Biotech Daily

Monday July 22, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMPEDIMED UP 6%; ACTINOGEN DOWN 12%**

*** MESOBLAST OPENS PHASE III REXLEMESTROCEL-L BACK PAIN TRIAL**

*** CHIMERIC ENROLS 1st PHASE I/II CHM CDH17 PATIENT**

*** IMMUTEP: FDA OKAYS PHASE III EFTI NSCLC TRIAL**

*** RESPIRI PLACEMENT RAISES $3m**

*** MTP CONNECT: WA GOVERNMENT $350k FOR INNOVATION HUB**

*** ANTERIS REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** DORSAVI REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** LTR REQUESTS 'CAPITAL RAISE' TRADING HALT**

*** REGAL FUNDS TAKES 33% OF OPTHEA**

*** ALLEGRA DIRECTOR DR NICHOLAS HARTNELL TAKES 65%**

MARKET REPORT

The Australian stock market fell 0.5 percent on Monday July 22, 2024, with the ASX200 down 39.9 points to 7,931.7 points. Thirteen of the Biotech Daily Top 40 stocks were up, 20 were down and seven traded unchanged.

Impedimed was the best, up 0.4 cents or 6.25 percent to 6.8 cents, with 361,483 shares traded. Syntara climbed 5.3 percent; Atomo improved four percent; Resonance rose 3.8 percent; Nanosonics, Proteomics, Starpharma and Telix were up more than two percent; Cochlear, Emvision and Medadvisor were up one percent or more; with Genetic Signatures, Mesoblast, Pro Medicus and Resmed up by less than one percent.

Actinogen led the falls for the second trading day in a row, down one cent or 12.35 percent to 7.1 cents, with 22.3 million shares traded. Next Science lost 8.6 percent; Compumedics, Curvebeam and Medical Developments fell more than four percent; both Cynata and Orthocell were down 3.85 percent; Avita, Clarity, Cyclopharm, Micro-X and Nova Eye shed two percent or more; 4D Medical, Alcidion, Clinuvel, Dimerix, Imugene and Percheron were down more than one percent; with CSL, Neuren and Polynovo down by less than one percent.

MESOBLAST

Mesoblast says it has begun enrolment for its 300-patient, phase III trial of rexlemestrocel-L for degenerative disc disease-related chronic low back pain.
In 2021, Mesoblast said that a 404-patient, phase III, randomized, controlled trial of rexlemestrocel-L, with and without hyaluronic acid compared to placebo, “did not reach statistical significance across the entire study” (BD: Feb 11, 2021).
In 2022, the company said that a 36-month follow-up of the phase III trial of rexlemestrocel-L mesenchymal precursor cells (MPCs) for back pain showed durable pain reduction (BD: Jan 16, 2022).
Last year, Mesoblast said the US Food and Drug Administration had granted rexlemestrocel-L, formerly known as MPC-06-ID, regenerative medicine advanced therapy (RMAT) designation for chronic low back pain (BD: Feb 9, 2023)
At that time, the company said the designation was for the drug as a treatment for chronic low back pain associated with disc degeneration, in combination with hyaluronic acid as the delivery agent for injection into the lumbar disc.
Today, Mesoblast said the trial of its “allogeneic, immune-selected and industrially manufactured stromal cell product rexlemestrocel-L” would enrol patients with chronic low back pain due to inflammatory degenerative disc disease of less than five years duration at multiple sites in the US.
The company said the US Food and Drug Administration had previously approved the design of the randomized, placebo-controlled phase III trial.
Mesoblast said the 12-month primary endpoint of the trial was pain reduction as an approvable indication, with key secondary measures including improvement in quality of life, function, and reduced opioid usage.
Mesoblast chief medical officer Dr Eric Rose said the company was “very excited to be actively enrolling our pivotal trial of rexlemestrocel-L across multiple sites and look forward to confirming the durable pain reduction previously observed in the first phase III trial”.
“There is a significant need for a safe, effective, and durable treatment in patients with [chronic low back pain] and degenerative disc disease, in particular one that reduces or eliminates opioid use,” Dr Rose said.
Mesoblast said that back pain was “the leading cause of disability in Americans under 45 years, with an annual prevalence in the general US population of 10 to 30 percent”.
Mesoblast was up half a cent or 0.4 percent to $1.155 with four million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says it has enrolled the first of 12 patients in its phase I/II trial of its CDH17 cell therapy for colorectal and gastric cancer and intestinal neuroendocrine tumors.
In May, Chimeric said it opened the phase I/II trial of CHM CDH17, or CHM2101, for gastrointestinal cancers at the Nashville, Tennessee-based Sarah Cannon Research Institute (BD: May 22, 2024).
Today, the company said the trial was a two-stage study that would first determine a phase II dose of CHM CDH17 and then evaluate its safety and objective response rate in patients with advanced colorectal cancer, gastric cancer and intestinal neuroendocrine tumors.
Chimeric said it expected to open more trial sites “in the second half of 2024”.
Chimeric chief operating officer Dr Rebecca McQualter said enrolling the first patient was “great progress for this first-in-human study for bowel cancer patients with significant unmet need”.
Chimeric was up 0.2 cents or 10.5 percent to 2.1 cents with 3.2 million shares traded.

IMMUTEP

Immutep says it has “positive feedback” from the US Food and Drug Administration for its phase III trial of efti with Keytruda for non-small cell lung cancer (NSCLC).

