Biotech Daily

Wednesday April 27, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: STARPHARMA UP 5%; NEXT SCIENCE DOWN 6%**

*** PROTAGONIST FALLS 50% ON PN-943 ULCERATIVE COLITIS MISS**

*** ACTINOGEN XANAMIA PHASE Ib PART A TRIAL MEETS ENDPOINTS**

*** ALTERITY: UK MHRA OKAYS ATH434 MSA TRIAL**

*** WOKE, MACQUARIE UNI TRIAL PSILOCYBIN FOR DEPRESSION**

*** LBT: 5 APAS INDEPENDENCE STUDIES AT LISBON CONFERENCE**

*** NUHEARA 16% OPPOSE EGM CONSOLIDATION**

*** ANTERIS 460k DIRECTORS' OPTIONS AGM**

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*** RESPIRI REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** CARDIEX APPOINTS LESA MUSATTO US DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.78 percent on Wednesday April 27, 2022, with the ASX200 down 56.8 points to 7,261.2 points. Five of the Biotech Daily Top 40 stocks were up, 23 fell, 11 traded unchanged and one was untraded. All three Big Caps fell.

Starpharma was the best of the five, up four cents or five percent to 84 cents, with 121,066 shares traded. Antisense and Atomo climbed more than four percent; Dimerix was up 3.6 percent; with Neuren up 0.3 percent.

Yesterday's 7.1 percent best, Next Science, led the falls, down 5.5 cents or 6.1 percent to 84.5 cents, with 31,070 shares traded.

Alcidion and Mesoblast lost more than five percent; Emvision, Genetic Signatures, Imugene and Polynovo fell more than four percent; Orthocell, Paradigm, Proteomics and Uscom were down more than three percent; Avita, Kazia, Micro-X, Resmed and Volpara shed more than two percent; Actinogen, Clinuvel, CSL, Cynata and Immutep were down one percent or more; with Cochlear, Cyclopharm, Medical Developments, Opthea and Pro Medicus down by less than one percent.

PROTAGONIST

Queensland's Protagonist fell 49.95 percent to $US9.41 ($A13.12) on news that its 159-patient phase II trial of PN-943 for ulcerative colitis missed its primary endpoint.

Protagonist has traded as high as $US50.54 in July 2021, but has had several recent set-backs, including a US Food and Drug Administration hold on its rusfertide or PTG-300 for cancer, which was later lifted (BD: Sep 20, Oct 13, 2021).

Last week, Protagonist said the FDA intended to rescind breakthrough status for rusfertide for poly-cythaemia vera due to "observed malignancies" (BD: Apr 19, 2022).

Today, the company said the randomized, double-blinded, placebo-controlled, 'Ideal' phase II study missed its primary endpoint.

Protagonist said the study, to evaluate the safety and efficacy of PN-943 in patients with moderate-to-severe active ulcerative colitis found the 450mg dose "did not meet the … primary endpoint" of remission at week-12 compared to placebo; but the 150mg dose achieved a placebo versus treatment delta [or difference] of 13 percent ($p = 0.08$) in the modified intent-to-treat group, and a delta of 16 percent ($p = 0.04$) in the bio-naïve group.

The company said that the 150mg data "showed strong concordance across multiple parameters including statistically significant histological remission and endoscopic improvement".

Protagonist said that patients were randomized to either twice daily doses of 450mg or 150mg PN-943, or placebo, for 12 weeks and analyzed for outcome measures.

The company said that PN-943 achieved 27.5 percent clinical remission, with "strong concordance across all key proxies including histological and endoscopic endpoints for efficacy, in the twice daily 150mg dose arm".

The company said that plans were underway for a registrational phase III study using a twice daily 150mg dose of PN-943, pending regulatory guidance.

Protagonist chief executive officer Dr Dinesh Patel said the company was "delighted with the strength of the results from the Ideal study and look forward to working with the regulatory agencies as we prepare for a phase III registrational program for PN-943 in moderate-to-severe ulcerative colitis".

"Our oral, gut-restricted alpha-4-beta-7-integrin antagonist agent PN-943 has demonstrated clinical efficacy on par with the approved injectable antibody drug working through the same biological target," Dr Patel said.

"We believe the results of the Ideal study may be paradigm-shifting and of broad scientific relevance in understanding [irritable bowel disease] pathogenesis and gut-restricted drug development via intervention of the integrin-MAdCAM pathway," Dr Patel said.

"Based on its convenience of oral administration and the favorable efficacy and safety results observed to date, we believe that PN-943 has the potential to become a first-in-class, foundational oral medicine for individuals living with moderate-to-severe ulcerative colitis," Dr Patel said.

Protagonist head of gastro-enterology Dr Scott Plevy said the study assessed two doses of PN-943, 150mg and 450mg twice daily, and showed "a very clear and consistent treatment effect at the lower 150mg [twice daily] dose across key endpoints".

