Biotech Daily

Thursday September 21, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PHARMAXIS UP 15%; COMPUMEDICS DOWN 14%**

*** WEHI TRIALS KEYTRUDA, HALAVEN FOR OVARIAN, UTERINE CANCER**

*** OPTHEA RETAIL RIGHTS RAISE $16.3m; TOTAL $90m**

*** BTC TO DISTRIBUTE MICREL INFUSION PUMPS**

*** IMMUTEP WINS EFTI MANUFACTURING OKAY**

*** EXOPHARM $2.7m FEDERAL R&D TAX INCENTIVE; CLEARS DEBTS**

*** MESOBLAST: 'FDA WANTS REMESTEMCEL-L CONSISTENCY DATA'**

*** RACE BISANTRENE 'POTENT ANTI-CANCER ACTIVITY, IN-VITRO'**

*** RHYTHM BREAST CANCER TEST '83% SENSITIVITY, IN-VITRO'**

*** EMYRIA: 'MIND MEDICINE, ANU TO SUPPLY TRIAL MDMA'**

*** THORNEY, TIGA TAKES 6% OF NEXT SCIENCE**

*** PAINCHEK PLEADS SCHULTZ TO ASX 55% PRICE QUERY**

*** AUSBIOTECH TO LOSE 5-YEAR CEO LORRAINE CHIROIU**

MARKET REPORT

The Australian stock market fell 1.37 percent on Thursday September 21, 2023 with the ASX200 down 98.1 points to 7,065.2 points. Eleven of the Biotech Daily Top 40 stocks were up, 21 fell, seven traded unchanged and one was untraded. All three Big Caps fell.

Pharmaxis was the best, up 0.5 cents or 15.15 percent to 3.8 cents, with 231,679 shares traded. Next Science climbed 4.3 percent; Genetic Signatures was up 3.1 percent; Nova Eye rose 2.6 percent; Antisense, Immutep, Orthocell and Universal Biosensors were up more than one percent; with Clinuvel, Cyclopharm and Pro Medicus up by less than one percent.

Compumedics led the falls, down three cents or 13.95 percent to 18.5 cents, with 48,446 shares traded. Dimerix lost 8.45 percent; Cynata and Impedimed fell more than seven percent; Starpharma shed 6.45 percent; Imugene, Kazia and Opthea were down more than five percent; Avita, Medical Developments and Micro-X fell more than four percent; SDI and Mesoblast were down more than three percent; 4D, CSL, Emvision, Resmed and Telix shed more than two percent; Cochlear, Nanosonics, Polynovo, Prescient and Volpara were down more than one percent; with Neuren down by 0.09 percent.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

WEHI says it has begun a 90-patient trial of eribulin (Halaven) with pembrolizumab (Keytruda) for women with recurrent ovarian and uterine carcino-sarcomas.
The Institute said the first stage of the trial aimed to recruit 30 women with relapsing carcino-sarcomas, with a further 60 patients planned for the second stage.
WEHI said the trial was based on a previous study which showed “a chemotherapy drug used to treat advanced stages of breast cancer was more effective for ovarian carcinosarcoma than the most proven chemotherapy, platinum chemotherapy”.
The Institute said the study used a variety of human ovarian carcinosarcoma pre-clinical models to investigate whether the chemotherapy drug eribulin could be used to reverse a process associated with tumour progression and drug resistance, known as epithelial-to-mesenchymal transition (EMT).
WEHI said the study showed that eribulin could reverse EMT in ovarian carcino-sarcoma, reducing the growth and aggressive nature of the tumors.
The Institute said the study titled ‘Epithelial-to-Mesenchymal Transition Supports Ovarian Carcinosarcoma Tumorigenesis and Confers Sensitivity to Microtubule Targeting with Eribulin” was published in Cancer Research and an abstract was available at: https://pubmed.ncbi.nlm.nih.gov/36206301/.
WEHI said that as part of the trial, researchers would also search for biomarkers that could help identify the patients who would best respond to the combination therapy.
The Institute said the cancers often presented with no symptoms, meaning most women were diagnosed at an advanced stage that significantly limited their treatment options.
WEHI principal investigator Prof Clare Scott said that “when a disease is rare, it means the research into it is much more challenging, halting the discovery of new treatments.”
“Ovarian carcino-sarcoma is currently treated with the same drugs used for the more common ovarian cancers, but these tumous generally respond poorly to standard-of-care treatments,” Prof Scott said.
“This is proof that blanket approaches aren’t viable when it comes to rare cancers and that new treatments are desperately needed,” Prof Scott said.
“That is why it is incredibly exciting to see our research, spanning over seven years, now translated into a clinical trial that could potentially help women living with rare diseases, like ovarian and uterine carcinosarcomas,” Prof Scott said.
The Institute said the trial was funded by the Australia New Zealand Gynaecological Oncology Group and open at Melbourne’s Peter MacCallum Cancer Centre and Monash Health, with plans to expand to other Australian hospitals, Canada and the United Kingdom in the coming months.

