Biotech Daily

Wednesday April 12, 2017

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: IDT UP 20%, COMPUMEDICS DOWN 7%**

*** ONJI: INHIBITING HCK REDUCES GASTRIC CANCER IN MICE**

*** MEDICAL DEVELOPMENTS SIGNS PENTHROX RUSSIA DISTRIBUTOR**

*** ANSELL LAUNCHES STARPHARMA VIVAGEL CONDOM IN CANADA**

*** CSL: 'WE WILL DEFEND CSL830 AGAINST SHIRE PATENT CLAIM'**

*** ALLEGRA RIGHTS ISSUE RAISES $1.2m**

*** IDT MANUFACTURING 2nd BATCH OF TEMOZOLOMIDE**

*** ANTEO TERMINATES $9m BERGEN DRAW-DOWN EQUITY FACILITY**

*** CYNATA APPLIES FOR STEM CELL FOR CANCER PATENT**

*** CLINUVEL, GERMAN INSURERS AGREE UNIFORM PRICE**

*** RESPIRI CLASS IIa CE MARK FOR AIRSONEA AT-HOME**

MARKET REPORT

The Australian stock market edged up 0.08 percent on Wednesday April 12, 2017 with the ASX200 up 4.7 points to 5,934.0 points. Sixteen of the Biotech Daily Top 40 stocks were up, 11 fell, 11 traded unchanged and two were untraded.

IDT was the best from a depressed base, up 2.5 cents or 20 percent to 15 cents with 1.3 million shares traded.

Dimerix climbed 14.3 percent; Impedimed and Orthocell improved more than four percent; Living Cell was up 3.7 percent; Benitec, Clinuvel, Medical Developments and Neuren rose more than two percent; Acrux, Bionomics, Factor Therapeutics, ITL and Universal Biosensors were up more than one percent; with Nanosonics and Reva up by less than one percent.

Compumedics led the falls, down 3.5 cents or 7.1 percent to 45.5 cents with 42,580 shares traded. Ellex and Opthea fell more than five percent; Oncosil lost 4.2 percent; Admedus and Cyclopharm were down more than three percent; Osprey shed 2.1 percent; Actinogen, Mesoblast and Sirtex shed more than one percent; with Cochlear, CSL and Pro Medicus down by less than one percent.

OLIVIA NEWTON-JOHN CANCER RESEARCH INSTITUTE

The Olivia Newton-John Institute says that inhibiting the haematopoietic cell kinase (HCK) protein can reduce human gastro-intestinal tumors in mice.

A media release from the Heidelberg, Melbourne-based Institute said that the HCK protein suppressed the growth of established gastrointestinal tumors and reduced the emergence of new cancers.

The Olivia Newton-John Institute said that gastro-intestinal cancers affecting the stomach and bowel were among the most common causes of cancer death, affecting more than 15,000 Australians each year.

Olivia Newton-John Institute scientific director Prof Matthias Ernst said that HCK had a powerful role in cancer development because of its effect on immune system macrophages.

“We have known for a long time that in non-cancer situations macrophages have two major roles;” Prof Ernst said. “These cells can behave like garbage collectors when they remove unwanted debris or damaged cells, or they can behave like nurses to help at sites of injury and wounding.”

“What we’ve now discovered is the more HCK activity a macrophage has, the more it nurtures cancer cell growth and survival,” Prof Ernst said. “The macrophage becomes a wound healer rather than a garbage collector that cleans up the cancer cells.”

The Institute said that the researchers found that inhibiting HCK using a small drug-like molecule reduced the growth of bowel and gastric cancers.

The research article, entitled ‘Inhibition of Hematopoietic Cell Kinase Activity Suppresses Myeloid Cell-Mediated Colon Cancer Progression’ was published in Cancer Cell with an abstract at: http://www.cell.com/cancer-cell/pdf/S1535-6108(17)30102-2.pdf.

The abstract said that abundant HCK in tumor leukocytes of human colon cancer correlated with poor survival, excessive myeloid HCK activity resulted in alternative macrophage polarization, myeloid HCK promoted colon tumorigenesis associated with increased [signal transducer and activator of transcription 3 (Stat3)] activity and “ablation of HCK or its therapeutic inhibition limits colon cancer xenograft growth”.

Prof Ernst said that drugs that modified the behavior of macrophages were showing promise as a treatment for solid tumors.

“Our discovery could potentially offer a new and complementary approach to chemotherapy and immunotherapy as options for treating gastrointestinal cancers,” Prof Ernst said. “Because kinases are among the preferred molecules for therapeutic inhibition by drugs, HCK is likely to become a target for the development of a new drug.”