"The dose response demonstrated by this study is consistent with several other modalities in the integrin pathway," Dr Plevy said. "The findings in the lower-dose arm provide consistent evidence of clinical efficacy and safety, and clear direction on the dosing regimen for the phase III registrational program."

In 2016, the University of Queensland spin-out Protagonist said it raised $US90 million ($A117.1 million) and listed on the Nasdaq to develop peptide drugs (BD: Aug 12, 2016).

On the Nasdaq last night, Protagonist fell $US9.39 or 49.95 percent to $US9.41 ($A13.12) with 8.0 million shares traded.

ACTINOGEN MEDICAL

Actinogen says its 107 healthy, cognitively normal, older adult phase Ib study of Xanamem for cognition met its primary safety, pharmacodynamic and efficacy endpoints.
Actinogen said the dose-ranging trial of adults aged 50 years to 80 years received 10mg or 5mg doses of Xanamem or placebo for six weeks and assessed cognitive abilities.
The company said that the study confirmed "Xanamem's ability to rapidly enhance attention and working memory, confirming prior findings with a 20mg dose" and the results were "consistent with a prior positron emission tomography (PET) dose-ranging study that indicated dose levels of 10mg daily or lower [were] likely to be effective".
Actinogen said the efficacy endpoint was defined as clinically significant "effect size" of Xanamem treatment on cognitive ability versus placebo, measured with validated tests of attention and working memory using the Cogstate cognition test.
The company said that daily Xanamem doses of 10mg and 5mg showed "a good safety profile and full pharmaco-dynamic activity supportive of continued development".
Actinogen chief medical officer Prof Paul Rolan said the results "consolidate demonstration of the positive effects of Xanamem on cognition, with excellent safety".
Prof Rolan said the results were "a major boost to our Alzheimer's disease program and open the door to Xanamem's evaluation in other chronic neurological and psychiatric diseases where poor cognition is a significant complaint".
Actinogen managing-director Dr Steven Gourlay said the company was "excited to see the positive clinical data for these lower Xanamem dose levels".
"Xanamem has the potential to be a novel daily oral therapy for Alzheimer's disease and other conditions that could be safely used alone or in combination with other therapies," Dr Gourlay said. "Our future clinical trials will evaluate if Xanamem can make a significant improvement in the lives of patients and their families living with serious neurological and psychiatric conditions."
Actinogen said the trial's efficacy objective was to estimate "effect size", especially for attention tests and confirm clinically significant effects, with the formal primary efficacy endpoint one or more cognitive domains showing an "effect size" of more than 0.3.
The company said that the primary efficacy endpoint was met at the end of treatment with 5mg, where the identification test of visual attention had a statistically significant effect size of 0.32 ($p < 0.05$).
Actinogen said it would review the results as it finalized the design of its next trial.
Actinogen fell 0.1 cents or 1.05 percent to 9.4 cents with 8.5 million shares traded.

ALTERITY THERAPEUTICS

Alterity says the UK Medicines & Healthcare Products Regulatory Agency has approved its phase II trial of ATH434 for multiple system atrophy.
Last year, Alterity said it was planning the 60-patient trial to be held in Australia, New Zealand, Europe and the US (BD: Dec 14, 2021).
Today, the company said the trial was a 12-month, randomized, double-blind, placebo-controlled investigation of ATH434 in patients in the early stages of the disease, which was a "rare and highly debilitating Parkinsonian disorder" with efficacy, safety, and pharmaco-kinetics the primary endpoints.
Alterity chief executive officer Dr David Stamler said that approval by the UK MHRA was "another important step forward for our ATH434 clinical development program".
Dr Stamler said the company expected to open its first phase II clinical trial site in New Zealand by July 2022.
Alterity was unchanged at 1.9 cents with 9.96 million shares traded.

WOKE PHARMACEUTICALS

Woke says Macquarie University will conduct a 266-patient, six-week, phase II trial of its WP001 low-dose 'magic mushroom' derived psilocybin for moderate depression.
Woke said the randomized, double-blind placebo-controlled trial would be in three parts: safety and efficacy, an evaluation of the efficacy of WP001 versus placebo, and a third, open-label extension, allowing participants in the placebo arm to access WP001.
The company said the primary outcome would be the Grid-Hamilton depression rating scale, with secondary outcomes including psychological measures, neuro-physiological measures and biomarkers.
Woke said patients would receive 11 doses over the course of the trial, which was expected to start enrolment in by the end of 2022 following ethics approval and completion of good manufacturing practice batch of WP001.
Woke said it would provide the WP001 clinical material, placebo and required funding, and retain exclusive rights to the study results, which would inform further development, including the design of a definitive phase III trial.
The company said the principal investigator for the trial would be Macquarie University's Dr Vince Polito.
Woke chief executive officer Nick Woolf said the trial was "ground-breaking on several fronts".
"It is the largest randomized trial of a psychedelic micro-dose … [and] combines a novel suite of secondary measures including neuro-imaging and biomarker analyses," he said.
Woke said the results were expected in 2024.
Woke is a private company.

