Biotech Daily

Wednesday April 13, 2022

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: ONCOSIL UP 74%; USCOM DOWN 9%**

*** ONCOSIL: 1st EURO PANCREATIC CANCER COMMERCIAL DEVICE**

*** IMUGENE DOSES 2nd CHECKVACC BREAST CANCER COHORT**

*** ELLUME TO 'VIGOROUSLY DEFEND' US SARS-COV-2 TEST ACTION**

*** NEUROSCIENTIFIC: EMTINB TOX STUDIES PREPARE FOR HUMAN TRIALS**

*** EMYRIA HIRES CLINITRIALS FOR PHASE III MARIJUANA DISTRESS TRIAL**

*** AUSTRALIAN SUPER BELOW 5% IN NANOSONICS**

MARKET REPORT

The Australian stock market was up 0.34 percent on Wednesday April 13, 2022, with the ASX200 up 25.0 points to 7,479.0 points. Sixteen of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and two were untraded.

Oncosil was the best, up 3.1 cents or 73.8 percent to 7.3 cents, with 163.1 million shares traded.

Pharmaxis climbed 18.0 percent on no news; Orthocell and Polynovo were up five percent or more; Impedimed, Imugene and Patrys improved more than four percent; Amplia was up 3.6 percent; Actinogen, Alcidion and Telix rose more than two percent; Clinuvel, Cochlear, Genetic Signatures and Volpara were up more than one percent; with CSL, Paradigm and Pro Medicus up by less than one percent.

Uscom led the falls, down one cent or 9.1 percent to 10 cents, with 377,236 shares traded.

Micro-X lost 8.2 percent; Dimerix was down 5.7 percent; Antisense and Proteomics fell four percent or more; Next Science was down 3.5 percent; Medical Developments shed 2.1 percent; Cynata, Emvision, Kazia, Neuren, Opthea, Resmed, Starpharma and Universal Biosensors were down one percent or more; with Avita and Cyclopharm down by less than one percent.

ONCOSIL MEDICAL

Oncosil says a hospital in Madrid has completed the first commercial use of its Oncosil radiotherapy device for pancreatic cancer in Europe.

Last year, the company said a study of its radiotherapy for pancreatic cancer showed local disease control in 38 of 42 (90.5%) of treated patients (BD: Dec 24, 2021).

In March, Oncosil said that Germany's Federal Joint Committee has approved a "fully-funded" trial comparing its radiotherapy device with chemotherapy for pancreatic cancer (BD: Mar 28, 2022).

Today, the company said the procedure was performed at Spain's Hospital Universitario de Fuenlabrada, and that it had trained 10 hospital sites in Spain on the implantation procedure of the Oncosil device.

Oncosil managing-director Nigel Lange said the company was "excited to achieve this important milestone for the first commercial patient being treated in Europe".

"Covid-19 has resulted in lengthy delays in gaining access to hospitals for the Oncosil team to provide training which is of vital importance when treating patients with this new therapy," Mr Lange said

"As restrictions are now beginning to ease, our team have been able to train more hospitals and work with key opinion leaders on the benefits of the Oncosil device for patients with locally advanced pancreatic cancer," Mr Lange said.

"We look forward to the Oncosil device becoming more accessible to patients throughout Spain and subsequently other European countries, to maximize the benefit from this novel treatment," Mr Lange said.

"Overall, following our recent success in Germany, we expect the momentum of Oncosil device sales to continue improving over the course of the current year," Mr Lange said.

Oncosil was up 3.1 cents or 73.8 percent to 7.3 cents with 163.1 million shares traded.

IMUGENE

Imugene says it has dosed the first patient of a second, escalated-dose cohort in a phase I trial of its Checkvacc oncolytic virotherapy for triple negative breast cancer.

In March, Imugene said that the trial of Checkvacc, or CF33-hNIS-anti-PDL1, would begin a second, higher-dose cohort of 12 patients (BD: Mar 24, 2022).

Last year, Imugene said the US Food and Drug Administration had approved its investigational new drug application for a phase I trial of CF33 for triple-negative breast cancer (BD: Jul 2, 2021).

The company said at that time that the study would evaluate the safety and initial evidence of efficacy of intra-tumoral administration of CF33 combined with a human sodium-iodide symporter (hNIS) and an anti-programmed death-ligand 1 (CF33-hNIS-anti PDL1) antibody, or Checkvacc, for metastatic triple-negative breast cancer.

Today, the company said the first of these patients had been dosed at the Duarte, California-based City of Hope Hospital, in the study to evaluate the safety and initial evidence of efficacy of intra-tumoral administration of Checkvacc in patients with metastatic triple negative breast cancer.

Imugene managing-director Leslie Chong told Biotech Daily that the first cohort was dosed at the rate of 3.0×10^4 plaque-forming units (PFUs) and the current second cohort was being dosed at 3.0×10^5 PFU.

In the media release, Ms Chong said "we are pleased with the results that we have seen so far in cohort 1 with no observed toxicity with early encouraging results in oncolytic virus infection and replication in the [triple-negative breast cancer] tumors".

Imugene was up one cent or 4.8 percent to 22 cents with 32.0 million shares traded.

ELLUME

A document filed to a US court claims a legal action is underway against Ellume relating to its severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) tests.

