Biotech Daily

Thursday July 11, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: SYNTARA UP 17%; COMPUMEDICS DOWN 15%**

*** KAZIA 'PAXALISIB INCREASES BRAIN CANCER SURVIVAL'; JUMPS 248%**

*** TELIX WELCOMES US ILLUCIX REIMBURSEMENT CHANGES**

*** ORTHOCELL WINS CANADA STRIATE+ APPROVAL**

*** ZELIRA: FDA GUIDES PHASE I MARIJUANA ZEL-HOP1 AUTISM TRIAL**

*** AUSTCO EXPECTS REVENUE UP 38% TO $58m**

*** INVESTORS MUTUAL TAKES 7.4% OF TRAJAN**

*** ALLEGRA DIRECTOR DR NICHOLAS HARTNELL TAKES 58.4%**

*** ASX LONG-TERM SUSPENSION LIST - 6 BIOTECHS**

MARKET REPORT

The Australian stock market was up 0.93 percent on Thursday July 11, 2024, with the ASX200 up 72.8 points to 7,889.6 points.

Nineteen of the Biotech Daily Top 40 stocks were up, 13 were down and eight traded unchanged. All three Big Caps were up.

Syntara was the best, up 0.5 cents or 16.7 percent to 3.5 cents, with 4.2 million shares traded; followed by Telix, up 10.5 percent to $19.39, with 6.7 million shares traded.

Clarity and Next Science climbed more than nine percent; Orthocell rose 8.1 percent; Starpharma was up 7.1 percent; Actinogen was up 5.7 percent; Genetic Signatures improved 4.1 percent; Atomo and SDI were up more than three percent; Neuren rose 2.9 percent; Clinuvel, CSL, Cyclopharm, Emvision, Immutep, Nanosonics and Resonance were up one percent or more; with Cochlear, Mesoblast, Pro Medicus and Resmed up by less than one percent.

Compumedics led the falls, down five cents or 14.7 percent to 29 cents, with 68,175 shares traded. Medical Developments lost 10.4 percent; Dimerix fell 7.2 percent; Amplia and Cynata were down more than three percent; Curvebeam, Percheron and Proteomics shed two percent or more; with 4D Medical, Impedimed, Medadvisor, Micro-X and Polynovo down by one percent or more.

KAZIA THERAPEUTICS

Kazia says the 313-patient, phase II/III GBM Agile study of paxalisib shows a “clinically meaningful improvement” in survival compared to standard-of-care in brain cancer.

In 2019, Kazia said GDC-0084, or paxalisib, had joined the multi-drug, glioblastoma adaptive, innovative learning environment (GBM Agile) trial (BD: Dec 11, 2019).

At that time, the company said the trial was sponsored and administered by the Global Coalition for Adaptive Research and included a stage 1 examination of the drug to meet pre-defined efficacy hurdles before stage 2 and it expected to recruit 200 patients for a primary endpoint of overall survival.

Kazia said in 2019 that the GBM Agile trial was “a ‘master protocol’ study into which different drug candidates can be placed for testing against a common control arm”.

In 2022, the company said the first stage of the paxalisib treatment arm in the study did not meet pre-defined criteria for continuing to a second stage, with enrolled patients to continue treatment as per protocol, and follow-up, until completion of the final analysis, expected by the end of 2023 (BD: Aug 1, 2022).

Today, Kazia said median overall survival for the 54 paxalisib-treated newly diagnosed unmethylated patients was 14.77 months compared to 13.84 months for the 75 newly diagnosed unmethylated patients treated with standard-of-care.

The company said secondary analysis showed median overall survival of 15.54 months in the paxalisib arm compared to 11.89 months in the 46 patients enrolled at the same time as the paxalisib patients and treated with standard-of-care.

Kazia did not disclose any ‘p-values’ with the results or discuss statistical significance.

The company said the trial enrolled newly diagnosed unmethylated patients with recurrent disease and that paxalisib was the third drug to complete evaluation in the study.

Kazia said paxalisib was “well tolerated” and that no additional safety signals were identified in the study population.

Kazia said an “efficacy signal was not detected in the recurrent disease population”, with a median overall survival rate of 9.69 months in the group of 113 recurrent disease patients treated with standard-of-care compared to 8.05 months in the 100 recurrent patients treated with paxalisib.

The company said that “similar results in this population have been reported in the other two drug candidates that have completed the GBM Agile trial” and it would conduct further analyses of the data.

Kazia said it would request a meeting with the US Food and Drug Administration to discuss the results and determine if a potential path to accelerated approval was appropriate for paxalisib.

The company said full data, including secondary endpoints from the paxalisib arm was expected to be presented at a scientific meeting later this year.

Kazia managing-director Dr John Friend said the company was “excited to have shown a 3.8-month improvement in overall survival, an approximate 33 percent improvement, for newly diagnosed unmethylated patients with [glioblastoma] compared to the concurrent standard-of-care arm”.

“Having comparable overall survival data across two independent studies is a compelling outcome in this difficult to treat glioblastoma population,” Dr Friend said. “We look forward to discussing possible approaches for an accelerated approval pathway for paxalisib with the FDA,” Dr Friend said.

Last year, the company said it would delist from the ASX on November 14, 2023, and remain on the Nasdaq, to reduce “costs and administrative burden”

On the Nasdaq, Kazia was up 47.62 US cents or 248.0 percent to 66.82 US cents (98.81 Australian cents) with 430,245,029 shares traded.

