Biotech Daily

Monday March 7, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: USCOM UP 9%; RESONANCE DOWN 12%**

*** IMPEDIMED: 'SOZO ASSESSES BONE MINERAL CONTENT'**

*** S&P ASX INDICES: 7 BIOTECHS UP; 9 DOWN**

*** MACH7: $2.4m TRINITY, PENN STATE VNA ORDERS**

*** ADHERIUM FILES US FDA 510K ELLIPTA, HAILIE APPLICATION**

*** CHIMERIC CORE-NK (CHM0201): NO GVHD, TOXICITIES**

*** RECCE R327 I-V DOSE INCREASE TO 1000mg**

*** UNIVERSAL BIOSENSORS APPOINTS GRAHAM MCLEAN DIRECTOR**

*** MALCOLM THOMPSON REPLACES AUDEARA CFO PETER HARDING-SMITH**

MARKET REPORT

The Australian stock market fell 1.02 percent on Monday March 7, 2022, with the ASX200 down 72.2 points to 7,038.6 points. Five of the Biotech Daily Top 40 stocks were up, 25 fell, eight traded unchanged and two were untraded. All three Big Caps fell.

Uscom was the best of the five, up 0.8 cents or 8.8 percent to 9.9 cents, with six (6) shares traded. Antisense climbed eight percent; Atomo was up 4.35 percent; Starpharma improved 1.2 percent; with Neuren up 0.5 percent.

Resonance led the falls, down 1.5 cents or 12.0 percent to 11 cents, with 111,096 shares traded, followed by Avita down 10.95 percent to $2.52, with 781,744 shares traded.

Micro-X lost 9.1 percent; Imugene retreated 8.2 percent; both Alcidion and Paradigm shed 7.7 percent; Actinogen, Nanosonics, Opthea, Orthocell and Telix were down more than six percent; Cyclopharm, Kazia, Oncosil, Prescient and Pro Medicus were down more than five percent; Emvision, Genetic Signatures, Medical Developments, Mesoblast, Polynovo and Volpara fell more than four percent; Cochlear, CSL, Next Science and Patrys were down more than three percent; with Clinuvel and Resmed down by less than one percent.

IMPEDIMED

Impedimed says its Sozo bioimpedance fluid volume system accurately assesses bone mineral content in cancer patients when tested against dual x-ray absorptiometry.

Impedimed said that the “strong correlation” between its Sozo device and dual x-ray absorptiometry, the current standard measure of bone mineral content.

A spokesperson for Impedimed told Biotech Daily that dual x-ray absorptiometry was more detailed and accurate than Sozo, but the Impedimed device was “quicker, easier and safer” and could be used more easily as a first line of detection.

The company said the data was in a presentation titled ‘The Routine Use of Bioimpedance Spectroscopy Measurements in the Clinic as a Surrogate for Bone Mineral Content in Oncology Patients: Practical Application of the Sozo Device’ presented at the Miami Breast Cancer Conference held on March 3 to 6, 2022 at Miami Beach, Florida.

Impedimed said that the Sozo bioimpedance spectroscopy platform delivered “a precise snapshot of fluid status and tissue composition in less than 30 seconds” and had a strong correlation between skeletal muscle mass collected using Sozo and bone mineral content (BMC) collected using dual x-ray absorptiometry (DXA) in three groups, including healthy subjects, cancer patients during treatment and cancer patients after treatment.

The company said that the correlation may be a “useful surrogate in the clinic to provide a quick, easy and reproducible indicator of change in BMC, particularly for those patients undergoing treatments that may affect BMC”.

“Tracking [skeletal muscle mass] during or after cancer treatment with Sozo may provide an estimate of changes in BMC allowing clinicians to obtain additional diagnostics testing and/or consider treatment modification,” Impedimed said.

In November, Impedimed said that it had used Sozo to monitor body fluid volumes to evaluate the efficacy, safety and tolerability of a combination of two Astrazeneca drugs in heart failure patients with chronic kidney disease (BD: Nov 4, 2021).

In September, the company said that Brisbane’s Icon Group would install Sozo units for lymphoedema screening services for breast cancer patients in Australia and New Zealand (BD: Sep 30, 2021).

