Biotech Daily

Wednesday June 2, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ANTISENSE UP 7%; NOVOGEN DOWN 53%**

*** NOVOGEN DROPS 57% ON NON-SIGNIFICANT PHASE III CANCER TRIAL**

*** BIOGUIDE BRIEF: NOVOGEN JOINS THE FAILED PHASE III CLUB**

*** AUSTRALIAN STEM CELL CENTRE FUNDS RUN OUT JUNE 2011**

*** EVADO'S ASEAN CLINICAL TRIALS JOINT VENTURE**

MARKET REPORT

The Australian stock market fell 0.73 percent on Wednesday June 2, 2010 with the S&P ASX 200 down 32.1 points to 4381.0 points.

Seven of the Biotech Daily Top 40 stocks were up, 15 fell, 10 traded unchanged and eight were untraded.

Antisense was best, up 0.1 cents or 7.1 percent to 1.5 cents with 300,000 shares traded followed by Heartware up 10 cents or 5.2 percent to $2.02 with 78,085 shares traded.

Avexa climbed 3.3 percent; Circadian rose 2.99 percent; with Cochlear, Resmed and Starpharma up more than one percent.

Novogen led the falls, closing down 21 cents or 53.2 percent at 18.5 cents with 1.6 million shares traded, followed by LBT down 14.5 percent to 7.1 cents with 71,682 shares traded, and Patrys down 14.3 percent to 12 cents with 313,000 shares traded.

Clinuvel lost 6.1 percent; Alchemia and Universal Biosensors were down more than five percent; Cellmid fell 4.8 percent; Chemgenex was down 3.3 percent; Biota, Cellestis, Living Cell, Tissue Therapies and Viralytics shed two percent or more; with Acrux down 1.3 percent.

NOVOGEN

Novogen fell as much as 57.0 percent to 17 cents in early trading following the release of non-significant results for its 142-patient phase III phenoxodiol ovarian cancer trial.

Novogen said the announcement came through its 72 percent US subsidiary Marshall Edwards which licenced phenoxodiol and dosed the first phase III trial patient in 2006.

The company said the trial of oral phenoxodiol in women with recurrent ovarian cancer "determined that the trial did not show a statistically significant improvement in its primary (progression-free survival) or secondary (overall survival) endpoints".

Last year, the trial was closed for recruitment with 142 of the planned 340 patients enrolled to conserve cash (BD: Apr 15, 2009).

The multi-centre, randomized, double-blind trial studied daily phenoxodiol in combination with weekly carboplatin, versus weekly carboplatin with placebo in patients with platinum-resistant or platinum-refractory, late-stage epithelial ovarian, fallopian or primary peritoneal cancer following at least second line platinum therapy.

Marshall Edwards' chief executive officer Dr Daniel Gold said that "owing to the fact that this trial was significantly underpowered due to the small number of patients enrolled, we were disappointed, but not entirely surprised by the final outcome".

"However, we remain confident that our investigational isoflavone platform, including triphendiol, a potentially more potent, second-generation analogue of phenoxodiol, may be of benefit to women with ovarian cancer, particularly when administered intravenously," Dr Gold said.

Dr Gold said that previously reported results of a phase II trial demonstrated a 30 percent response rate (six patients of 20), when testing the activity of intravenous phenoxodiol plus weekly cisplatin in a similar platinum-resistant or refractory patient population, compared to less than one percent (one patient of 142 patients) in the phase III study in which phenoxodiol was administered orally.

Dr Gold said his company remained "excited with the progress of another product candidate in our pipeline, NV-128, a novel isoflavone analogue with a mode of action distinct from both phenoxodiol and triphendiol".

Novogen's director of research Prof Alan Husband told Biotech Daily that the phase II trial indicated up to 12-weeks progression-free advantage with intravenous phenoxodiol.

Prof Husband said it was possible the different routes could have played a part in the different results. He said the two companies would review the impending phase II triphendiol trial and rethink its protocols, including whether the trial should have oral and intravenous arms.

Prof Husband said Novogen retained the isoflavone platform which showed promise in both oncology and inflammatory disease.

The 2006 interim phase II results presented at the Society of Gynecologic Oncology's meeting showed that phenoxodiol restored sensitivity to chemotherapy in some women with ovarian, fallopian tube or primary peritoneal cancers (BD: Mar 30, 2006).

Yale Medical School research fellow Dr Michael Kelly said phenoxodiol resulted in "an encouragingly high proportion of tumors either shrinking or stabilizing with standard drugs, when we know that the tumor is unlikely to respond to those standard drugs alone".

The Yale researchers reported that 74 percent of patients with late-stage, platinum-resistant tumors who received the phenoxodiol and cisplatin showed evidence of a change in tumor growth through tumor shrinkage or no increase in tumor size.

Novogen peaked at $6 in June 2005 and today closed down 21 cents or 53.2 percent at 18.5 cents with 1.6 million shares traded.

Novogen will replaced in the Biotech Daily Top 20 by Sunshine Heart and joins the Second 20.

BIOGUIDE BRIEF: NOVOGEN

Novogen joined a club today that includes Neuren, Progen and Avexa - the club for companies that have taken un-partnered projects into pivotal trials only to see them fail.

Novogen's phenoxodiol didn't just fail, though; it bombed miserably with only one responder out of 142 ovarian cancer patients given the drug. This was despite a 30% response rate in a phase II trial.

It is hard to tell exactly what went wrong in the trial, but suffice to say that all of those companies who looked at licensing Phenoxodiol and chose not to, were right.

