Biotech Daily

Thursday January 23, 2014

Daily news on ASX-listed biotechnology companies

* **ASX, BIOTECH DOWN: BENITEC UP 7%, PATRYS DOWN 14%**

*** PATRYS COMPLETES PHASE I/IIa PAT-SM6 MULTIPLE MYELOMA DOSING**

*** STARPHARMA TO BEGIN PHASE I DENDRIMER-DOCETAXEL TRIAL**

*** WOOLCOCK INSTITUTE: 'LF-15 FOR STEROID-RESISTANT ASTHMA'**

*** PERSISTENCY REDUCES BELOW 5% OF LIVING CELL**

MARKET REPORT

The Australian stock market fell 1.07 percent on Thursday January 23, 2014 with the S&P ASX 200 down 56.8 points to 5,263.0 points.

Nine of the Biotech Daily Top 40 stocks were up, 17 fell, 10 traded unchanged and four were untraded.

Benitec was the best for the second day in a row, up 5.5 cents or seven percent to 84.5 cents, with 556,989 shares traded.

Anteo, Neuren and Prana climbed five percent or more; Living Cell was up 4.4 percent; Atcor, Cellmid and Nanosonics rose more than three percent; with Psivida and Resmed up more than one percent.

Patrys led the falls, down 0.7 cents or 13.7 percent to 4.4 cents with 22.6 million shares traded.

Starpharma and Viralytics fell more than seven percent; Acrux, Genetic Technologies and Prima lost more than five percent; Medical Developments fell 4.8 percent; Mesoblast, Oncosil and Reva were down more than three percent; GI Dynamics and QRX shed more than two percent; Clinuvel, Optiscan, Sirtex and Tissue Therapies were down more than one percent; with Bionomics and CSL down by less than one percent.

PATRYS

Patrys says it has treated all 12 patients in its phase I/IIa trial of PAT-SM6 for refractory or relapsed multiple myeloma, meeting the primary endpoint of safety and tolerability.

Patrys said the 12 patients, including those treated at the highest dose level of 6mg/kg/dose, tolerated PAT-SM6 very well, with no drug-related serious adverse events and no dose-limiting toxicities.

In November 2013, Patrys released safety data on 11 evaluable patients ahead of the American Society of Hematology meeting (BD: Nov 29, 2013).

Today the company said that of the 12 treated patients, which included 10 males and two females, with a median age 71 years, all of whom had failed their current therapeutic regimes) four (33%) with end-stage, multi-resistant multiple myeloma showed evidence of stable disease and two of the four were stable for more than 100 days.

Patrys said that patients treated with PAT-SM6 also had a mean time to next therapy of 47 days which was clinically significant.

The company said that a full and detailed analysis of the complete laboratory data would be released before the end of March 2014.

Patrys said that on the basis of the results and the strong preclinical package, Patrys was preparing for the next trial, a combination study of PAT-SM6 and Carfilzomib, to be sponsored by Amgen subsidiary Onyx Pharmaceuticals (BD: Nov 11, 2013).

The company said that “a strong cash position has enabled Patrys to commit to completing the large-scale manufacturing of PAT-SM6 which is required for this planned combination study” expected to cost about $4 million and be completed by the middle of 2014.

Patrys said it would seek approval, from Germany’s Paul-Erhlich Institute to conduct the clinical study at the University of Würzburg under the direction of Prof Hermann Einsele.

The company said it continued to collaborate with a number of groups on a variety of preclinical projects involving PAT-SM6 and expected two or three publications in 2014.

Patrys said it held worldwide rights to PAT-SM6 and on conclusion of the planned combination study expected to partner the drug with a major pharmaceutical or biotechnology company.

The company said that in 2014 it expected to secure new research collaborations to escalate the rate and quality of data generation from early pre-clinical anti-bodies.

Patrys said that discussions were ongoing and details would be provided later in 2014, but the company expected to spend about $500,000 on the early-stage program.

Patrys chief executive officer Dr Marie Roskrow said that “after a very successful 2013, in which we hit all of our program milestones and raised a significant amount of new capital, we are now looking forward to an even better 2014”.

“Our lead asset PAT-SM6 performed excellently in the recently-completed clinical trial and 2014 will see this program move forward significantly, creating value for our shareholders,” Dr Roskrow said.

“This year we are in a position to also advance PAT-LM1 and a couple of other earlier-stage assets,” Dr Roskrow said.

“Moving multiple programs forward in parallel is critical for us both to create shareholder value and to diversify risk,” Dr Roskrow said.

“The data coming out of these program look very exciting and we look forward to reporting more as we progress through the year,” Dr Roskrow said. “Presentation and publication of data is very important and we will be focussing considerable effort in this area this year.”

Patrys fell 0.7 cents or 13.7 percent to 4.4 cents with 22.6 million shares traded.

STARPHARMA

Starpharma says it is ready to begin a 30-patient Australian phase I dose-escalation trial of dendrimer-enhanced docetaxel for solid tumors.

Starpharma said its dendrimer-enhanced docetaxel or DEP-docetaxel was a new formulation of the docetaxel chemotherapy marketed as Taxotere.

The company said the trial would be held at the Nucleus Network facility at Melbourne's Alfred Hospital, with plans to add one or two additional sites.