LBT INNOVATIONS

LBT says five studies featuring its automated plate assessment system (APAS) Independence have been presented in Lisbon, Portugal from April 23 to 26, 2022.
LBT said the studies presented at the European Congress of Clinical Microbiology and Infectious Diseases came from France, Germany, the UK and the US.
In 2019, the company said it had sold its first APAS Independence to the Cologne, Germany-based Wisplinghoff Laboratories (BD: Oct 21, 2019).
Today, LBT said it would present a study conducted by Wisplinghoff Laboratories, titled 'Artificial intelligence-assisted antimicrobial susceptibility testing: automated imaging and the use of artificial intelligence for interpretation of disc-diffusion AST according to EUCAST, including rapid antimicrobial susceptibility testing'.
The company said the study compared the APAS Independence with manual plate reading by two experienced microbiologists at six-hours and 18-hours.
LBT said two studies, titled 'Evaluation of the APAS Independence with Thermo Fisher Brilliance MRSA Analysis Module at NHS William Harvey Hospital', and 'Artificial Intelligence and Diagnostic Microbiology: Comparison the APAS Independence using Thermo Fisher UTI Brilliance Clarity Analysis Module with routine Plate-in-hand using CLED at NHS William Harvey Hospital', were conducted by the Kent, England-based William Harvey Hospital.
LBT said a study, titled 'Comparison of the APAS Independence Automated Plate Reader System with manual Standard-of-Care for processing urine culture specimens', was conducted by the University of California San Diego.
The company said a study, titled 'Streamlining urine processing with modular automation: a French experience with CPSE media', was conducted by Dijon's Bio Med 21.
LBT fell 0.1 cents or 1.25 percent to 7.9 cents.

NUHEARA

Nuheara says all resolutions to its extraordinary general meeting were passed but with up to 16.21 percent opposition to its proposed 20-to-one consolidation.
In March, Nuheara said the meeting would vote on a 20-to-one consolidation and the ratification of the issue of shares and options to investors (BD: Mar 25, 2022).
Today, the company said the consolidation was passed with 303,840,108 votes (83.79%) in favor and 58,766,942 votes (16.21%) against.
Nuheara said that six resolutions relating to share and options issues faced more than 15 percent dissent with placement shares opposed by more than 11.7 percent.
According to the company's most recent filing, Nuheara had 2,005,624,037 shares on offer, meaning the opposition to the consolidation amounted to 2.93 percent of the company, not sufficient to requisition extraordinary general meetings.
Nuheara fell 0.2 cents or 13.3 percent to 1.3 cents with 4.8 million shares traded.

ANTERIS TECHNOLOGIES

Anteris says its annual general meeting will vote on the issue of 460,000 options to managing-director Wayne Paterson and three directors.
Anteris said it would seek to issue Mr Paterson with 300,000 options, of which it said 41,222, worth $344,410, were part of his 2021 remuneration package, and exercisable at $9.48 up to five years from grant.
The company said that a further 258,778 further options to Mr Paterson as part of his 2022 package, as well as 80,000 options to John Seaberg and 40,000 options each to Stephen Denaro and Wenyi Gu would be exercisable at $12.96 within five years from grant, and vest in three equal annual tranches.
Anteris said that shareholders would vote on the adoption of the remuneration report, the re-election of Mr Seaberg as a director, the approval of a 10 percent placement facility, the ratification of a prior issue of options to Evolution Capital, the ratification of a prior issue of shares to Perceptive Life Sciences Master Fund, approval of an employee incentive plan, and the appointment of an auditor.
The meeting will be held through a webcast and at Radisson Blu Plaza Hotel, 27 O'Connell Street, Sydney on May 25, 2022 at 3pm (AEST).
Anteris was unchanged at $17.40.

ONCOSIL MEDICAL

Oncosil has requested a trading halt "pending the release of an announcement by the company about a potential capital raising".
Trading will resume on April 29, 2022, or on an earlier announcement.
Oncosil last traded at 6.1 cents.

RESPIRI

Respiri has requested a trading halt pending an announcement "in relation to a capital raise".
Trading will resume on April 29, 2022, or on an earlier announcement.
Respiri last traded at 5.1 cents.

CARDIEX

Cardiex says it has appointed Lesa Musatto as a San Francisco, California-based non-executive director.

Cardiex said Ms Musatto previously held executive and marketing roles for Levi Strauss, Gap, Safeway and Auction Technology Group.

Cardiex fell three cents or 8.6 percent to 32 cents.