye were down more than five percent; Micro-X fell 4.35 percent; Avita, Mesoblast and Paradigm were down more than three percent; 4D Medical, Kazia, Orthocell, Pharmaxis and Telix shed more than two percent; Clinuvel, Imugene and Prescient were down by more than one percent; with Cochlear, CSL, Opthea, Pro Medicus and Resmed down by less than one percent.

BENITEC BIOPHARMA INC

Benitec says the US Food and Drug Administration has cleared its investigational new drug application for BB-301 for oculo-pharyngeal muscular dystrophy-related dysphagia.

Benitec said that dosing of the first subject was expected by the end of 2023, following the rollover of subjects currently enrolled in an ongoing natural history study.

On the Nasdaq, the company climbed as much as 33.15 US cents or 167.0 percent to 53.0 US cents (78.9 Australian cents) from 19.85 US cents.

In 2020, Benitec said its scheme of arrangement to leave Australia for the US had been implemented (BD: Mar 26, 30, Apr 16, 2020).

In 2019, Benitec said it planned to conduct three dog studies for an application to the FDA for a BB-301 phase I oculo-pharyngeal muscular dystrophy (OPMD) trial to “facilitate the filing of an investigational new drug application” and the initiation of a phase I trial for oculo-pharyngeal muscular dystrophy (OPMD) (BD: Sep 19, 2019).

In June 2019, the company said that its up-to $US665 million ($A953.6 million) deal with Axovant Sciences for BB-301 for oculo-pharyngeal muscular dystrophy had been terminated (BD: Jun 7, 2019).

Today, Benitec said that there were about 15,000 oculo-pharyngeal muscular dystrophy patients in the US, Canada, Western Europe and Israel.

The company said that OPMD patients lose the ability to swallow liquids and solids, resulting in chronic malnutrition, aspiration and fatal episodes of aspiration pneumonia, with no approved therapeutic agents available to treat the illness.

Benitec executive chair Dr Jerel Banks said that “the clearance of BB-301 for clinical use represents the first potential treatment for these frequently debilitating and possibly fatal symptoms of OPMD”.

Benitec said that subjects in its ongoing natural history study would be eligible for rollover onto the phase Ib/IIa study of BB-301 for OPMD-related dysphagia after six months of baseline data collection.

The company said that following a one-day dosing procedure for BB-301, each study subject would be evaluated for the same radiographic and clinical outcome measures as were evaluated during the natural history study, including quantitative radiographic swallowing studies to facilitate objective assessments of swallowing safety, swallowing efficiency, and functional performance of the pharyngeal muscles underlying the OPMD-related dysphagia.

Benitec said that currently, there were 13 subjects enrolled in the natural history study, with each subject having the potential to rollover onto the phase Ib/IIa trial.

The company said that interim safety and efficacy data was expected to become available from the BB-301 phase Ib/IIa study about every 90 days following dosing.

Benitec said that BB-301 was a novel, modified adeno-associated virus-9 (AAV9) capsid expressing a unique, single bi-functional construct promoting co-expression of both codon-optimized poly-a binding protein nuclear-1 (PABPN1) and two small inhibitory RNAs (siRNAs) against mutant PABPN1.

The company said that the two siRNAs were modeled into micro-RNA (mRNA) backbones to silence expression of faulty mutant PABPN1, while allowing expression of the codon-optimized PABPN1 to replace the mutant with a functional version of the protein.

Benitec said BB-301’s silence and replace strategy was “uniquely positioned for … OPMD by halting mutant expression while providing a functional replacement protein”.

Benitec closed up 16.15 US cents or 81.36 percent to 36.0 US cents (53.6 Australian cents) with 182.9 million shares traded.

Yahoo Finance reported that Benitec had 27.98 million shares on offer, implying a current market capitalization of $US10.07 million ($A15.0 million).

