Biotech Daily

Monday May 27, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: DIMERIX UP 25%; CYCLOPHARM DOWN 16%**

*** NEUREN NNZ-2591 'SHOWS PITT HOPKINS IMPROVEMENT'**

*** STARPHARMA PHASE II DEP IRINOTECAN MEETS ENDPOINTS**

*** EMVISION A.I. STROKE ALGORITHM 'HELPS DIAGNOSE ISCHAEMIA'**

*** PERCHERON: ATL1102 'NO UNEXPECTED TOXICITY', IN MONKEYS**

*** ALLEGRA $478k SALE TO DR NICHOLAS HARTNELL-RELATED COMPANY**

*** HYDRIX $2.3m HARTMANN PRODUCT DEVELOPMENT CONTRACT**

*** DIMERIX: TAIBA 'UP-TO $120m' FOR MIDDLE EAST DMX-200 FSGS RIGHTS**

*** GENETIC SIGNATURES HALTS US RESPIRATORY KIT DEVELOPMENT**

*** TELIX FILES TLX007-CDX PROSTATE IMAGING KIT TO FDA**

*** UNIQUEST APPOINTS ANNE-MARIE BIRKILL DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.79 percent on Monday May 27, 2024, with the ASX200 up 60.7 points to 7,788.3 points. Seventeen of the Biotech Daily Top 40 stocks were up, 16 were down, six traded unchanged and one was untraded.

Dimerix was the best, up 8.5 cents or 25 percent to 42.5 cents, with 36.2 million shares traded. Neuren climbed 15.7 percent to $23.97 with 1.4 million shares traded; Cynata was up 5.45 percent; Starpharma improved 4.55 percent; Paradigm was up 3.9 percent; Clarity, Prescient and Telix rose more than two percent; Cochlear, Immutep, Imugene, Medadvisor, Nanosonics, Next Science, Polynovo, Proteomics and Resmed were up more than one percent; with Avita and Clinuvel up by less than one percent.

Cyclopharm led the falls, down 26 cents or 15.8 percent to $1.39, with 170,715 shares traded. Actinogen lost 7.4 percent; Atomo was down 6.45 percent; Genetic Signatures and Nova Eye fell more than five percent; Compumedics, Opthea and Orthocell were down more than three percent; Curvebeam, Impedimed, Pro Medicus and SDI shed more than two percent; Amplia, Medical Developments, Mesoblast and Micro-X down more than one percent; with CSL down by 0.1 percent.

NEUREN PHARMACEUTICALS

Neuren says 11 of 16 patients from its phase II trial of NNZ-2591 for Pitt Hopkins syndrome showed “statistically significant improvement … in all four efficacy measures”.

In 2022, Neuren said it had begun a phase II trial of oral, liquid NNZ-2591 in up-to 20 children with Pitt Hopkins syndrome (BD: Mar 23, 25, Aug 8, 2022).

Last year, the company said the US Food and Drug Administration had approved Acadia’s Daybue, or Neuren’s trofinetide, for Rett syndrome (BD: Mar 13, 2023).

Today, Neuren said the open-label trial in children aged three-to-17 years was conducted at five US sites and examined safety, tolerability, pharmacokinetics and efficacy of NNZ-2591 at a dose of up-to 12mg/kg twice daily for 13 weeks of treatment.

The company said 11 patients were evaluable in the trial, with one patient not able to meet safety monitoring procedures and four subjects discontinuing due to treatment emergent adverse events, which were all resolved.

Neuren said Pitt Hopkins syndrome affected between one in 34,000 and one in 41,000 people and led to a range of developmental delays with moderate-to-severe intellectual disability and behavioral differences, hyperventilation and/or breath-holding while awake, seizures, gastro-intestinal issues, lack of speech, sleep disturbance, stereotypic hand movements and distinctive facial features.

The company said that NNZ-2591 was “well tolerated and demonstrated a good safety profile … [and that] all treatment emergent adverse events were mild-to-moderate, and most were considered not related to study drug”.