The vibe coming from Novogen when they closed the phase III trial in April of last year was not good. The company said the trial was closed for two reasons: one was that the global economic downturn made raising the funds to complete the trial difficult and the second was that a change in the standard-of-care for ovarian cancer patients during the trial period had slowed recruitment rates.

Nonetheless, the spectacular failure of the trial does raise ones eyebrows as to whether Novogen had an idea the trial would fail when they decided to close it early.

When I reviewed Novogen in 2007, I noted that a compound very similar to phenoxodiol, Sanofi Aventis's flavopiridol, had been extensively studied for numerous indications and produced disappointing results, albeit with some success in ovarian cancer patients.

The combined results of phenoxodiol and flavopiridol do not auger well for Novogen's other isoflavonoid-derived compounds and the company should probably review these compounds to see if it is really worth taking them forward.

On the positive side, there is interest in flavopiridol as a treatment for chronic lymphocytic leukaemia and results so far have been encouraging. So, all hope may not be lost for isoflavonoids.

The fortunes of Neuren, Progen, Avexa and, now, Novogen, suggest that investors be wary of companies taking un-partnered compounds into phase III trials.

However, Chemgenex's Omapro, Pharmaxis's Aridol and Peplin's ingenol mebutate should ultimately gain marketing approval after the companies took their respective compounds into phase III trials on their own. It should be noted that some have hit a few fairly nasty speed bumps along the way.

All of this suggests that investors need to pick and choose which companies with un-partnered compounds they follow into phase III.

A few of the questions that should be asked are: has the company previously tried and failed to licence the compound; how solid are the phase II results; what will the phase III program cost and can the company access this level of funding; and has the company appropriately killed under-performing projects in the past?

Marc Sinatra
Analyst

AUSTRALIAN STEM CELL CENTRE

Innovation Minister Senator Kim Carr says the Australian Stem Cell Centre's funding runs out on June 30, 2011.

Senator Carr told Biotech Daily through his media officer that the Australian Stem Cell Centre was funded by the Biotechnology Centre of Excellence Program, "established by the Howard Government in 2002 with an end date of June 30, 2011".

"The centre has received more than $98 million in Australian Government funding since it was established. It was always intended that the centre would become self-sustaining," Senator Carr said.

"The Australian Government has established a $21 million Special Research Initiative in Stem Cell Science to continue building Australia's capacity to conduct stem cell research," Senator Carr said (BD: May 31, 2010).

"This new initiative will ensure that Australian researchers remain at the forefront of this important and rapidly developing field," Senator Carr said.

Senator Carr said the Government also supported stem cell research through other programs administered by the Australian Research Council and the National Health and Medical Research Council.

It is uncertain whether the Centre would be able to or allowed to continue, should it be able to attract other funding.

Asked whether the ASCC could continue should it find funding before June 30, 2010 and spokesman for Senator Carr told Biotech Daily: "This is a matter for the board of the Australian Stem Cell Centre."

Asked whether the Federal Government would consider a final termination or start-up grant, Senator Carr's spokesman said: "There are many Australian Government industry support programs available to companies."

The Centre's chair Prof Graham Macdonald told Biotech Daily that "in theory … the ASCC could continue beyond June 2011 if it were to find funding to do so".

But Prof Macdonald said the Australian Stem Cell Centre was ineligible to apply for funding under the Australian Research Council scheme announced by Senator Carr earlier this week (BD: May 31, 2010).

Prof Macdonald said the National Health and Medical Research Council scheme details were yet to be announced, "so it is unknown as to whether the ASCC would be eligible to apply for funding in that scheme".

"In any case, the quantum of funding from this would be inadequate for the Centre to accomplish its critical aims of professional education, public information, intellectual property advice and international networking, leaving aside the core business of basic research and translation to human health solutions," Prof Macdonald said.

"The ASCC is working to find suitable funding for all of its other important activities including its core laboratories, developing the stem cell skills base and public engagement and communications activities beyond June 2011," Prof Macdonald said.

The Special Research Initiative in Stem Cell Science fund will have $21 million over seven years, compared to the $98 million the Australian Stem Cell Centre received over nine years.

The funds also compare to the Federal Government's contribution to the National Information and Communication Technology Australia total funding of $564.6 million from inception in 2002 and taking it through to 2015, according to NICTA's website.

EVADO

Clinical trial software company Evado says it has a joint venture with the Singapore Clinical Trials Institute and Singapore's Kooprime for Asian trials.

Evado said the venture would "help meet the current and anticipated demand among local and global companies planning investigator-led, drug and device trials in Asia over the next decade".

Evado said its software applications would be used by Singapore Clinical Trials Institute for registry studies, investigator-led studies and clinical trial management.

The Melbourne based company said the joint venture company would be situated at the Biopolis, a high-tech biomedical park built by the Singapore Government.

Evado said its clinical trial applications would be available in Singapore and the Association of South East Asian Nations region as stand-alone versions and as software-as-a-service.

Evado said its software "maps the workflow of subjects from enrollment through to trial completion with the functionality and reliability of the larger systems at a fraction of their cost".

The company said the Singapore Clinical Research Institute assists in the development of human capital and infrastructure as part of the second phase of Singapore's Biomedical Sciences Initiative and was established as a one-stop entity providing expertise, support, scientific leadership and scientific collaborations for the conduct of both investigator initiated and commercially sponsored clinical research studies in Singapore.

Evado said Kooprime was one of the first software companies to provide component-based services to the life sciences industry and had a presence in Singapore, Japan, Malaysia, Thailand, Taiwan, China and India and the US.

Evado is a private company.