Biotech Daily

Monday March 11, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MICRO-X UP 24%; EMVISION DOWN 10%**

*** DIMERIX EARLY ANALYSIS: DMX-200 REDUCES FSGS PROTEINURIA; HALT**

*** PAINCHEK SHARE PLAN RAISES $2.5m**

*** IMEX PLACES $1.25m; $250k FROM DIRECTORS TO GO**

*** CLINUVEL: 'SCENESSE SIGNIFICANT RE-PIGMENTATION' IN VITILIGO PATIENT**

*** 4D MEDICAL: US PACT ACT INCLUDES 4D IMAGING**

*** IMUGENE MONOTHERAPY COHORT TAKES ONCARLYTICS TO COMBO**

*** IMRICOR: SOUTH PARIS OKAYS VISION-MR ATRIAL FLUTTER ABLATION TRIAL**

*** MESOBLAST: FDA 'SUPPORTS' REXLEMESTROCEL-L HEART FAILURE PATH**

*** ARCHER MINIATURIZES BIOCHIP DESIGN**

*** PERENNIAL BELOW 5% OF IMMUTEP**

MARKET REPORT

The Australian stock market fell 1.82 percent on Monday March 11, 2024, with the ASX200 down 142.8 points to 7,704.2 points. Eleven of the Biotech Daily Top 40 stocks were up, 20 fell, eight traded unchanged and one was untraded. All three Big Caps fell.

Micro-X was the best on no news, up 2.5 cents or 23.8 percent to 13 cents, with 2.1 million shares traded. Proteomics climbed 5.2 percent; Atomo was up 3.6 percent; Next Science rose 2.8 percent; Compumedics, Mesoblast Paradigm and SDI were up more than one percent; with 4D Medical, Neuren and Polynovo up by less than one percent.

Emvision led the falls, down 25 cents or 9.6 percent to $2.35, with 112,998 shares traded.

Medical Developments lost 5.6 percent; Impedimed, Imugene, Opthea and Syntara (Pharmaxis) fell more than four percent; Actinogen, Resmed, Telix and Universal Biosensors were down more than three percent; Alcidion, Clarity, Genetic Signatures, Immutep, Nova Eye, Prescient and Pro Medicus shed two percent or more; Clinuvel, Cochlear, CSL and Orthocell were down one percent or more; with Avita and Nanosonics down by less than one percent.

DIMERIX

Dimerix says an interim analysis of its phase III focal segmental glomerulo-sclerosis (FSGS) trial shows that DMX-200 reduces proteinuria more than placebo.

Dimerix said that passing the analysis of the first 72 randomized patients in the 286-patient trial “suggests a statistically significant and clinically meaningful result in reducing proteinuria at the end of the study may be possible”.

In 2022, the company said it had recruited the first patients in the phase III trial of DMX200 for FSGS kidney disease; with proteinuria, or percentage of protein in the urine, and estimated glomerular filtration rate, as primary endpoints (BD: May 31, 2022).

Today, Dimerix said that “the analysis indicates that, using a statistical measure, DMX-200 is performing better than placebo in terms of reducing proteinuria, a surrogate marker of kidney disease progression, in patients with FSGS”.

Dimerix chief executive officer Dr Nina Webster told Biotech Daily: “The company remains blinded to the specific data at this stage.”

"Current guidance is that Part 2 analysis, which, if compelling, may be appropriate for conditional marketing approval, is expected mid-2025, subject to recruitment, with final full analysis approximately 12 months after that,” Dr Webster said.

"We are already at 94 patients of the 144, so only 50 to go," Dr Webster said.

Dimerix said that the independent data monitoring committee “noted no safety concerns to date, which is entirely consistent with the existing and growing strong safety profile of DMX-200” and recommended the trial continue unchanged.

The company said the analysis was “extremely valuable as it is based on a significantly larger cohort than the prior Dimerix phase II study which was conducted in eight patients”.

Dimerix said an interim analysis with a futility assessment would ensure a trial did not continue unnecessarily if there was no efficacy signal and it expected a second interim analysis would be conducted after the first 144 patients completed 35 weeks’ treatment.

The company said that following the interim analysis the trial would expand into Part 2 with new clinical sites to be opened in additional countries, including China, to further enhance recruitment.

Dimerix said it would “focus on the execution of potential licencing deals for available jurisdictions including in the US and China”.

Dimerix advisor and co-chair of the UK Glomerulonephritis Clinical Study Group Prof Jonathan Barratt said “the positive signal suggests that treatment with DMX-200 may indeed result in a clinically meaningful improvement in kidney function when added to the standard of care in patients with FSGS”.

“With limited treatment options currently available, there remains a significant unmet need for more efficacious and durable therapies,” Prof Barratt said.

Dimerix said proteinuria was an indicator of renal disease, and the degree of proteinuria correlated with disease progression.

Dimerix chief medical officer Dr David Fuller said that passing the first interim analysis was “a key milestone for Dimerix and our FSGS program”.