Neuren said efficacy was measured by four measures specifically designed for Pitt Hopkins syndrome, which were Clinical Global Impression of Improvement (CGI-I), Caregiver Overall Impression of Change (CIC), Clinical Global Impression of Severity (CGI-S) and Caregiver Top 3 Concerns.

Neuren said nine of 11 evaluable patients had an improved CGI-I score ($p = 0.0039$), with a mean score of 2.6 and five children receiving a score of either one, “very much improved”, or two, “much improved”.

The company said eight children showed improvement in CIC score ($p = 0.0234$), with a mean CIC score of 3.0 and four children receiving a score of two, or “much improved”.

Neuren said six patients showed improvement in CGI-S score ($p = 0.0313$), with three children improving from a baseline score of six to a post-treatment score of five, and three children improving from a baseline score of five to four after treatment.

The company said eight children showed improvement in Caregiver Top Three Concerns score, an individualized assessment by the caregiver of their child’s most concerning symptoms, with language and communication being the most common concern.

Neuren said it had paused its phase II Prader-Willi syndrome trial because it believed the good safety profile of NNZ-2591 shown in the Pitt Hopkins and Phelan-McDermid trials meant it could simplify the study protocols, subject to FDA agreement.

The company said after its planned end-of-phase II FDA meeting for NNZ-2591 in Phelan-McDermid syndrome, expected by October, it would consider whether to proceed with an optimized protocol and design for the Prader-Willi syndrome trial.

Neuren said it was conducting pre-clinical studies for NNZ-2591 in other indications and would assess the best candidate, or candidates, to move into phase II development with an optimized protocol.

Neuren managing-director Jon Pilcher said the company was “very excited about the results of this first clinical trial in Pitt Hopkins patients”.

“This underserved community has such urgent unmet need, and we can now continue towards our goal of developing a first approved treatment,” Mr Pilcher said.

Neuren was up $3.26 or 15.7 percent to $23.97 with 1.4 million shares traded.

STARPHARMA HOLDINGS

Starpharma says its 114-patient, phase II trial of dendrimer enhanced (DEP)-irinotecan for cancers “met its objectives, with endpoints demonstrating positive anti-tumor efficacy”.

In 2020, Starpharma said its seven-patient, phase I trial would take DEP-irinotecan to an up-to 30-patient phase II trial for colorectal, pancreatic and breast cancer and last year, said early data from its phase I/II trial of DEP-irinotecan for colorectal and ovarian cancer showed “durable anti-tumor responses” (BD: May 7, 2020; Sep 13, 2023).

Today, Starpharma said 55 colorectal cancer patients had median progression-free survival of 4.2 months, or 68 percent longer than historical data, when dosed with DEP-irinotecan in combination with 5-fluorouracil chemotherapy and leucovorin.

The company said DEP-irinotecan led to a disease control rate of 86 percent in the colorectal cancer cohort and an objective response rate of 14 percent, compared to four percent in non-DEP-irinotecan with standard-of-care.

Starpharma said the 38-patients with colorectal cancer in the DEP irinotecan monotherapy arm showed median progression-free survival of 2.1 months and a disease control rate of 48 percent in the 31 evaluable patients, with disease control lasting up-to 72 weeks.

The company said in eight advanced, platinum-resistant/refractory ovarian cancer patients dosed with DEP-irinotecan monotherapy every two weeks led to a median progression-free survival of 9.3 months.

Starpharma said seven evaluable ovarian cancer patients had a disease control rate of 100 percent and an objective response rate of 43 percent, with stable disease and partial responses of up-to 62 weeks, to date.

The company said two ovarian cancer patients were continuing to receive DEP irinotecan therapy “due to ongoing responses and significant clinical benefit”.

Starpharma said one ovarian cancer patient with no measurable target lesions had a complete response, and another had a partial response with a 100 percent reduction in tumor size and 98 percent biomarker reduction.

The company said the 23 ovarian cancer patients in both the two and three-week monotherapy dosing cohorts had a median progression-free survival of 3.2 months.

Starpharma said DEP-irinotecan was “very well tolerated in this trial, with an improved safety profile including significantly fewer severe gastro-intestinal treatment-related adverse events compared to published data on conventional irinotecan”.