Today, Impedimed managing-director Richard Carreon said that “studies like this correlation analysis between Sozo and DXA begin to unlock the full potential of Sozo in cancer care”.

“Our lympheodema prevention program is establishing Sozo in cancer centers worldwide,” Mr Carreon said.

“Adding new indications, such as bone, will open more opportunities in the oncology pathway and will make Sozo an even more essential part of cancer care,” Mr Carreon said.

Impedimed said that expanding the use of Sozo “to help care for cancer patients [was] central to [its] growth strategy in oncology”.

The company said that developing broader oncology indications created the opportunity to expand demand for additional Sozo devices and adding new licences to existing devices, with bone analysis “one of a number of potential indications on [its] oncology product roadmap”.

Impedimed said that several corporate accounts, as well as some institutions, had “expressed an interest in the co-development of these potential indications with the goal of benefiting their cancer patients and improving health economics”.

The company said it had begun “some small-scale clinical investigations and is currently assessing the opportunities”.

Impedimed was unchanged at 15.5 cents with 2.15 million shares traded.

STANDARD AND POOR'S DOW JONES INDICES

Seven biotechnology companies will be promoted in changes to Standard & Poor's ASX indices, with nine demoted, effective from March 21, 2022.

Standard & Poor's said Mesoblast would be removed from the ASX300, Opthea and Paradigm would be removed from the ASX200, with Cyclopharm, Emvision, Genetic Signatures, Imricor, Mach 7 and Recce to be demoted from the ASX All Ordinaries Index and Mach7 also to be demoted from the All Technology Index.

Standard & Poor's said Alcidion, Cogstate, Incannex, Impedimed, Neuren, Rhythm and Trajan would be promoted into the ASX All Ordinaries Index.

Previously, Standard & Poor's has told Biotech Daily that inclusion in the indices is based solely on market capitalization.

The Biotech Daily Top 40 Index (BDI-40) is based on quality of science, benefit to human health, board and management, investment potential and market capitalization.

MACH7 TECHNOLOGIES

Mach7 says it has orders worth $2.4 million from Trinity Health and Penn State Milton S Hershey Medical Center for its vendor neutral archive imaging system.

Mach7 said that a $900,000 order from the Livonia, Michigan-based Trinity Health would implement its platform for image storage and access at facilities in its 92 hospitals.

The company said Penn State Milton S Hershey Medical Center had signed a contract renewal and licence expansion for the Mach7 enterprise imaging platform worth $1.5 million, of which $1.1 million was capital software revenue to be recognized in the year to June 30, 2022, with $400,000 was support revenue to be recognized until March 2023.

Mach7 was up half a cent or 0.7 percent to 74 cents.

ADHERIUM

Adherium says it has filed a 510(k) application to the US Food and Drug Administration to connect its next generation Hailie sensor to Glaxosmithkline Ellipta inhalers.

Adherium said the upgraded Hailie sensor had physiological parameters for monitoring asthma and chronic obstructive pulmonary disease (COPD), was designed for use with the Glaxosmithkline Ellipta dry power inhaler and would "capture physiological parameters such as respiratory flow rate in litres per minute".

The company said that the additional information and reporting adherence would provide insight into inhaler use and technique which would give "patients immediate feedback and [promote] greater engagement with the Hailie phone [application]".

Adherium said the Hailie sensor for Ellipta dry powder was "the second in [its] series of new sensors, following Astrazeneca's Symbicort … inhaler".

The company said that recording inhaler adherence and physiological parameters would provide remote, automated and objective data to guide patient care and support.

Adherium said that Ellipta's addition to the Hailie range of products would "broaden the pathway for [its] customers in the US to access reimbursement for remote monitoring of patients prescribed asthma and COPD medications".

Adherium chief technology officer Geoff Feakes said that "physiological parameters were consistently identified as a valuable data set to improve patient management".

"As part of [our] market expansion we intend to rollout additional new sensors with physiological parameters taking our asthma and COPD medication coverage in the US to over 80 percent of the addressable market volume supporting 18 medications," he said.