The Institute said that a collaboration with the Cancer Therapeutics Cooperative Research Centre had begun a program to develop new drugs to block HCK.

Olivia Newton-John Cancer Research Centre head of medical oncology Dr Niall Tebbutt said the research presented an “important insight” into future treatment approaches for gastro-intestinal cancers.

“Immunotherapy has been much spoken about as a new approach for treating advanced cancer and has shown impressive results in a number of cancers including in melanoma and lung cancer,” Dr Tebbutt said. “Yet unfortunately, bowel cancer is generally resistant to conventional immunotherapy treatment.”

“This research may help us to understand why bowel cancer is so resistant to immunotherapy but, more importantly, it provides a new approach to possibly overcome this resistance through inhibition of HCK,” Dr Tebbutt said. “Future clinical trials of this approach in patients with advanced bowel cancer are worth pursuing.”

The research was supported by the National Health and Medical Research Council, Ludwig Cancer Research, La Trobe University and the Victorian State Government.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it has signed the Moscow-based JSC Lancet to distribute its inhaled methoxyflurane analgesic Penthrox in Russia.
Medical Developments said the agreement included milestone payments of $2.3 million.
The company said that Lancet was “one of Russia’s leading and fastest growing pharmaceutical companies” and acted as Russian distributors for Novartis, Glaxosmithkline, Pfizer, Bayer, Astrazeneca, Teva, Roche and others and had achieved Russian Ministry of Health approval for a number pharmaceutical products.
Medical Developments said that as part of the agreement Lancet would pay the costs of clinical trials, registration and approval of Penthrox in Russia.
The company said that Lancet’s estimate of the acute trauma pain market was that Penthrox sales could reach two million units a year over time in Russia.
Medical Developments chief executive officer John Sharman said that Russia had 143 million people and was a significant market.
Lancet managing-director Anton Zybin said that his company was expert in the Russian regulatory process “and we believe Penthrox can be the market leader in the acute pain market”.
Medical Developments was up 10 cents or two percent to $5.05.

STARPHARMA HOLDINGS

Starpharma says that its Vivagel condom has been launched in Canada by Ansell under the Lifestyles Dual Protect brand.
Starpharma said that the condoms had the Vivagel brand on the packaging and it would receive royalties based on sales.
The company said that it was “the only condom of its type, providing barrier protection and incorporating the proprietary anti-viral compound, astodrimer sodium (SPL7013, Vivagel) in the condom lubricant … proven in laboratory studies to inactivate HIV, herpes simplex virus and human papillomavirus”.
Starpharma chief executive officer Dr Jackie Fairley said she was “delighted to see Lifestyles Dual Protect with Vivagel launched in the North American market, a major commercial milestone for the product, and to be working with Ansell, one of the world’s leading protection companies”.
Starpharma was unchanged at 66.5 cents.

CSL

CSL says that the Dublin, Ireland-based Shire Viropharma has filed a complaint in the US District Court for the District of Delaware alleging a patent infringement.
CSL said the alleged infringement related to a newly-granted US patent for a method of treating hereditary angio-oedema by subcutaneously administering C1-esterase inhibitor.
The company said it was “highly confident that CSL830 does not infringe any valid claim of the Shire Viropharma patent and will vigorously defend against the claims”.
CSL said that in August 2016, the US Food and Drug Administration accepted for review its biologics licence application for CSL830, a low-volume subcutaneous C1- esterase inhibitor (human) replacement therapy for the prevention of hereditary angio-oedema attacks, the product of independent research and development work at CSL Behring.
The company said that subject to FDA approval, it was looking forward to bringing the therapy to patients later this year.
CSL fell 76 cents or 0.6 percent to $127.71 with 748,298 shares traded.

ALLEGRA ORTHOPAEDICS

Allegra says its non-renounceable rights issue at 12.5 cents a share has raised the maximum of $1,219,023 (BD: Feb 23, 2017).
Allegra said that it received entitlement applications for 6,156,758 shares and the 3,595,423 shortfall shares were oversubscribed and scaled back.
Allegra was untraded at 34 cents.