The company said adverse events for DEP-irinotecan were “mostly mild to moderate in severity and included nausea, vomiting, fatigue, constipation, decreased appetite and hair loss” with bone marrow toxicity generally uncomplicated and manageable.

Starpharma managing-director Cheryl Maley said “the final results reported today show very positive efficacy outcomes for DEP-irinotecan in both colorectal and ovarian cancer indications”.

“The results compare very favorably with published data on standard-of-care treatments, indicating the potential for improved quality of life for patients with advanced cancers,” Ms Maley said.

“The patients involved in Starpharma’s DEP-irinotecan phase II study were heavily pre-treated, with the colorectal cancer cohort having had a median of three lines of prior antiz-cancer treatment before entering our study, and the platinum-resistant ovarian cohort having had a median of six lines of previous treatment,” Ms Maley said.

“Almost all the colorectal cancer patients had already progressed following prior treatment with standard irinotecan,” Ms Maley said. “This level of pre-treatment and advanced disease makes the efficacy outcomes for DEP-irinotecan even more impressive, especially when the results are compared with standard approved therapies.”.

Starpharma was up 0.5 cents or 4.55 percent to 11.5 cents with 1.5 million shares traded.

EMVISION MEDICAL DEVICES

Emvision says its 180-patient, stage two study confirmed its artificial intelligence-based Emu algorithm could “help answer the clinical question of ischaemia or not”.

Earlier this year, Emvision said it had enrolled all 180 patients in a stage two, multi-site study of its artificial intelligence-based ‘Emu’ portable brain scanner for stroke and stroke mimic patients in emergency departments (BD: May 29, Jun 29, 2023, Mar 27, 2024)

Today, the company said its algorithm displayed “an encouraging ability to identify patterns and features across complex ischaemic patient data sets, including early onset hyperacute ischaemic stroke which is often challenging to detect on non-contrast computed tomography”.

Emvision said the data was being used to enhance the algorithm and that it had conducted cross validation interim analysis to prepare for an upcoming validation trial.

The company said the interim cross validation analysis for stage two data showed “the potential of the Emvision technology to significantly improve the diagnosis, care, and outcomes for both haemorrhagic (bleeding) and ischaemic (blockage) stroke patients, from early at the patient presentation, including prioritized care of hyperacute/acute strokes at the point-of-care”

Emvision said the results were in addition to interim data which confirmed the algorithm’s performance in determining whether a patient was having a haemorrhage or not.

The company said patient recruitment for the final stage three of the pre-validation trial was expected to be completed in the coming months, more than half the target cohort of up-to 30 haemorrhages recruited to date.

Emvision chief executive officer Scott Kirkland said “the ability of our technology to also detect hyperacute and acute ischaemic cases in this cross validation interim analysis is incredibly exciting for our team, our clinical collaborators, and most importantly, what this may mean for the improvement of care pathways and outcomes for future stroke patients.”

Emvision was unchanged at $1.91.

PERCHERON (FORMERLY ANTISENSE THERAPEUTICS)

Percheron says preliminary results from its nine-month toxicology study of ATL1102, in monkeys, shows no unexpected toxicities and no monkeys died in the study.

In 2021, the then Antisense said the US Food and Drug Administration required updated clinical and toxicology protocols to be resubmitted to lift the ATL1102 partial clinical hold and later said it planned a nine-month chronic toxicology study to support the dosing of patients with ATL1102 beyond six months (BD: Aug 12, Dec 9, 2021).

In 2022, the company said it expected the nine-month toxicology study of ATL1102 would allow the FDA to lift the partial clinical hold on ATL1102 limiting dosing to 25mg weekly for six months (BD: Nov 22, 2022).

Today, Percheron said the recovery phase of the study remained ongoing, with final data from all animals expected to be available before the end of 2024, and it would discuss results with the FDA in order to lift the clinical hold on ATL1102 in the US.

Percheron chief executive officer Dr James Garner said the company was “very encouraged by the results we have seen so far”.

“While some analyses remain ongoing, and definitive interpretation awaits completion of the recovery phase, the observations to date seem quite consistent with earlier data, and the study has not identified any new or unexpected toxicities associated with ATL1102,” Dr Garner said. “We await data from the recovery phase of the study before we can draw final conclusions, but the results appear to be broadly confirmatory so far.”