Adherium fell 0.05 cents or 4.35 percent to 1.1 cents with 8.3 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says that one of nine “heavily pre-treated” cancer patients in its phase I trial of CHM0201 achieved a complete response at 100 days.

Chimeric said that the phase I trial of its “clinically validated, off the shelf, robust, enhanced natural killer cell” (Core NK) platform, or CHM0201, was an open label, single-center trial designed primarily to establish that escalating doses of off-the-shelf Core NK cell products generated from third-party adult donors can be infused without inducing graft-versus-host disease or other significant toxicities.

Last year, the company began a separate up-to 36-patient, phase I study dose-escalation trial of its chlorotoxin chimeric antigen receptor T-cells (CLTX-Car-T) for glioblastoma at the Duarte, California-based City of Hope (BD: Mar 18, 2021).

The study, titled ‘A Phase I study to determine maximum tolerated dose of ex-vivo expanded natural killer cells derived from unrelated, HLA-disparate adult donors’ was published in the journal Transplantation and Cellular Therapy and an abstract is at: https://www.sciencedirect.com/science/article/abs/pii/S2666636722000641?via%3Dihub.

Today, the company said that the phase I clinical trial, at the Cleveland, Ohio-based Case Comprehensive Cancer Center, administered two infusions, at day zero and day 14, of CHM0201 at three different dose levels of 10 $x10^6$ cells, 24 x 10^6 cells and 50 x 10^6 cells.

Chimeric said that of the nine heavily pre-treated patients, three had blood cancers and six had solid tumors, with results showing the patients with blood cancers achieving “stable disease” at day 28.

The company said that of the six patients with the solid tumors colorectal cancer and colon cancer, two had stable disease by day 28, and one “maintained their disease stability at day 100”.

Chimeric said that all three blood cancer patients had stable disease at day-28, with one having a complete response by day-100, and following an allogeneic transplant was in remission after 15 months.

A chart provided with a presentation of the data showed that at day-28 four patients were progressing and five had stable disease; and at day-100, one patient had a complete response, two were stable, two showed progression and four were “N/A”.

The company said that all patients tolerated CHM0201 well with no dose limiting toxicities, no cytokine release syndrome and no graft-versus-host disease (GvHD) and “all observed events were expected … attributable to the lymphocyte-depleting chemotherapy regimen”.

Chimeric chief executive officer Jennifer Chow said that “by establishing safety without GvHD, substantial efficacy with a highly durable [complete response], robust ex vivo expansion and promising persistence of cells without exogenous cytokine support, we now have a strong foundation upon which to amplify our therapeutic efficacy”.

Chimeric fell half a cent or 3.1 percent to 15.5 cents with 2.8 million shares traded.

RECCE PHARMACEUTICALS

Recce says an independent safety committee has approved increasing the dose of R327 from 150mg to 1000mg after positive data from the third cohort in its phase I trial.

Recce said the phase I trial was an ascending dose, randomized, placebo-controlled, parallel, double-blind, single-dose study being conducted at Adelaide's CMax clinical trial facility with phase I dosing expected to be completed by July 2022.

Recce chief executive officer James Graham said the recommendation to start dosing of cohort four at 1,000mg per dose was “a wonderful endorsement for the compelling safety and tolerability profile demonstrated among 10 subjects of cohort three”.

Recce was up 3.5 cents or 3.8 percent to 95 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says that it has appointed Graham McLean as a non-executive director.

Universal Biosensors said that Mr McLean had more than 20 years of business and corporate governance experience, most recently at Stryker Corp as head of Asia-Pacific and was previously Lion Nathan's finance director.

The company said Mr McLean had been a director of Suicide Prevention Australia and Cleanspace Holdings, as well as other companies, and an adviser to Bain & Co.

Universal Biosensors said that Mr McLean held a Bachelor of Science from England's Durham University.

Universal Biosensors was unchanged at 95 cents.

AUDEARA

Audeara says that Malcolm Thompson will replace Peter Harding-Smith as its chief financial officer and company secretary, effective from today, March 7, 2022.

Audeara said that Mr Thompson had previously worked at Pipe Networks as company secretary and chief financial officer, as well as advising companies on corporate governance, accounting, fundraising and complex negotiations.

Audeara was untraded at 11 cents.