Biotech Daily

Thursday March 22, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PRIMA UP 9%, LIVING CELL DOWN 6%**

*** EUROPE, US APPROVE AVEXA 300-PATIENT ATC PHASE III HIV TRIAL**

*** STARPHARMA BEGINS PHASE III VIVAGEL VAGINOSIS TRIALS**

*** VENTUS IPO TO RAISE $40m FOR SLEEP APNEOA NASAL PLUGS**

*** GI DYNAMICS ANGEL INVESTOR BLOCK SHARE TRADE**

*** M&G GROUP BUYS 3m MORE STARPHARMA SHARES**

*** ORBIS REDUCES TO 13% OF PHOSPHAGENICS**

*** BIO-MELBOURNE APRIL BREAKFAST: PROF IAN CHUBB ON FUNDING**

MARKET REPORT

The Australian stock market climbed 0.46 percent on Thursday March 22, 2012, with the S&P ASX 200 up 19.4 points to 4273.7 points.

Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and seven were untraded.

Prima was the best, up two cents or 9.1 percent to 24 cents, with 7.4 million shares traded.

Genetic Technologies climbed 8.25 percent; Benitec and Sunshine Heart were up more than five percent; Acrux was up 4.9 percent; Nanosonics and Optiscan were up more than three percent; Phosphagenics rose 2.3 percent; Alchemia, Clinuvel, Impedimed and Mesoblast were up more than one percent; with CSL up 0.06 percent.

Living Cell led the falls, down half a cent or 5.6 percent to 8.5 cents with 166,830 shares traded.

Allied Health, Neuren, Prana, Psivida and QRX lost more than three percent; Avita, Bionomics, Pharmaxis, Reva and Starpharma shed more than two percent; Viralytics was down 1.35 percent; with Cochlear, Resmed, Sirtex and Universal Biosensors down by less than one percent.

AVEXA

Avexa says it expects to conduct a relatively short 300-patient phase III trial of Apricitabine (ATC) for European and US regulatory approval.

Avexa said that following two meetings, the European Medicines Agency response was "very similar to that received by the company after meeting with the US Food and Drug Administration".

Last year, Avexa said it had found a regulatory pathway with the FDA for ATC and in a presentation to its annual meeting chief executive officer and chief scientific officer Dr Jonathan Coates detailed the FDA-approved 300-patient monotherapy trial against 3TC, which he co-invented, or placebo (BD: Mar 28, 2011).

Today, Dr Coates told Biotech Daily the FDA trial included "conditional approval" at 14 days pending defined, but undisclosed, viral load reductions, at which time ATC could be sold in the US.

Dr Coates said that the FDA conditions included an undisclosed percentage of patients, with less than 200 copies of virus per millilitre at 24 weeks.

Dr Coates said that the European trial design was broadly in line with the FDA protocols and there would be a single trial of 300-patients for both jurisdictions.

Dr Coates said the trial would cost "about $50 million" and the company had about $15 million in cash and cash equivalents.

"The EMA response was broadly in line with that of the FDA who agreed that a trial with a 14 day end-point would be acceptable," Dr Coates said.

"This shortened time, and with a viral load drop as a measure, lowers the costs and risks," Dr Coates said.

"They also agreed with a much smaller number of patients than previously required [and] the new trial is in the order of 300 patients," Dr Coates said.

"This reduces the cost considerably from the thousand patient 12 month paradigm previously required," Dr Coates said.

Avexa closed its previous 1000-patient at 200-patients in 2009, when 24-week data showed no significant difference in efficacy to 3TC (BD: Oct 2, 2009; Nov 23, 2011).

Previous 96-week data showed ATC benefit for salvage patients (BD: Mar 16, 2009).

Dr Coates said that the FDA would accept data from the previous trials to support the application.

In a media release Dr Coates said that "an expedited pathway for approval of ATC has now been clarified with both the FDA and EMA, which together regulate the approval of drugs in the world's two largest pharmaceutical markets".

"Importantly, regulatory authorities in many other countries typically follow the requirements of one or both of these two key authorities," Dr Coates said.