IMMUTEP

Immutep says its one-for-7.6 retail entitlement offer raised about $6.5 million at 26 cents a share, taking the total to $74.4 million in the underwritten $80 million raising.
Earlier this month, Immutep said its placement and oversubscribed institutional rights offer raised $50 million and $17.9 million, respectively (BD: Jun 2, 2023).
Today, Immutep said it received $4.7 million in valid applications for retail entitlements and applications for a further $1.8 million in additional new shares.
The company said that the shortfall of about $6.5 million would be allocated to the underwriters Bell Potter Securities, Wilsons Corporate Finance and Jefferies (Australia) Pty Ltd,
Immutep was unchanged at 28 cents with 1.2 million shares traded.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall says it has shown how the protein optineurin identifies damaged mitochondria, which could lead to treatments for Parkinson's disease.
WEHI said the study showed how PINK1 and Parkin proteins "tagged" malfunctioning mitochondria for disposal and how optineurin recognized these damaged cells by binding to TBK1 enzymes and activating a specific cellular machine to generate cellular "garbage bags".
The Institute said mutations in these proteins in Parkinson's disease could result in the accumulation of damaged mitochondria in the brain and lead to motor symptoms.
The Institute said the study titled, 'Unconventional initiation of PINK1/Parkin mitophagy by Optineurin', was published in Molecular Cell, with the full article available at: www.bit.ly/434OxCK.
WEHI laboratory head Prof Michael Lazarou said the discovery "filled a vital knowledge gap that would transform our understanding of this cellular pathway".
"Until this study, optineurin's precise role in initiating our body's garbage disposal process was unknown," Prof Lazarou said.
"Knowing how optineurin does this provides us with a framework on how we might be able to target PINK1 and Parkin mitophagy in disease and prevent the build-up of damaged mitochondria in neurons as we age," Prof Lazarou said.
WEHI senior research officer and study author Dr Thanh Nguyen said other proteins did not need TBK1 enzymes to help trigger the disposal process, making optineurin "a real outlier when it came to how the body removes mitochondria".
"This has allowed us to look at the features of this pathway involving TBK1 as a potential drug target, which is a significant step forward in our search for new Parkinson's disease treatments," Dr Nguyen said.
"The ultimate goal would be to find a way to boost levels of PINK1/Parkin mitophagy in the body - especially the brain - so that damaged mitochondria can be removed more effectively," Dr Nguyen said.
Dr Nguyen said that the clinical application of the research would still be years away.
"Our next step is … to validate our findings in neuronal model systems to understand why optineurin behaves this way, which will provide further insight into how we can target optineurin and TBK1 to enhance treatment options," Dr Nguyen said.
WEHI said the study was in collaboration with the University of Vienna's Prof Sascha Martens and was supported by the National Health and Medical Research Council, the Australian Research Council, the Human Frontiers Science Program and Aligning Science Across Parkinson's through the Michael J. Fox Foundation for Parkinson's Research.

CLARITY PHARMACEUTICALS

Clarity says Northstar has produced “high activity, high specific activity and high purity copper-67” for its three active and recruiting diagnostic and therapeutic trials.

Earlier this year, Clarity said the Beloit, Wisconsin-based Northstar Medical Radioisotopes expected its copper-67 radioisotopes for its therapeutic program to be available “within a few weeks” (BD: Apr 4, 2023).

Today, the company said Northstar’s product would be used in its trials evaluating the safety and efficacy of its copper-67 Sar-bis prostate-specific-membrane-antigen, copper-67 Sar-bombesin and copper-67 Sartate for cancers.

Clarity executive chairman Dr Alan Taylor said the company was “really excited about the large-scale manufacture of copper-67 … [and the] timing could not be better” as it continued to recruit at increasingly higher activities of copper-67 in all three of its trials.

“In addition, we also continue to support clinicians’ requests for additional therapy doses for patients under the US Food and Drug Administration expanded access program,” Dr Taylor said.

“The timely manufacture of commercial-scale, high specific activity copper-67 complements our development with end-to-end production of radioisotope through to finished product, all in the largest oncology market in the world, the US,” Dr Taylor said.

Clarity was up 4.5 cents or 6.7 percent to 72 cents.

INOVIQ

Inoviq says it has “excellent results” from a 483-sample, independent, case-control clinical validation study of its Sub-B2M-CA15.3 blood test for breast cancer.

Inoviq has previously said that Sub-B2M was an engineered protein that detected the pan-cancer biomarker Neu5Gc (BD: Sep 16, 2022)

Earlier this year, Inoviq said a 94-serum sample study showed that its cancer test could discriminate “between breast cancer and health controls across all cancer stages” (BD: Feb 8, 2023).

At that time, Inoviq said that study showed that its test correctly identified 69 of 94 samples (73.4%) tested, with 69 percent sensitivity and 78 percent specificity for breast cancer across all stages, compared to 56 percent sensitivity and 71 percent specificity for the Roche Elecsys CA15.3 II test.

Today, the company said the independent study showed an accuracy of 87 percent, sensitivity of 81 percent and specificity of 93 percent for its Sub-B2M test, outperforming the approved CA15.3 test.

Inoviq said its Sub-B2M test “significantly” reduced misdiagnosis with seven percent lower false positive rates and 19 percent lower false negative rates in the 483-sample set.

The company said its next step was to conduct a cross-sectional monitoring study to show the “superior performance” of the Sub-B2M-CA15.3 test for treatment response and/or disease recurrence over approved CA15.3 tests.

Inoviq chief executive officer Dr Leearne Hinch said the “outstanding results” were a “major milestone” for the company.

“These positive results support the commercial potential of our simple, cost-effective SubB2M/CA15-3 test for screening and monitoring of breast cancer,” Dr Hinch said.

“Inoviq intends to present these data and our development plans to potential partners and [key opinion leaders] to advance commercial discussions for its Sub-B2M-CA15.3, Sub-B2M-CA125 and Sub-B2M multi-cancer tests,” Dr Hinch said.