Percheron was unchanged at 7.2 cents.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra says Allegra Innovations Pty Ltd, a related party of director Dr Nicholas Hartnell, will pay 0.4 cents a share in a cash take-over bid, valuing it at $478,444.

Allegra said its board other than Dr Hartnell “unanimously recommended that … shareholders accept a cash takeover bid”.

According to Commsec, the board comprised three directors, Dr Hartnell, chair Peter Kazacos and Sean St Clair Mulhearn.

The company said the offer was “an acceptable opportunity for … shareholders to realize a certain value for their shares at a time when … shareholders cannot presently sell their shares on the ASX, along with paying no transaction costs and by selling the shares, having no exposure to the potential risks associated with a continuing investment in a company whose shares remain suspended from quotation”.

Earlier this year, allegra said it had been suspended under ASX Listing Rule 17.5, due to a delay in lodging its half year report, it expected to resume trading on March 22, 2024 and that the delay was due to “continued discussions with its lenders in relation to its funding requirements, which remain ongoing” (BD: Mar 8, 2024).

Later, the company said that revenue for the six months to December 31, 2023 fell 69.0 percent to $484,235, with net loss after tax up 71.8 percent to $1,444,171 and that it remained suspended (BD: Mar 25, 2024).

Today, the company said Allegra Innovations was a Sydney-based orthopaedic devices distribution company, and that Dr Hartnell held an indirect controlling stake.

Last year, Dr Hartnell and Robinwood Investments said they had a substantial 52,257,354 shareholding (43.69%) after Robinwood, an associated entity of Dr Hartnell, bought Allegra’s orthopaedic division for $4.3 million (BD: Aug 29, Sep 6, 2023).

Allegra chief executive officer Jennifer Swain said the offer “arose following communication with the FDA … which highlighted the need for additional supporting information to initiate a new submission”.

“Given [Allegra’s] limited working capital and the significant expense required to obtain the necessary data for a new FDA submission, with no guaranteed result, accepting the takeover bid is in the best interest of all shareholders,” Ms Swain said.

“The board diligently assessed various strategies and potential buyers to ensure that the chosen course of action would be in the best interest of all shareholders,” Ms Swain said.

Allegra remained in a suspension and last traded at 2.9 cents.

HYDRIX

Hydrix says it has a $2.3 million product development services contract with Heidenheim, Germany’s Paul Hartmann AG.

Hydrix said the contract through subsidiary Hydrix Services was the second stage of works that it would undertake for Hartmann as part of a multi-stage medical product development program.

The company said it expected that the stage of works under this contract would “be completed by the end of … 2024”.

Hydrix chair Gavin Coote said the company was “very pleased to partner with such a high-quality company like Hartmann”.

“Winning important projects with leading international medical technology companies demonstrates meaningful progress of Hydrix’s expansion overseas,” Mr Coote said.

Hydrix was up 0.3 cents or 27.3 percent to 1.4 cents with 3.45 million shares traded.

DIMERIX

Dimerix says Dubai's Taiba FZ LLC has bought the rights to commercialize DMX-200 for focal segmental glomerulosclerosis (FSGS) in the Middle East for $500,000, up-front.
Dimerix said it would receive $US350,000 ($A500,000) in up-front payments within 30 days, and that it could receive up-to $US80.4 million ($120 million) on certain development and commercialization milestones being achieved and royalty payments.
The company said it would receive tiered royalties of 30 percent of net sales for the first five years, which would decrease by five percent every five years down to 20 percent on sales of DMX-200 in the region, if successfully commercialized.
Dimerix said the agreement covered the commercialization of DMX-200 for FSGS kidney disease in the United Arab Emirates, Saudi Arabia, Oman, Kuwait, Qatar, Bahrain and Iraq; and Taiba would be responsible for submission and maintenance of the regulatory dossier in its licensed territories, as well as all sales and costs of marketing activities
The company said it would retain rights in all other unlicenced territories including the US and China and would continue to fund and complete its phase III study for DMX-200 in FSGS patients.
Dimerix managing-director Dr Nina Webster said the company was "very pleased to be partnering with the Taiba group for the Middle East".
"The unique knowledge and expertise that the Taiba team has built in the rare disease space, as well as the established regulatory support and supply chain, places them in the ideal position to achieve the optimum outcome in the Middle East territories for all stakeholders," Dr Webster said.
Dimerix was up 8.5 cents or 25 percent to 42.5 cents with 36.2 million shares traded.