OPTHEA

Opthea says the retail component of its entitlement offer has raised about $16.3 million, taking the total raised with the institutional offer and placement to $90 million.
In August, Opthea said it hoped to raise $80 million through a $10.0 million private placement and a $70.0 million, one-for-3.07 institutional and retail, pro-rata, non-renounceable entitlement offer, at 46 cents a share (BD: Aug 24, 2023).
Later that month, the company said it accepted $10.0 million in oversubscriptions, taking the placement and institutional rights offer total to $73.7 million (BD: Aug 28, 2023).
Today, Opthea said the retail rights offer had a 22.8 percent take-up rate and Biotech Daily calculates it raised $3.72 million from investors, with a $12.58 million shortfall underwritten by MST Financial Services and or sub-underwriters.
Opthea fell two cents or 5.6 percent to 33.5 cents.

BTC HEALTH

BTC says it will distribute the Athens, Greece-based Micrel Medical Devices SA Rhythm Evolution infusion pumps in Australia and New Zealand.
BTC said Micrel's Rhythm Evolution were electronic, portable infusion pumps, administration sets and related accessories for pain management, obstetrics, antibiotic therapy, oncology and immunoglobulin infusions both in hospital and at home.
The company said the agreement was through its subsidiary Bioimpact Pty Ltd and, subject to marketing approval from the Australian Therapeutic Goods Administration and New Zealand's Medsafe, it expected to launch the products in 2024.
BTC did not state the commercial terms of the agreement.
BTC chair Dr Richard Treagus said that with a "strong market position in acute pain management, we are executing on our strategy to replace and expand our infusion product offering to hospitals".
"The Rhythm Evolution is a sophisticated infusion pump, with many high-end features, offering both the accuracy and versatility which is highly sought after by clinical staff".
BTC was up 0.4 cents or 11.1 percent to four cents.

IMMUTEP

Immutep says European authorities have approved the manufacture of eftilagimod alpha, or efti, for non-small cell lung cancer at 2,000 litre scale for clinical trials.
Immutep chief executive officer Marc Voigt told Biotech Daily that the approvals came from "different European competent authorities have, such as the Paul Ehrlich Institute, the German equivalent of the US Food and Drug Administration".
The company said that after successfully scaling-up the manufacturing process of efti to commercial scale at Wuxi Biologics, the process-related changes were presented in a substantial amendment of the investigational medicinal product dossier.
Immutep said overall comparability of the first 2,000 litre and the previous 200 litre scale clinical stage manufacturing process was achieved.
In the media release, Mr Voigt said that "with late-stage clinical development underway … commercial scale manufacturing of efti for use in clinical trials is a significant achievement and brings us closer to realizing efti's potential to help cancer patients".
Immutep was up half a cent or 1.7 percent to 29.5 cents.

EXOPHARM

Exopharm says it received $2,713,673 from the Australian Taxation Office under the Federal Research and Development Tax Incentive Program and has cleared its debts.
Exopharm said that $1,544,709 was paid to Radium Capital to satisfy the research and development loan facility, with the $1,168,964 net proceeds from the Federal Government adding to the company's net cash reserves.
The company said it had sold surplus equipment for $570,000, reduced operating costs to about $130,000 a month and expected to have $2.6 million cash by November 2023.
Exopharm said with its Radium loan paid, it was debt-free.
Exopharm managing director Dr Ian Dixon said that the RDTI and closing the Radium Capital loans "further improves the financial position of the company".
Exopharm was untraded at one cent.