Avexa said that ATC was well-positioned for an expedited and less costly path to approval in the world's two largest HIV drug markets.

The company said that together with the recent patents filed, ATC's phase III clinical development and eventual commercial value had become clearer (BD: Nov 23, 2011).

Avexa chairman Iain Kirkwood said the company was "very pleased to receive this positive response from a second major regulatory body".

"Avexa continues to improve ATC's commercial potential, underlined by the two patent applications filed late last year," Mr Kirkwood said.

"We continue to evaluate and implement the best strategy to get ATC to market," Mr Kirkwood said.

"This is a key objective as we remain convinced that the potential sales for ATC are likely to be substantial," Mr Kirkwood said.

Avexa was up 0.9 cents or 31.0 percent to 3.8 cents with 27 million shares traded.

STARPHARMA

Starpharma says it has begun two concurrent pivotal phase III clinical trials of Vivagel for the treatment of bacterial vaginosis.

Starpharma chief executive officer Dr Jackie Fairley told Biotech Daily that Vivagel was one of the first Australian discovered and developed new chemical entities to be taken to phase III registration trials by the discovering company.

Dr Fairley said the original dendrimer technology was spun-out from the Commonwealth Scientific and Industrial Research Organisation into Starpharma which discovered the new chemical entity and developed the compound.

Dr Fairley said the two identical US Food and Drug Administration required trials were fully funded by her company.

Starpharma said that about 30 sites, primarily in the US, would be involved in the two trials, each enrolling about 220 participants, with results expected before the end of 2012.

Last year Starpharma said that the phase III trials would have a primary endpoint of clinical cure, as assessed by resolution of symptoms and other standard clinical criteria measured against a placebo gel (BD: Oct 10, 2011).

The company said a second indication in phase II trials was the prevention of bacterial vaginosis in women with a prior history of disease recurrence (BD: Aug 15, 2011).

Starpharma said the phase III trials would complete the development program for Vivagel for the treatment of bacterial vaginosis and following the results, it expected to prepare and submit a new drug application to the FDA, concurrently with partnering discussions for the marketing rights of Vivagel for the treatment of bacterial vaginosis.

Starpharma said the FDA agreed to the trials' special protocol assessment submission, approving the phase III trials' design, clinical endpoints and statistical analyses.

The company said the trials were designed to confirm the results of the phase II trials, which "demonstrated that Vivagel was safe and effective for the treatment of [bacterial vaginosis]" demonstrating ($p = 0.0002$) significant efficacy.

Dr Fairley said the beginning of the pivotal phase III studies was "a landmark achievement in the development of Vivagel".

"The use of Vivagel for the management of [bacterial vaginosis] is an exciting prospect, with the potential to improve the quality of life for many millions of women around the world," Dr Fairley said. "The fact that Vivagel is not a conventional antibiotic and also has the potential for use in the prevention of recurrent [bacterial vaginosis] will represent a major advance in the management of this highly problematic condition."

The company said that bacterial vaginosis was the most common vaginal infection and the most common cause of vaginal irritation, discharge and malodor and was particularly prevalent in the US, where it affected one-third of the adult female population, and was implicated in pelvic inflammatory disease, pre-term birth and led to an increased risk of sexually transmitted infections, including HIV.

Starpharma said that the market for topical treatments of bacterial vaginosis was about $300-$350 million, but existing treatments were considered sub-optimal with relatively low cure rates, high rates of recurrence, unpleasant side-effects and high levels of bacterial resistance.

The company said that Vivagel was a non-antibiotic gel that was applied to the vagina with an applicator and was not absorbed into the bloodstream, as antibiotics are, and does not result in the side effects often associated with antibiotics.

Starpharma said that Vivagel had shown a very high level of patient acceptability.

Starpharma said that Vivagel was also being developed for the prevention of sexually transmitted infections and has been licensed as a condom coating to Ansell and Okamoto.

Starpharma fell four cents or 2.4 percent to $1.60.