GENETIC SIGNATURES

Genetic Signatures says it has stopped development of its Easyscreen respiratory detection kit in the US "due to increased competition and changing market dynamics".
Genetic Signatures said that following "an internal assessment of the commercial landscape" it ceased US clinical development activities for the Easyscreen product and no longer intended to file a 510(k) application to the US Food and Drug Administration.
The company said it began developing a US-specific Easyscreen detection kit after the increase in molecular testing for respiratory pathogens during the Sars-Cov-2 pandemic.
Genetic Signatures said since it started development "several high-throughput, fully-automated respiratory syndromic molecular tests have been cleared by the FDA and become established in the US market" and molecular testing for respiratory pathogens in the US had "declined significantly over the past 24 to 26 months".
Genetic Signatures said it did not believe "its benefit over established and recently cleared incumbent automated products are sufficient for it to secure a commercially meaningful share of this increasingly crowded market".
The company said it had decided to focus its near-term effort on the expected US commercialization of its Easyscreen gastro-intestinal parasite detection kit.
Genetic Signatures interim chief executive officer Dr Neil Gunn said that while it was "disappointing to conclude the development of a key product at this late stage, we are very mindful that any investment we make in new products must continue to be aligned with a compelling commercial opportunity."
"We remain committed to our respiratory products in our domestic market of Australia where we see increasing use as the winter season arrives," Dr Gunn said.
Genetic Signatures fell four cents or 5.5 percent to 69 cents.

TELIX PHARMACEUTICALS

Telix says it has submitted a new drug application to the US Food and Drug Administration for its TLX007-CDx cold kit for prostate cancer imaging.

Telix said the kit would allow the use of a prostate specific membrane antigen (PSMA) imaging product with a considerably extended distribution profile compared to current approved gallium-68 positron emission tomography (PET) imaging agents.

The company said the kit was designed to "facilitate more flexible production including gallium-68 sourced from both newer high activity generators and cyclotrons powered by the ARTMS Quantm irradiation system and GE Fastlab solid and liquid target production system".

Last month, Telix said it acquired the Vancouver, British Columbia-based radio-isotope production company ARTMS Inc for up-to $US82.0 million ($A126.1 million) (BD: Apr 11, 2024).

Today, the company said it believed the product would "further expand the availability, distribution and scheduling flexibility" of PSMA-PET and give access to underserved patient demographics including African Americans and veterans.

Telix managing-director Dr Chris Behrenbruch said "the scheduling flexibility and accessibility, along with the excellent clinical performance of gallium-68-based PSMA-PET imaging, has enabled Telix to drive rapid geographic expansion of PSMA-PET imaging with our first product Illuccix".

"A core value of our company is the commitment to improving access to medicine and delivering clinical utility that will benefit patients, very much reflected in the development of this exciting new product," Dr Behrenbruch said.

"We believe this is particularly important as demand for PSMA-PET imaging is forecast to grow significantly over the coming decade," Dr Behrenbruch said.

Telix was up 42 cents or 2.7 percent to $15.89 with 976,146 shares traded.

UNIQUEST, THE UNIVERSITY OF QUEENSLAND

The University of Queensland's commercialization company Uniquest says it has appointed Anne-Marie Birkill as a director.

Uniquest said Ms Birkill was a co-founder and executive director of venture capital firm Oneventures, a director of Interfinancial and PPK Group and chair of the University of Queensland's Food and Beverage Accelerator, as well as having been chief executive officer of I-Lab Incubator Pty Ltd.

According to her Linkedin profile, Ms Birkill held a Bachelor of Science from Adelaide's Flinders University and a Master of Business Administration from the University of Queensland.