MESOBLAST

Mesoblast says the US Food and Drug Administration requires “further evidence” that the potency assay will assure the consistent efficacy” of its remestemcel-L.

Mesoblast said at a type A meeting, the FDA the regulatory told it that “the key remaining issue for paediatric approval [of its remestemcel-L] is providing further evidence that the potency assay will assure the consistent efficacy of commercial product”.

Last month, the company fell as much as 58.3 percent following the FDA’s second refusal of injected remestemcel-L for paediatric steroid-refractory acute graft versus host disease (SR-aGvHD) (BD: Aug 4, 2023).

Mesoblast said at that time that the FDA “requires more data to support marketing approval”.

In 2020, the company said the FDA required a further trial of remestemcel-L for graft versus host disease and “recommended that [it] conduct at least one additional randomized, controlled study in adults and/or children to provide further evidence of the effectiveness of remestemcel-L” (BD: Oct 2, 2020).

In August, Mesoblast said that following the 2020 refusal, it had negotiated with the FDA to provide more data but not conduct a new trial.

Biotech Daily asked Mesoblast in August when it negotiated not to conduct a trial with the FDA and whether it announced that decision, but did not receive a reply.

Today, Mesoblast said it had summarized the “existing clinical data with the improved Ryoncil product version of remestemcel-L, manufactured after 2008 using the current process inspected by [the] FDA for potential approval” and presented clinical data indicating an improved survival rate in children than the earlier Prochymal version, including in its phase III trial of the drug (BD: Feb 22, 2018).

The company said the FDA noted “the lack of a suitable potency assay for the Ryoncil product used during the phase III trial … [had] prevented the trial from being considered an adequate study for the purpose of demonstrating substantial evidence of effectiveness required for a marketing approval”.

Mesoblast said it intended to generate new potency assay data showing that Ryoncil used in the paediatric phase III trial “was standardized as to its identity, strength, quality, purity and dosage form to give significance to the results of the investigation”.

The company said it believed the additional data would provide a link between the Ryoncil product that was used in the phase III trial and the product which would be used in a future trial for the adult indication.

The company said it intended to address the adult indication with an externally controlled, single-arm registration trial design in adults and children over 12-years-old, with the FDA indicating “its willingness to consider Mesoblast’s proposed registrational trial design in adults, subject to agreement on the suitability of the potency assay for the product”.

Mesoblast said it expected to receive the formal minutes of the meeting within three weeks.

Mesoblast chief executive Prof Silviu Itescu said the meeting allowed the company to “establish the path forward for potential approval of remestemcel-L in SR-aGvHD”.

“We are gathering the additional potency assay data required to demonstrate the ability of Mesoblast’s potency assay to show both the product used in the phase III trial in children and the product made for commercial release are standardized,” Prof Itescu said.

“In parallel, we are focused on initiating a registration trial in adults in partnership with world-leading investigators at the Blood and Marrow Clinical Trials Network,” Prof Itescu said.

Mesoblast fell 1.5 cents or 3.9 percent to 37 cents with 4.35 million shares traded.

RACE ONCOLOGY

Race says a human cell line study shows bisantrene to have “potent anti-cancer activity when screened on a diverse panel of blood and solid organ tumor cells”.

Race said the study tested bisantrene in 143 cancer cell lines covering more than 15 cancer types and found it “to kill more than 79 percent of the cancer cell lines at a concentration bellow 500nM” or 500 nano-molar, or 500 x 10^{-9} moles per Litre (mol/L).

The company said that combining bisantrene with clinically relevant concentrations of doxorubicin, an anthracycline chemotherapeutic used in anti-cancer drugs, was “found [to enhance significantly] cancer cell killing in the majority of cells”.

Race said previous studies had shown doses of bisantrene that were well tolerated by patients in drug concentrations above 3,000nM in the blood, showing “the clinical relevance of this potent in-vitro tumour cell killing activity”.

Race said clinical trials of bisantrene as a single agent showed it had anti-cancer activity for breast cancer, acute myeloid leukaemia, other leukaemias and ovarian cancer.

The company said it planned to optimize the dose and drug combinations through further pre-clinical studies to identify the best clinical treatment opportunities and undergo further pre-clinical studies to explore the molecular mechanisms responsible for the enhanced cancer cell killing with doxorubicin.

