Biotech Daily

Thursday June 8, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ANTISENSE UP 11%; IMUGENE DOWN 7%**

*** AVITA: FDA OKAYS RECELL FOR FULL-THICKNESS SKIN DEFECTS**

*** KINOXIS WINS $5m FROM US NIDA FOR KNX100 OPIOID ABUSE TRIAL**

*** ANTISENSE DOSES 1st PHASE IIb ATL1102 DMD PATIENT**

*** SYDNEY UNI STARTS PHASE II KAZIA PAXALISIB GLIOMA TRIAL**

*** OSTEOPORE, CELLHEAL PREPARE FOR $4m CHINA PROJECTS**

*** EMYRIA ETHICS APPROVAL FOR OPEN-LABEL MDMA PTSD TRIAL**

*** DR JOHN TARRANT, BALMAIN, CADEX TAKE 11% OF HEXIMA**

*** BIOINTELECT APPOINTS 'EXECUTIVE STRATEGY PANEL'**

MARKET REPORT

The Australian stock market fell 0.26 percent on Thursday June 8, 2023, with the ASX200 down 18.3 points to 7,099.7 points. Eleven of the Biotech Daily Top 40 stocks were up, 23 fell, four traded unchanged and two were untraded. All three Big Caps fell.

Antisense was the best, up 0.7 cents or 11.1 percent to seven cents, with 1.2 million shares traded; followed by Avita up 10.7 percent to $4.75, with 1.3 million shares traded.

Pharmaxis climbed six percent; Compumedics and Kazia were up more than five percent; Prescient and Universal Biosensors improved more than four percent; Impedimed was up 3.2 percent; Starpharma rose 2.8 percent; Alcidion was up 1.1 percent; with Next Science up by 0.9 percent.

Imugene led the falls, down 0.7 cents or seven percent to 9.3 cents, with 40.1 million shares traded.

Polynovo lost 5.9 percent; 4D Medical, Actinogen, Emvision, Immutep, Micro-X, Nanosonics and Telix fell four percent or more; Cynata, Nova Eye and Resmed were down three percent or more; Amplia, Clinuvel, Mesoblast, Neuren and Volpara shed more two percent or more; CSL, Cyclopharm, Medical Developments, Orthocell, Paradigm, Pro Medicus and Proteomics were down one percent or more; with Cochlear and Opthea down by less than one percent.

AVITA MEDICAL

Avita says the US Food and Drug Administration has approved the pre-market application for its Recell spray-on-skin to treat full-thickness skin defects.

In December, Avita said it had submitted a pre-market approval supplement to the FDA for its Recell spray-on skin to include soft tissue repair (BD: Dec 19, 2022).

Today, the company said the indication covered a broad label of full-thickness skin defects, including wound injuries following traumatic avulsion, such as degloving, surgical excision, including necrotizing soft tissue infection, or resection, for example skin cancer.

Avita chief executive officer Jim Corbett said that anticipating the expanded indication "we more than doubled our field sales organization in the first few months of the year".

"Our sales team is now ready, trained and fully prepared for the commercial launch, which will commence July 1, 2023," Mr Corbett said.

Avita was up 46 cents or 10.7 percent to $4.75 with 1.3 million shares traded.

KINOXIS THERAPEUTICS

Kinoxis says the National Institute of Drug Abuse has awarded it $US3.6 million ($A5.4 million) for a 48-volunteer phase I trial of its opioid replacement KNX100.

Kinoxis said it had begun the US Food and Drug Administration-approved double blind, placebo-controlled, randomized phase I trial, investigating the safety, tolerability and pharmacokinetics of daily KNX100, and expected to complete it by September 30, 2023.

The company said that KNX100 was "a small molecule in development for the treatment of substance use disorders, including symptoms associated with withdrawal from opioids".

Kinoxis said it won the grant having completed milestones in a 2019 grant from the Baltimore, Maryland-based National Institute of Drug Abuse (NIDA) through the US Federal Government's 'Helping to End Addiction Long-term' initiative.

Kinoxis chief executive officer Hugh Alsop said the opioid use disorder was "a major and worsening problem in the US and many other countries".

"New treatment options are needed for managing withdrawal symptoms and helping people to recover from opioid addiction," Mr Alsop said.

"The progression of our NIDA grant to the UH3 phase is an important milestone for Kinoxis as it represents further, significant external validation of the KNX100 program and provides the capital required to study key clinical safety endpoints," Mr Alsop said.

Kinoxis is a private company.

ANTISENSE THERAPEUTICS

Antisense says it has dosed the first of 45 patients in its phase IIb trial of ATL1102 for non-ambulant boys with Duchenne muscular dystrophy, in Istanbul, Turkey.

In February, Antisense said Turkey had approved its 45-patient, double-blind, placebo-controlled trial (BD: Feb 14, 2023).

Today, the company said patients would be treated with placebo, 25mg or 50mg ATL1102 subcutaneously, once weekly for six months and then continue an open-label treatment for six months, with results from the blinded phase expected by mid-2024.

Antisense said the trial would be conducted in Australia, Bulgaria, UK and Turkey.

The company said that Turkey and Bulgaria had regulatory approvals, with ethics approval granted in Australia, and UK approval expected within the coming weeks.

Antisense chair Dr Charmaine Gittleson said the dosing was "a major milestone for Antisense Therapeutics and the [Duchenne muscular dystrophy] community".

Antisense was up 0.7 cents or 11.1 percent to seven cents with 1.2 million shares traded.