Starpharma said the primary objective was to establish the maximum tolerated dose and dose limiting toxicities of dendrimer-docetaxel, dosed intravenously once every three weeks.

The company said that the secondary objective is to identify the safety, pharmacokinetic and tolerability profile of DEP-docetaxel in patients with advanced cancer and the key outcomes would be to define a recommended dose for future studies as well as to explore preliminary anti-tumor efficacy of the product.

Starpharma said that preclinical studies showed a significantly superior anti-cancer effectiveness of dendrimer-docetaxel compared to Taxotere across a range of cancer types including breast, prostate, lung and ovarian cancer and the dendrimer-enhanced docetaxel exhibited a lack of the severe toxicity neutropenia, the most important dose-limiting side effect of Taxotere.

Starpharma said its dendrimer technology also improved the water solubility and tissue targeting of docetaxel meaning that unlike other marketed formulations of docetaxel, its DEP-docetaxel was detergent-free, delivering a number of potential patient tolerability and safety advantages compared to other formulations.

Starpharma chief executive Dr Jackie Fairley said the trial of DEP-docetaxel was "a key development milestone for this product and follows very strong preclinical results, which have included both improved efficacy and the reduction in important dose limiting side effects".

"The multiple, clinically significant benefits of Starpharma's DEP-docetaxel will place the product in a very compelling competitive position," Dr Fairley said.

"In addition, findings from this trial have potential flow-on benefit for Starpharma's dendrimer platform more broadly, particularly in oncology," said Dr Fairley.

The company said that DEP-docetaxel was the first clinical candidate using its dendrimer technology.

Starpharma said the study would employ a variety of imaging techniques and specific investigations aimed at exploring anti-tumor efficacy including computed tomography scans and bone scans, as well as tumor markers.

The company said that Nucleus Network medical director and oncologist Dr Jason Lickliter had been appointed as the principal investigator.

Starpharma said that its dendrimer-based drug delivery technology had been used to reformulate and improve a number of marketed cancer drugs including docetaxel, oxaliplatin and doxorubicin and preclinical studies of the dendrimer-enhanced versions had shown these reformulated versions to be superior to the commercially available formulation, often in multiple ways including improved efficacy, reduced toxicity and lower side effects.

The company said it had several partnered programs with leading pharmaceutical companies, including in oncology.

Starpharma said that docetaxel was a leading chemotherapy drug used to treat a wide range of solid tumors including breast, lung and prostate and marketed by Sanofi Aventis as Taxotere generated sales of more than $US3 billion in 2010.

Starpharma fell 5.5 cents or 7.5 percent to 67.5 cents with 1.3 million shares traded.

WOOLCOCK INSTITUTE OF MEDICAL RESEARCH

Sydney's Woolcock Institute of Medical Research says the LF-15 fragment or peptide of the large molecule tumstatin could be effective in treating steroid-resistant asthma.

The Woolcock Institute was formerly known as the Institute of Respiratory Medicine based at Sydney's Royal Prince Alfred Hospital but was named after founder Prof Ann Woolcock after her death in 2001 and is based in Glebe.

The Institute said that clee biologist Dr Brian Oliver led the work on LF-15 whih was trialed on asthmatic mice and on human airway tissue grown in a petri dish.

The article, entitled 'LF-15 & T7, Synthetic Peptides Derived from Tumstatin, Attenuate Aspects of Airway Remodelling in a Murine Model of Chronic OVA-Induced Allergic Airway Disease' was published by the Public Library of Science and an abstract is at: http://ww.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0085655.

"Excitingly, we were able to show the peptide reduced airway hyperactivity and inflammation, markers of asthma, in both the lab mice and in human tissue," Dr Oliver said.

"And we were able to do so with a totally new approach that reduces inflammation by stopping new blood vessels from forming, a very different mechanism when compared to traditional anti-inflammatory drugs," Dr Oliver said.

"That makes our discovery a potentially new and exciting treatment alternative," Dr Oliver said.

The Institute said that asthma affected 10 percent of Australians, with sufferers experiencing episodes of wheezing, breathlessness and chest tightness due to widespread narrowing of the airways and one in 10 asthmatics were steroid-resistant meaning the common steroid-based medications did not work for them and those patients accounted for about 90 percent of asthma health care expenditure.

The Woolcock Institute said the study was a collaboration with the University of Sydney and the University of Newcastle.

The Institute said that $655 million was spent on asthma in Australia in 2008-'09, with 37,830 Australians hospitalized by asthma in 2010 and 416 people dying from the condition

LIVING CELL TECHNOLOGIES

Persistency Private Equity has reduced its substantial holding in Living Cell from 22,037,675 shares (6.17%) to 17,792,675 shares (4.98%).

Persistency said it sold 745,000 shares for 9.0 cents a share on January 22, 2014 and between December 5, 2013 and January 21, 2013 it sold 3,500,000 shares at "various price levels".

Last year, the Gibraltar-based Persistency has reduced its Living Cell holding from 25,610,891 shares (7.17%) to 22,037,675 shares (6.17%) selling 130,000 shares for 9.9 cents a share on December 5, 2013 and between January 15, 2009 and December 5, 2103 it sold 3,573,216 at "various price levels" (BD: Dec 9, 2013).

Living Cell was up 0.4 cents or 4.4 percent to 9.4 cents.