VENTUS MEDICAL

Ventus Medical hopes to raise $40 million through the issue of shares at 50 cents each to list on the ASX to commercialize its Provent sleep apneoa nasal plug device.
The Belmont California-based Ventus said on its website that the nasal plugs created expiratory positive airway pressure helping to keep compromised airways open during sleep.
Ventus says its device is an alternative to continuous positive airways pressure, typically found in sleep apneoa masks.
The company said that the Provent nasal plugs had US Food and Drug Administration approval.
Ventus' website said the company launched Provent in Australia in October 2011.
Biotech Daily understand that although Inteq and CCZ Equities are involved in the initial public offer, that no prospectus has been lodged and no other details are available.
Biotech Daily understands that the funds are to further commercialize the Provent technology.
For more information go to: http://www.proventtherapy.com.

GI DYNAMICS

GI Dynamics says that several institutions completed an off-market purchase of about $21.75 million of its Australian shares at 87 cents each.
GI Dynamics said that the sale of about 25 million Chess depositary interests (CDIs) at 87 cents was equivalent to $A4.35 per US common share.
The company said that the block trade enabled some pre-ASX listing "angel" shareholders and venture capital shareholders "to attain liquidity for some of their shares and CDIs".
GI Dynamics said there were no sales by the company, the executive team or directors.
The company said the trade was conducted by Bell Potter Securities.
GI said that the sellers included Advanced Technology Ventures, Domain Associates, Polaris Venture Partners and Cutlass Capital and they continued to hold at least a majority of their original shares and CDIs.
In a series of notices GI said that Cutlass reduced its holding from 12,163,876 CDIs to 2,432,774 CDIs with no US shares of common stock, and held 4.28 percent.
The company said that Seedling Enterprises LLC reduced its holding from 11,062,500 CDIs to 2,212,500 CDIs with no US shares, and held 3.90 percent.
GI said that Polaris converted 6,335,480 US shares and increased its holding from 4,838,460 CDIs to 25,075,763 CDIs, reducing from 13.18 percent to 8.83 percent of GI Dynamics and Advanced Technology converted 6,375,480 US shares and increased from 4,869,008 CDIs to 33,638,773 CDIs, reducing from 13.27 percent to 11.84 percent.
GI Dynamics was unchanged at $1.00.

STARPHARMA

M&G Investment Funds has increased its substantial shareholding in Starpharma from 19,490,077 shares (7.01%) to 22,494,398 shares (8.01%).
The London-based M&G companies first acquired18,604,651 shares (6.70%) shares In November 2011 month for $19,999,999 or an average price of $1.075 a share (BD: Nov 24, Dec 13, 2011).
Today the M&G Group said it bought and sold shares between December 12, 2011 and March 20, 2012, with the largest parcel 471,384 shares for $654,054 or an average price of $1.3875 a share.

PHOSPHAGENICS

Orbis Investment Management has further reduced its substantial holding in Phosphagenics from 144,286,354 shares (14.18%) to 133,609,911 shares (13.13%).
Orbis said it sold 10,676,443 shares between March 14 and March 19, 2012 for $2,401,485 or an average price of 22.5 cents each.
Orbis has reduced its Phosphagenics holding by more than four percent since February (BD: Feb 20, Mar 7, 16, 2012).
Phosphagenics was up half a cent or 2.3 percent to 22.5 cents.

BIO-MELBOURNE NETWORK

Australia's chief scientist Prof Ian Chubb will discuss the Federal Government's funding of translational research at the April 3, 2012 Bio-Melbourne Network Bio-Breakfast
The Network said the Federal Government had spent "billions of dollars on research over the past 20 years" through the National Health and Medical Research Council and the Australian Research Council, as well as other programs aimed at maintaining and increasing basic discovery science.
The Network said that Prof Chubb would discuss the escalating priority of translational research in being able to realize the heavy investment in basic research and the role of Government in supporting translational research.
The April, 3 2012, Bio-Breakfast will be held at the Commonwealth Scientific and Industrial Research Organisation premises on the Monash University Campus, Bayview Avenue, Clayton.
Registration is from 7:15am for a presentation at 8am.
For more information go to: http://www.biomelbourne.org/events/view/223.