In June, Immutep said it would conduct a 750-patient, randomized, double-blind, controlled phase III trial of eftilagimod alpha, or efti, for lung cancer with Keytruda and standard chemotherapy (BD: Jun 3, 2024).

At that time, the company said the trial would evaluate the combination of efti with Keytruda and standard-of-care chemotherapy compared to Keytruda and standard-of-care chemotherapy alone, or placebo (BD: Jun 3, 2024).

Today, the company said the FDA’s feedback from its type C meeting, with recent feedback from Frankfurt, Germany’s Paul-Ehrlich Institut and the Spanish Agency for Medicines and Health Products, concluded the preparatory regulatory interactions for the design of the registrational trial.

Immutep said the FDA feedback was “a significant step forward” to develop an effective treatment for non-squamous and squamous first-line NSCLC patients with have high, low, or no programmed death ligand-1 expression and were eligible for anti-PD-1 therapy.

Immutep regulatory and strategy head Christian Mueller said the company was “pleased with the FDA’s feedback as this allows us to successfully conclude our regulatory preparation for the Tacti-004 registrational trial”.

“This represents a key milestone in our late-stage development process for efti, centred on potentially driving a new standard of care globally, in the treatment of non-small cell lung cancer,” Mr Mueller said.

“We hope to achieve this through efti in combination with Keytruda, which has led to strong efficacy data with a favorable safety profile in [first line] NSCLC patients regardless of PD-L1 expression,” Mr Mueller.

Immutep was unchanged at 29.5 cents with 3.3 million shares traded.

RESPIRI HEALTH TECHNOLOGIES

Respiri says it has “firm commitments” to raise $3 million at 3.0 cents a share in a placement to sophisticated and professional investors.

Respiri said the issue price was a 3.4 percent premium to its last closing price of 2.9 cents on July 19, 2024.

The company said the funds would be used for US commercialization, including patient recruitment, as well as its “clinic in cloud” services and “finalizing the risk share capitated contracts” all of which were “critical to achieving the company’s goal of breaking even in cashflow by late 2024”.

Respiri said the placement was “organized by the investor pursuant to the share subscription agreement” and had previously said in a prospectus for the share subscription agreement on June 18, 2024 that the investor was Benjamin Richards.

The company said that it was in discussions with Principal Wealth Group, a party “connected to the investor under the share subscription agreement”, Mr Richards, to raise a further $5 million in a placement at three cents a share.

Separately, Respiri said in its Appendix 4C that receipts from customers for the year to June 30, 2024 was $134,000, it had a three-month cash burn of $1,725,000, with cash and equivalents of $767,000, giving it no quarters cash.

The company said it expected “to continue operating and meet its business objectives using equity raised from its planned US listing and an increase in revenues following the acquisition of Access Telehealth”.

Respiri was unchanged at 2.9 cents.

MTP CONNECT, WESTERN AUSTRALIAN GOVERNMENT

MTP Connect says the Western Australian Government has granted $325,000 in "additional funding" to expand the Western Australian Life Sciences Innovation Hub.
MTP Connect said the funding would allow the hub "to deliver more services and assist start-ups and [small-to-medium enterprises] in finding further investment opportunities and become investment ready".
The Federally-funded industry organization said the Hub was a partnership between MTP Connect, the Western Australia Government and the University of Western Australia and was located at the University's campus in Nedlands, Perth.
MTP Connect chief executive officer Stuart Dignam said that for the last six years the organization "had a strong relationship with the WA Government through the hub's activities ... [and were] united in our commitment to accelerate the growth of the state's life sciences sector and power the creation of new jobs and economic diversification".
"The WA life sciences sector is at an exciting inflection point in its growth and development, as companies are increasingly born and developed locally, rather than relocating elsewhere," Mr Dignam said.

ANTERIS TECHNOLOGIES

Anteris has requested a trading halt pending an announcement "in relation to a proposed capital raising".
Trading will resume on July 24, 2024 or on an earlier announcement.
Anteris last traded at $17.05.

DORSAVI

Dorsavi has requested a trading halt pending an announcement "in relation to a capital raising".
Trading will resume on July 24, 2024, or an earlier announcement.
Dorsavi last traded at 1.3 cents.

LTR PHARMA

LTR Pharma has requested a trading halt pending an announcement "in relation to a proposed capital raise".
Trading will resume on July 24, 2024, or on an earlier announcement.
LTR Pharma last traded at 90 cents.

OPTHEA

Regal Funds Management says it has increased its substantial holding in Opthea from the equivalent of 312,995,827 shares (28.68%) to 404,818,462 shares (32.88%).
Sydney's Regal Funds said that between June 27 and July 5, 2024 it bought 4,424,541 shares for $1,541,467, or 34.8 cents a share, sold those shares for the same price and then on July 17, 2024 bought 91,822,635 shares for $36,729,054, or 40 cents a share.
Last week, Opthea said it had raised $227.31 million at 40.0 cents a share in a placement and one-for-1.22 rights offer (BD: Jun 12, 14, Jul 15, 2024).
Regal Funds said it currently held 381,559,238 Australian shares (30.99%) and 2,907,403 American depository shares (1.89%), with each ADS equivalent to eight Australian shares.
Opthea was unchanged at 38 cents with 1.2 million shares traded.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra director Dr Nicholas Hartnell says he has increased his substantial share-holding from 75,555,842 shares (63.17%) to 77,886,881 shares (65.12%).

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.