IDT AUSTRALIA

IDT says it is manufacturing a replenishment batch of generic temozolomide, following the sale of the first batch launched by Mayne Pharma last year (BD: Nov 22, 2016).
IDT chief executive officer Dr Paul MacLeman told Biotech Daily that he was “surprised and delighted by Mayne’s performance to date”.
Dr MacLeman said that Mayne was distributing six strengths of temozolomide or generic Temodar, for glioblastoma multiforme ranging from 5mg to 250mg.
In a media release, IDT said one batch of each strength was shipped for the launch, which was expected to be sufficient to meet Mayne’s early market efforts until mid-2017.
The company said that since the launch a further order was received from Mayne for the 180mg and 250mg dose strengths, with an aggregate value larger than the launch stock.
IDT said that the replenishment stock was being manufactured and expected to be shipped by July 2017, but due to the structure of the distribution, revenue would fall in the first half of the 2017-’18 financial year, that is by December 31, 2017.
The company said that Mayne’s higher than expected market share was “encouraging and should provide a solid platform for future temozolomide sales growth and operational efficiencies created by higher throughput manufacture”.
IDT said that other products in the process of approval or development that could be marketed this year included Pindolol, Leucovorin and Doxazosin, with Mexiletine, Carbidopa/Levodopa and Prazosin in development for a later launch.
IDT was up 2.5 cents or 20 percent to 15 cents with 1.3 million shares traded.

ANTEO DIAGNOSTICS

Anteo says that having secured additional funds its $9 million “investment facility” with New York’s Bergen Global Opportunity Fund has been terminated (BD: Mar 3, 2016).
Anteo said that funds were raised from shareholders, chief executive officer Dr Jef Vangenechten and directors and Diasource vendors extended the payment date.
Anteo chairman Dr John Hurrell said the company had been “advancing a number of alternatives to meet its earn-out and vendor finance liabilities”.
“In the meantime, the funds raised from Bergen provided the company with working capital to meet its obligation,” Dr Hurrell said.
Anteo was unchanged at 3.5 cents with 3.2 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has filed a further patent application with IP Australia covering “novel and innovative applications of its proprietary Cymerus mesenchymal stem cell technology”.
Cynata said that the patent application, entitled ‘Method’ built on its intellectual property portfolio and, if granted, would provide coverage until 2037, giving additional protection for its mesenchymal stem cells, particularly in relation to cancer.
Cynata fell three cents or 5.7 percent to 50 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has reached agreement with German insurers for the cost of treatment of erythropoietic protoporphyria with Scenesse, but did not disclose the price agreed.
Clinuvel said it had been in mandatory “negotiation” with the German National Association of Statutory Health Insurance Funds (GKV-Spitzenverband or GKV-SV) since August 2016 and a pricing agreement was reached through a legally-binding arbitration board.
The company said that the annual costs of therapy with Scenesse ranged between EUR56,404 and EUR84,606 ($A79,871 to $A119,806) per patient per year.
Clinuvel has previously said that the sub-cutaneous injected dissolving implant lasts up to two months, implying that the average cost is about $16,640 per injection.
The company said it had a uniform global pricing policy, acknowledging that patients migrated across borders for treatment, physicians were associated through networks and hospitals collaborated internationally to purchase products for orphan diseases.
Clinuvel said it would bear the risk of foreign exchange fluctuation over a 24 month period from February 15, 2017 and would not make inflationary adjustments to the uniform price.
Clinuvel UK general-manager Lachlan Hay said the company was “constrained as to the insight it can provide on the negotiations and GKV-SV story”.
“It has been shown that Scenesse is priced uniformly in Europe, there is no alternative effective treatment for [erythropoietic protoporphyria] and as per [European Medicines Agency] approval in 2014 there are no scientific instruments to quantify and measure the impact of disease or therapy,” Mr Hay said.
“In an era where pharmaceutical companies are scrutinised by media, the general public and insurers, we intend to set an example through our uniform product pricing policy,” Mr Hay said. “This outcome is a well-deserved and long-awaited blessing for the German EPP patients and healthcare providers, who have been seeking clarity on pricing and supply conditions since the drug’s European approval in October 2014.”
Clinuvel was up 14 cents or two percent to $7.05.

RESPIRI (FORMERLY ISONEA, KARMELSONIX)

Respiri says that its next generation Airsonea at-home monitoring device has been granted class IIa Conformité Européenne (CE) mark approval.
Respiri said the approval was “integral to partnership discussions” allowing the sale of the Airsonea device in Europe, including the UK.
Respiri chairman Leon L'Huillier said the European approval to market Airsonea “was important to advance partner discussions”.
“It provides the commercial opportunity to pilot and test market the product from current inventory,” Mr L'Huillier said.
In 2013, the then Isonea received Australian Therapeutic Goods Administration approval for the Airsonea wheeze detection monitor, later filing an application for Conformité Européenne (CE) mark approval (BD: Aug 6, Sep 4, 23, 2013).
Respiri was unchanged at five cents.