The document filed to the US District Court of Maryland on March 22, 2022 said that Karen Kerschen and Wallace Lovejoy on behalf of themselves and all others similarly situated were the plaintiffs in the matter against Ellume USA LLC.

The plaintiffs said they were purchasers of Ellume's Rapid Antigen At Home Covid-19 Test Kits, which were subject of a voluntary recall "due to the potential for providing false positive test results" on October 1, 2021 and November 10, 2021, respectively.

A spokesperson for Ellume told Biotech Daily that the company was "aware that it has been named as a defendant in a lawsuit challenging the adequacy of the reimbursement program that Ellume announced months ago in connection with its voluntary recall of some of its Covid-19 Home Test, after Ellume noted an increased chance that these tests might provide an incorrect positive result".

"The tests worked as intended for the majority who used the products, including those who received a negative test result," Ellume said.

"Ellume also has provided refunds to most customers who used an affected test and received a positive result, even if the positive test result was accurate," the company said.

"The claims in this lawsuit are wholly without merit, and Ellume intends to mount a vigorous defence," the company said.

"As this matter is now before the courts Ellume will not be making any further comment," the company said.

Last year, Ellume said it had recalled "specific product lots of [Sars-Cov-2] tests" after they reported false-positive test result rates higher than was observed in clinical testing (BD: Oct 7, 2021).

Ellume chief executive officer Dr Sean Parsons said at that time that that "upon determining that a portion of our test kits were reporting higher than expected false-positive test results, we worked quickly with the Food and Drug Administration to voluntarily recall the problematic test kits and correct the issue".

"In this case, we noted that some tests from specific lot numbers may provide an incorrect positive result at a higher rate than was observed in clinical testing," Dr Parsons said.

"Following a thorough investigation, we isolated the cause and confirmed that this incidence of false positives is limited to specific lots," Dr Parsons said.

The company said that customers who attempted to use the affected tests would be notified in the application that the test had been recalled and affected tests disabled and customers who purchased recalled tests with affected lot numbers and who previously tested positive were being contacted by the company.

The company said that the reliability of negative results was unaffected by the issue.

The plaintiffs in the US case said the lawsuit "arises from Ellume's failure and refusal to refund purchasers of recalled Ellume Covid tests, despite Ellume recalling certain production lots because they were inaccurate, unsafe, and ineffective".

The document alleged that the tests provided false positive test results or became unusable because certain production lots reportedly produced higher than acceptable false positive results due to a manufacturing issue.

The document said that the Court had subject matter jurisdiction over the action because at least one member of the class is a citizen of a different state than defendant, there are more than 100 members of the class, and the aggregate amount in controversy exceeds $US5,000,000 exclusive of interest and costs.

Ellume is a public unlisted company.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says safety and toxicology studies show Emtinb for neurology indications is safe and well-tolerated to 100mg/kg/day, in readiness for a phase I human clinical trial.
Neuroscientific said and that the drug demonstrated an impressive safety profile in multiple animal species, with doses as high as 100mg/kg/day over a period of 28-days not resulting in any major safety concerns.
The company said the study observed a 100 percent survival rate at the conclusion of the dose period.
Neuroscietific said the study dosed up to 20 times above the predicted efficacious dose-range in humans, a standard which it said exceeded the typical requirement of regulatory agencies, including the US Food and Drug Administration.
Neuroscientific managing-director Matt Liddelow said the company was “excited to report the outstanding safety outcomes for Emtinb and the successful completion of the pre-clinical safety and toxicology program to support initiation of phase I clinical studies for our neurology indications”.
“This safety data provides clear validation that we have met all requirements of achieving the significant milestone of advancing our novel lead drug candidate Emtinb into the clinical development phase and we have been working closely with our clinical development partner Linear Clinical Research to execute on our first-in-human clinical trial [by July] 2022,” Mr Liddelow said.
Neuroscientific was up two cents or 7.55 percent to 28.5 cents.

EMYRIA

Emyria says that Perth’s Clinitrials will coordinate a phase III trial of its over-the-counter EMD-RX5 cannabidiol candidate for patients with psychological distress.
Emyria said Clinitrials would “lead the preparation, ethics submission, patient recruitment and conduct of … [the] pivotal phase III clinical trial” at up to six Australian sites.
The company said the phase III trial was expected to support the registration of the marijuana-based EMD-RX5 with the Australian Therapeutic Goods Administration as a schedule 3 over-the-counter treatment for the symptoms of psychological distress.
Emyria said that the master services agreement allowed Clinitrials to begin additional clinical trials to support its drug registration programs including cannabinoid-based medicines and novel 3,4-Methylene-dioxy-meth-amphetamine, or MDMA, analogues.
The company did not disclose the payment to Clinitrials but said that fees would be invoiced on a monthly basis, with all intellectual property rights to remain with Emyria.
Emyria was unchanged at 30 cents.

NANOSONICS

Australian Super says it has ceased to be a substantial shareholder in Nanosonics.
Earlier this month, Australian Super said it had become substantial in Nanosonics, with 15,091,912 shares, or 5.00 percent of the company (BD: Apr 6, 2022).
Today, the company said that between March 31 and April 5, it bought shares at prices ranging from $3.83 to $4.02 and sold shares at prices ranging from $3.82 to $3.99.
Nanosonics was unchanged at $3.88 with 412,568 shares traded.