Inoviq was up 21 cents or 42.0 percent to 71 cents with 2.4 million shares traded.

PHARMAUST

Pharmaust says it has dosed all 12 patients in cohort 3 of its open label, phase I/II trial of monepantel for motor neuron disease and amyotrophic lateral sclerosis.
Earlier this month, Pharmaust said it had begun dosing the third cohort for its monepantel for motor neuron disease trial at 6.0mg/kg (BD: Jun 9, 2023).
Today, the company said the study aimed to determine tolerability, safety, pharmaco-kinetics and preliminary efficacy of oral monepantel for patients with MND.
Pharmaust said dosages for the three cohorts had been well tolerated with no serious adverse events observed “implying” the drug had a good safety profile.
The company said interim independent analysis of the biomarkers and pharmaco-dynamics for the current phase I/II study were underway, and it expected “to proceed to phase II with favorable efficacy biomarker results”.
Pharmaust was up 0.4 cents or 5.6 percent to 7.6 cents.

STARPHARMA

Starpharma says a voluntary partial clinical hold has been implemented on an Astrazeneca trial in which its dendrimer enhanced product (DEP) is used.
Starpharma said the phase I/II trial of AZD0466 as a monotherapy or in combination in patients with advanced haematological malignancies and was in dose escalation phase.
The company said the asymptomatic reported events leading to the voluntary partial hold were assessed as not related to Starpharma’s DEP dendrimer.
Starpharma said that the voluntary partial clinical hold did not impact its platform technology, or other clinical DEP programs or partnerships, and a study of AZD0466 in patients with non-Hodgkin’s lymphoma was not impacted by the hold.
Starpharma fell 3.5 cents or 10.8 percent to 29 cents with 1.9 million shares traded.

STARPHARMA

Starpharma says that Inova Pharmaceuticals has acquired Mundipharma’s consumer health product portfolio including its Vivagel BV for bacterial vaginosis.
Starpharma said that Inova was majority owned by TPG Inc and was a multi-national healthcare company operating in more than 20 countries across Asia-Pacific and Africa and its portfolio included products for coughs and colds, skincare and natural health.
Starpharma said the acquisition would “significantly expand” Inova’s portfolio of consumer healthcare products, primarily from the Betadine product range and increase its presence in Asia, the Middle East, Europe, and Canada.
In 2018, Starpharma said it extended its licence with Mundipharma to market Vivagel BV to European countries and Latin America, in addition to the previously announced China, Japan, Korea, the Middle East and Africa (BD: May 3, Jun 27, 2018).

MICROBA LIFE SCIENCES

Microba says with the Queensland University of Technology it has received $2.92 million from the Federal Government’s Medical Research Future Fund for a microbiome biobank.
Yesterday, the Federal Government said it would provide $73 million for 19 medical research projects including gut health (BD: Jun 27, 2023).
Today, Microba said the funding would help establish a comprehensive microbiome biobank through its collaboration with the Queensland University of Technology.
Microba was up half a cent or 1.7 percent to 29.5 cents.

OSTEOPORE

Osteopore says it will dispose of chair Mark Leong's 200,000 rights offer shares and 200,000 options as his participation was in breach of ASX Listing Rule 10.11.
Osteopore said as a related party to the company Mr Leong could not participate in the offer without prior shareholder approval, and that this mistake was an "administrative oversight … [and it] regrets this oversight".
Osteopore was up half a cent or 4.8 percent to 11 cents.

IMMUTEP

Immutep says the US Patent and Trademark Office has granted a third patent for eftilagimod alpha or efti, and a programmed death-1 (PD-1) pathway inhibitor.
Immutep said that the patent, titled 'Combined Preparations for the Treatment of Cancer or Infection' would protect its intellectual property until November 15, 2036, including 312 days of patent term adjustment.
The company said the US patent was filed as a second divisional application and followed the grant of the US parent patent and first divisional patent announced in December 2020 and March 2021, respectively.
Immutep said that the claims of the new patent built on the protection provided by the two previously granted patents, and were directed to methods of treating cancer by administering lead immunotherapy candidate eftilagimod alpha and a PD-1 pathway inhibitor, specifically BMS-936559, durvalumab, atezolizumab or avelumab.
Immutep chief executive officer Marc Voigt said that efti was "a unique biomolecule and shows great promise in being able to ultimately help diverse sets of cancer patients, including those with more complex needs".
"Here we add another key US patent which is closely aligned with our clinical development pipeline," Mr Voigt said.

CANN GROUP

Cann says chair Allan McCallum will retire by October 2023, with non-executive director Dr Julian Chick has been appointed deputy chairman, effective from today.
Cann said Dr Chick was appointed a director last year (BD: Sep 20, 2022).
Cann was unchanged at 11.5 cents.