KAZIA THERAPEUTICS, UNIVERSITY OF SYDNEY

Kazia says it will provide its paxalisib to the University of Sydney for a 76-patient, open-label, phase II study treating adults with grade two and three glioma.
Kazia said the University of Sydney-sponsored trial's primary objective was to determine progression-free survival at six months in recurrent and progressive isocitrate dehydrogenase (IDH) mutant glioma, with secondary endpoints including overall survival, response rate and health-related quality of life.
The company said gliomas were the most common form of primary brain cancer, accounting for about a third of brain malignancies, with grade two and three mutant isocitrate dehydrogenase astrocytomas the second largest group after glioblastoma.
Kazia said grade two and three gliomas were an area of "significant unmet need" with very few US Food and Drug Administration approved therapies and limited options for patients with recurrent disease.
The company said the 'Lumos2' study would be co-ordinated by the University's Clinical Trials Centre with the Co-Operative Trials Group for Neuro-Oncology.
Kazia said the study would be funded by the Federal Medical Research Future Fund with Kazia in-kind support.
The company said the University of Sydney's Centre for Research Excellence in Brain Cancer's Prof Hui Gan would be the study's lead investigator.
"Relapsed [isocitrate dehydrogenase] mutant gliomas are an important area of unmet need in brain cancer, and [the study] builds on early phase II data seen with paxalisib in this population," Prof Gan said.
"[The trial] will complement some of the ongoing work with paxalisib evaluating the efficacy of the drug in high-grade gliomas, and we expect the study to add substantially to our understanding of this investigational drug in brain cancer," Prof Gan said.
Kazia was up one cent or 5.9 percent to 18 cents.

OSTEOPORE

Osteopore says it will work with Cellheal to on two projects worth $4 million using its regenerative implant technology in China, Macau and Taiwan.
Osteopore said the collaboration would use its three-dimensional-printed implant technology, and use stem cells for dental applications, with the second project developing applications for tendon and cartilage regeneration.
According to the company's website, Cellheal co-founder Joy Song was a member of its corporate advisory panel.
The company said the aim of the project was to complete trials to secure Chinese regulatory approval and proceed to commercializing Osteopore technologies in China.
Osteopore said Cellheal would pay its own costs for the research and development and commercialization of the projects, estimated to be at least $4 million.
The company said it would retain intellectual property rights for the dental project and would share ownership of the tendon and cartilage property.
Osteopore said the first phase would include finalizing commercial terms and technical activities with Cellheal to begin the preliminary work required for conducting clinical trials.
The company said the second phase would be clinical research, with pre-clinical animal studies and human trials for Chinese regulatory approval, with the steering committee to apply for China government grants to fund further research, trials and commercialization.
Osteopore said that if regulatory approval was obtained it would begin the final stage of commercializing and launching its products in China.
Osteopore was up one cent or 11.9 percent to 9.4 cents.

EMYRIA

Emyria says it has ethics committee approval to begin a phase II, open-label trial of MDMA for an initial 70 patients with treatment-resistant post-traumatic stress disorder.
In 2021, Emyria said it had launched its 'EMDMA-001' phase II, open-label trial of 3,4-methylene-dioxy-meth-amphetamine (MDMA)-assisted psychotherapy at its Melbourne clinic (BD: May 5, 2021).
Today, the company said it would launch the 12-month trial with its partner the Perth-based Pax Centre, a trauma-focused psychiatric service.
Emyria chief executive officer Dr Michael Winlo told Biotech Daily that the company had "drug supply for 70 patients initially but it's an open running study so we can add as many as we like with more drug".
"Our goal, however, is to use the study as an on-boarding for our network psychiatrists to become authorized prescribers which will allow us to see many more patients," he said.
The company said data from the trial would help improve its care modal, support cost-effectiveness studies and its MDMA-inspired drug development program with the University of Western Australia.
Emyria said therapist training by Dr Ben Sessa had been completed for 20 psychiatrists, general practitioners, mental health nurses, clinical psychologists and counsellors.
"This trial is expected to improve patient outcomes in a safe environment and generate valuable real-world data, allowing program improvements and furthering Emyria's drug analogue development," Dr Winlo said.
Dr Winlo said the ethics approval was "a significant milestone".
Emyria was up one cent or eight percent to 13.5 cents.

HEXIMA

Dr John Tarrant says he has increased his shareholding in Hexima from 12,676,021 shares (7.59 percent) to 18,426,187 shares (11.03 percent).
On Tuesday, Dr John Tarrant, with Balmain Resources and Cadex Petroleum, said he has become substantial in Hexima with 12,676,021 shares (7.59%) (BD: June 6, 2023).
Today, the Sydney-based Dr Tarrant said that on June 6 and 7, 2023 he bought 5,750,166 shares for $76,687 or 1.33 cents a share.
Hexima was up 0.2 cents or 15.4 percent to 1.5 cents with 2.4 million shares traded.

BIOINTELECT

Biointelect says it has appointed an 'executive strategy panel' to support clients on health policy, commercialization, partnerships and organizational transformation.
Biointelect said the panel would be supported by its client service teams working in patient organizations, medical research institutes, start-ups, bio-pharmaceutical companies and government.
The company said the panel included Omico acting chief executive Bruce Goodwin, former Eli Lilly executive David Grainger, Biointelect co-founder Jennifer Herz, former European Medicines Agency executive director Thomas Lonngren, Biointelect acting chief executive officer Cheryl Maley, former Pfizer executive Melissa McGregor and former Eli Lilly executive Franz Pichler.
Biointelect is a private company.