Race said it would seek to publish the completed data in a peer-reviewed journal and consult with key opinion leaders to explore clinical studies using bisantrene in combination with doxorubicin to improve outcomes for cancer patients.

Race executive director Dr Pete Smith said that “due to its history, plus a wealth of published pre-clinical and clinical data, bisantrene has long been known to be an active anti-cancer drug”.

“What is interesting from these recent studies is the remarkable breadth of its activity, where bistantrene was shown to kill a wide range of cancer cells, representing tumors from many human tissues,” Dr Smith said.

“The strength of bisantrene’s performance with doxorubicin, a standard-of-care chemotherapy drug, is particularly exciting as it informs our clinical development plans and bolsters confidence that combining other cancer drugs with bisantrene will produce positive results for patients,” Dr Smith said.

Race was up two cents or 2.3 percent to 88.5 cents.

RHYTHM BIOSCIENCES

Rhythm says Adelaide’s Agilex Biolabs has shown that its four biomarkers for breast cancer test has 83 percent sensitivity and 90 percent specificity ($p \leq 0.0003$).

Rhythm said the preliminary assessment of the potential biomarkers by Agilex was in a research use only immunoassay study evaluating blood-based biomarkers from 100 breast cancer patients and 100 healthy volunteers.

The company said the study “identified important biomarker combinations that can distinguish between patients with breast cancer and health controls”.

Rhythm said verification of these results supported investment in a research and development program “to develop, validate, clinically evaluate the performance of the biomarkers, and translate these results into a commercially scalable, proprietary blood test for the early detection of breast cancer”.

Rhythm said that “not unlike Colostat, which is aimed at providing a simple blood test for the early detection of colorectal cancer, the team at Rhythm will look to advance this project to provide a simple blood test for the early detection of breast cancer”.

Rhythm was up 1.5 cents or five percent to 31.5 cents.

EMYRIA

Emyria says Mind Medicine Australia and the Australian National University (ANU) will supply it 3,4-methylene-dioxy-meth-amphetamine (MDMA) for its clinical trials.
Emyria said the supply allowed the start of its ethics-approved MDMA-assisted therapy trial while waiting for a comprehensive shipment from Canada.
Emyria chief executive officer Dr Michael Winlo said with milestones including the Pax acquisition, team training and ethics approval, MDMA supply was “the final component”.
According to its website Mind Medicine Australia is a Melbourne charity founded by Tania De Jong and Peter Hunt.
Emyria was unchanged at 7.8 cents with 1.1 million shares traded.

NEXT SCIENCE

Thorney Investment Group, Tiga Trading, Alex Waislitz and Jasforce Pty Ltd say they have become substantial share-holders in Next Science with 13,964,280 shares (5.74%).
The Melbourne-based Thorney and Tiga said that they bought shares between June 29 and September 20, 2023, with the single largest purchase 3,482,142 shares in the September 6 placement for $1,462,500, or 42 cents a share.
Last month, Next Science said it had raised $12 million in a placement at 42 cents a share and hoped to raise $6.5 million in a share plan (BD: Aug 31, 2023).
Next Science was up two cents or 4.3 percent to 49 cents.

PAINCHEK

Painchek has told the ASX that it is not aware of any information that has not been announced, which, if known, could explain the recent trading in its securities.
The ASX said the company’s share price rose 55.2 percent from 2.9 cents on September 19, 2023 to 4.5 cents today and noted a “significant increase” in the trading volume.
Painchek closed up 0.7 cents or 21.2 percent to four cents with 6.8 million shares traded.

AUSBIOTECH

Ausbiotech says that five-year chief executive office Lorraine Chiroiu will resign, effective on December 15, 2023.
Ausbiotech said Ms Chiroiu would resign “after more than five years at the helm and 15 years of successful and dedicated service to the organization and the life sciences sector”.
The organization said Ms Chiroiu was “pivotal in the growth of the organization and strengthened its position as the peak industry body for the biotechnology sector”.
Ausbiotech said that Ms Chiroiu had been an advocate for the sector, representing the industry to government bodies to maintain continuity of the Research and Development Tax Incentive and shape policy.
Ausbiotech chair Geoffrey Kempler said the organization was “grateful and proud of Lorraine’s sustained service and loyalty … and sincerely thank her for her dedication and achievements”.
Ausbiotech said it had begun a chief executive officer recruitment process.