It demonstrates that DMX-200 is performing better than placebo in reducing proteinuria in a much larger cohort than our prior eight-patient phase II study, and this validates our strategy and our prioritization of this potentially valuable program in a disease where there are no FDA approved therapies,” Dr Fuller said.

“We now look forward to rapidly expanding this study, which will include recruiting children down to 12 years old as well as adults,” Dr Fuller said.

Separately, Dimerix requested a trading halt until March 13, 2024 “for the purposes of considering, planning and executing a capital raising”.

Dimerix last traded at 30 cents.

PAINCHEK

Painchek says it has raised $2,522,500 in its fully-underwritten share purchase plan at 2.51 cents a share.
Last month, Painchek said it would raise $2.5 million in a fully-underwritten share plan and intended to raise a further $2.5 million in a placement (BD: Feb 14, 2024).
Today, the company said the funds would be used for commercialization of its Adult application, including US Food and Drug Administration de novo regulatory application, as well as commercialization of its Infant application, cyber security, a technology upgrade and working capital requirements.
Painchek fell 0.1 cents or 3.3 percent to 2.9 cents with 6.7 million shares traded.

IMEX HEALTH SERVICES

Imex says it has raised $1,250,000 in a placement at 55 cents a share, with a further $250,000 to be raised in a placement to directors, subject to shareholder approval.
Imex said the issue price was a 13 percent discount to the five-day volume weighted average price and a 15.4 percent discount to the last closing price of 65 cents.
The company said the funds would be used to strengthen its “balance sheet and drive growth with a focus on supporting new and future contracts”.
Imex said its directors had committed an additional $250,000 on the same terms as the placement, with shareholder approval to be sought at its upcoming annual general meeting expected in April, 2024.
Imex fell four cents or 6.15 percent to 61 cents.

CLINUVEL

Clinuvel says one patient treated systemically with Scenesse for vitiligo with narrowband ultraviolet B phototherapy had “significant re-pigmentation of vitiliginous lesions”.
Clinuvel said the female patient was administered seven Scenesse implants, 16mg afamelanotide, and 39 narrowband ultraviolet B phototherapy treatments over 134 days.
The company said that following treatment, re-pigmentation of the patient’s lesions was observed on the face, neck, torso and back.
Clinuvel said Scenesse had clinical benefits including the speed of visible re-pigmentation, intensity of full-body re-pigmentation, safety, patient satisfaction and improved patient self-esteem.
Clinuvel said the case was presented at the American Academy of Dermatology meeting in San Diego on March 9, 2024.
Clinuvel head of North America operations Dr Linda Teng said since vitiligo was “such a visible disease in darker skin with limited treatment options, it is understandable that physicians want to present and discuss patients’ responses to afamelanotide combination treatment, and we were pleasantly surprised to see a new case discussed.”
“It is underestimated how the ability to reinstate complexion has such a deep psychological impact, since the treatment restores the patient’s lost identity,” Dr Teng said.
“These full body results shown from the combination treatment confirm our clinical hypothesis and results from the phase II trial,” Dr Teng said.
“Scenesse is the first pharmaceutical vitiligo therapy offering systemic re-pigmentation while avoiding immunosuppression,” Dr Teng said.
Clinuvel fell 13 cents or one percent to $13.21 with 130,130 shares traded.

4D MEDICAL

4D Medical says the US Congress has included language on “non-invasive [US Food and Drug Administration]-approved screening technologies” in its Pact Act.

Last year, the US White House said President Joe Biden had signed into law the Promise to Address Comprehensive Toxics, or Pact, Act for the expansion of benefits and services for toxicity-exposed veterans, including the use of four-dimensional imaging for a range of respiratory illnesses (BD: Aug 11, 2022).

Today, the company said the six-Bill, $460 billion package approved full-year funding for the Department of Veterans Affairs and other offices and included 23 respiratory illnesses and cancers related to the smoke from military burn pits and other toxic exposures.

4D Medical said the Bill’s associated report encouraged “the Department [of Veterans Affairs] to continue its efforts to identify and use in clinical practice non-invasive FDA-approved screening technologies that save veterans from invasive procedures such as surgical lung biopsies that are often required to establish a diagnosis”.

4D Medical managing-director Prof Andreas Fouras said “five and a half million veterans have deployed to conflicts in the Middle East and been exposed to airborne hazards such as burn pits”.

“Many of them now suffer from debilitating respiratory diseases which existing technologies fail to detect,” Prof Fouras said.

“It’s clear non-invasive FDA-approved screening technologies, such as 4D Medical’s XV Technology, will help more people get the right medical assistance sooner,” Prof Fouras said.

“We are pleased this language on screening technologies was included in the new law and look forward to building on our recent momentum, and work with congress and the [Department of Veterans Affairs] to help veterans get the help they need and deserve,” Prof Fouras said.

4D Medical was up half a cent or 0.6 percent to 79 cents with 2.2 million shares traded.

IMUGENE

Imugene says it has completed the first cohort of the monotherapy arm of its phase I trial of Oncarlytics for CD19-expressing solid tumors and is ready for the second cohort.