TELIX PHARMACEUTICALS

Telix says it welcomes US Centers for Medicare and Medicaid Services proposed changes to improve reimbursement for diagnostic radio-pharmaceuticals, like Illucix.
Telix said that under the changes, the US Centers for Medicare and Medicaid Services would continue to pay for diagnostic radio-pharmaceuticals, such as its Illucix for prostate cancer, after the transitional pass-through payment status expired for hospital outpatients.
The company said that currently costs associated with diagnostic radio-pharmaceuticals were packaged together into the payment for the nuclear medicine tests.
Telix said the US Medicare was proposing refinements to improve the accuracy of overall payment amounts by paying separately for any diagnostic radio-pharmaceutical with a cost greater than $US630 ($A933) a day.
The company said the change would apply to its additional diagnostic products currently in development, if approved, and the final reimbursement change would be issued in “early November 2024 and take effect January 1, 2025”.
Telix Americas chief executive officer Kevin Richardson said the proposed rule would “facilitate more equitable and reliable access to advanced imaging for all patients and support physicians to prescribe the most clinically appropriate solution”.
“We commend the vision of CMS and the coalition, along with patient groups, for raising awareness about the necessity to reform the payment system,” Mr Richardson said.
Telix was up $1.84 or 10.5 percent to $19.39 with 6.7 million shares traded.

ORTHOCELL

Orthocell says Health Canda has granted it a medical device licence for its Striate+ collagen membrane dental implant, allowing it to sell the product in the territory.
Orthocell said Canadian approval complemented existing approvals in the US, Europe, the UK, Australia and New Zealand, and that its distribution partner the Birmingham, Alabama-based Biohorizons Implant Systems was well-established in Canada.
The company said Biohorizons was seeking approvals in other jurisdictions.
Orthocell managing-director Paul Anderson said Canadian approval for Striate+ was “further validation of Orthocell’s expanding global footprint … [and] complements our FDA approval and strengthens the company's position to increase revenue”.
Orthocell was up three cents or 8.1 percent to 40 cents.

ZELIRA THERAPEUTICS

Zelira says it has a “positive response” from the US Food and Drug Administration for an investigational new drug application for its Hope ZEL-HOP1 marijuana for autism.
Last year, Zelira said it had a joint venture with the Dallas, Texas’s Cantheon Capital LLC to develop its Hope marijuana product for autism in exchange for 55 percent ownership in the subsidiary and an investment of $US8.6 million ($A12.4 million) (BD: Feb 15, 2023).
Today, the company said it discussed the design of a phase I trial in healthy volunteers to open an investigational new drug application with the FDA, which hoped to evaluate the safety and pharmacokinetics of the proposed doses of the marijuana-based ZEL-HOP1.
Zelira said the FDA’s response included “clarity on all matters presented, particularly in defining the indication for treatment of irritability associated with autism spectrum disorder in patients with Phelan McDermid Syndrome and Smith-Magenis Syndrome”.
Zelira managing-director Dr Oludare Odumosu said the positive outcome of the FDA meeting was “a major milestone”.
Zelira was up 12.5 cents or 26.0 percent to 60.5 cents.

AUSTCO HEALTHCARE

Austco says it expects revenue from its healthcare communication and workflow management products for the year to June 30, 2024 to be up 38 percent to $58 million.
Austco said it expected earnings before interest, taxes, depreciation and amortization (Ebitda) of between $7.5 million and $8.0 million, an increase of 108 percent to 122 percent compared to $3.6 million for the year to June 30, 2023.
The company said it expected to release its audited full year results “on or before August 29, 2024”.
Austco was up 2.5 cents or 12.8 percent to 22 cents with 3.5 million shares traded.

TRAJAN GROUP HOLDINGS

Investors Mutual Ltd says it has increased its substantial shareholding in Trajan from 9,236,502 shares (6.07%) to 11,209,603 shares (7.36%).
The Sydney-based Investors Mutual said that with Citicorp it bought and sold shares on market between May 16 and July 10, 2024, with the single largest purchase 600,000 shares for $613,346, or $1.02 a share.
Trajan was up half a cent or 0.5 percent to $1.045.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra director Dr Nicholas Hartnell says he has increased his shareholding in the company from 68,117,741 shares (56.95%) to 69,834,014 shares (58.38%).
In May, Allegra said Dr Hartnell would pay 0.4 cents a share in a cash bid, valuing it at $478,444; and later, filed his bidder’s statement (BD: May 27, Jun 20, 2024).
Today, the Bowral, New South Wales-based Dr Hartnell said that with Robinwood and Allegra Innovations he acquired the shares “as a result of acceptances of takeover offers made by [Allegra Innovations] dated June 20, 2024”.
Allegra was in a suspension and last traded at 2.9 cents.

ASX, ALLEGRA, AUSCANN, BOD, EPSILON, MEDLAB CLINICAL, NUHEARA

The ASX has released its list of 78 long-term suspended entities and their deadlines, which includes Allegra, Auscann, Bod Science, Epsilon, Medlab and Nuheara.
The ASX said the companies had been suspended for more than three months for failing to lodge their periodic financial reports, and that if they did not meet the one-year or two-year deadlines they would be removed from the official list.