Last month, Imugene said it had dosed the first of 52 patients in the intravenous monotherapy arm of its phase I trial of its Oncarlytics CD19 oncolytic virotherapy for solid tumors (BD: Feb 15, 2024).

Today, the company said its cohort review committee had observed “no safety issues in the Oncarlytics monotherapy lead-in study and recommended opening of the combination arm of the study”.

Imugene said the study aimed to target adult patients with advanced or metastatic solid tumors and would evaluate the safety and efficacy of intra-tumoral injection and intravenous infusion alone or in combination with blinatumomab (marketed as Blincyto).

The company said it had treated ovarian cancer, breast cancer and melanoma patients in the first cohort of the monotherapy arm.

Imugene managing-director Leslie Chong said “completion of this first monotherapy intra-tumoral cohort where ovarian, breast and melanoma patients were dosed paves the way for us to move into an important combination dosing with Blincyto, where we’ll be eager to see the greater potential of Oncarlytics in targeting and eradicating solid tumors."

Imugene fell half a cent or 4.55 percent to 10.5 cents with 11.1 million shares traded.

IMRICOR MEDICAL SYSTEMS

Imricor says the Cardiovascular Institute of South Paris has approved its up-to 91-patient trial of the Vision-MR cardiac ablation catheter for atrial flutter ablation.
Earlier this year, Imricor said it had approval for a study of its cardiac ablation catheter and irrigation pump products at the Baltimore's Johns Hopkins Hospital, and last week said it had ethics approval from Switzerland's Lausanne University Hospital (BD: Mar 8, 2024).
Today, the company said ethics approval was the first of two approvals needed to open the trial at the Cardiovascular Institute of South Paris, or the l'Institut Cardiovasculaire Paris Sud, with National Agency for Medicines and Health Products approval still required.
Imricor chair Steve Wedan said the approval was "another big step forward" for the trial supporting the US Food and Drug Administration approval process and US launch.
Imricor was up 1.5 cents or 3.2 percent to 49 cents.

MESOBLAST

Mesoblast says the US Food and Drug Administration "supports an accelerated approval" for rexlemestrocel-L mesenchymal precursor cells for ischemic heart failure.
In 2020, Mesoblast said its 537-patient phase III trial of its rexlemestrocel-L, formerly MPC-06-ID, for chronic heart failure reduced cardiac events, but did not meet its primary endpoint (BD: Dec 15, 2020).
In 2022, the company said that a single dose of rexlemestrocel-L improved left ventricular ejection fraction and reduced major adverse events in class II and III cardiac patients at 12 months relative to controls (BD: Jul 19, 2022).
Today, Mesoblast said the FDA had provided feedback for "potential pathways to licensure for rexlemestrocel-L" and the regulator's comments suggested that clinical results "may support a reasonable likelihood of clinical benefit of [rexlemestrocel-L] against mortality in [left ventricular assist device] patients, consistent with the criteria for accelerated approval".
Mesoblast chief executive officer Dr Silviu Itescu said the company intended "to request a pre-biologics licence application meeting to discuss data presentation, timing and FDA expectations for an accelerated approval filing".
Mesoblast was up half a cent or 1.6 percent to 32 cents with 31.7 million shares traded.

ARCHER MATERIALS

Archer Materials says it has designed a miniature version of its Biochip graphene field effect transistor chip for applications in biotechnology at a commercial foundry.
Earlier this year, Archer Materials, formerly Archer Exploration, said it had developed a computer chip to detect the electronic signals from genetic sequence reactions, enabling the potential detection of multiple diseases (BD: Jan 23, 2024).
At that time, the company told Biotech Daily the micro-chip technology was a 10cm (four inch) silicon wafer able to hold 40-to-45 microchips and was expected to be able to detect multiple unnamed diseases from a single liquid sample on a micro-chip in a mobile device.
Today, Archer said it had miniaturized the chip to 1.5mm by 1.5mm by redesigning the layout of the circuits and had sent it to the Delft, Netherlands-based Applied Nanolayers.
The company said if successful, its lab-on-a-chip platform for medical diagnostics could lead to "the ability to parallelize the detection of biologically relevant targets on a chip".
Archer chief executive officer Dr Mohammad Choucair said "the significant reduction in the size of the Biochip was a great achievement by the Archer team".
Archer was up three cents or 7.7 percent to 42 cents with 4.9 million shares traded.

IMMUTEP

Sydney's Perennial Value Management says it has ceased its substantial shareholding in Immutep.

Perennial said that between February 23 and March 7, 2024 it sold 4,840,108 shares for $1,923,300, or 39.7 cents a share.

Last month, Perennial said it became substantial in Immutep with 59,458,280 shares, or 5.00 percent (BD: Feb 27, 2024).

According to its most recent notice, Immutep had 1,188,834,559 shares on issue, meaning that Perennial's remaining 54,618,172 share-holding amounts to about 4.59 percent of the company.

Immutep fell one cent or 2.4 percent to 40 cents with 2.1 million shares traded.