Biotech Daily

Thursday September 20, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: USCOM UP 7%; ITL DOWN 6%**

*** BIOCELECT, 60 DEGREES TAFENOQUINE FOR MALARIA FDA, TGA OK**

*** MESOBLAST: '69% DAY-100 PAEDIATRIC GVHD SURVIVAL'**

*** GI DYNAMICS RAISES $7m; CRYSTAL AMBER NOTE; CONSOLIDATION**

*** IMAGION $4.3m RIGHTS OFFER**

*** OSPREY, GE US KIDNEY HEALTH EDUCATION PROGRAM**

MARKET REPORT

The Australian stock market fell 0.33 percent on Thursday September 20, 2018 with the ASX200 down 20.5 points to 6,169.5 points.

Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, six traded unchanged and five were untraded.

Uscom was the best, up one cent or 6.9 percent to 15.5 cents with 32,067 shares traded.

Dimerix and Mesoblast climbed five percent or more; Imugene improved 4.8 percent; Genetic Signatures was up 3.2 percent; CSL, Immutep and Universal Biosensors rose more than two percent; Avita, Compumedics and Pro Medicus were up more than one percent; with Ellex up 0.6 percent.

ITL led the falls, down one cent or 6.25 percent to 15 cents, with 40,000 shares traded.

Neuren fell 5.95 percent; Actinogen, Cynata and Impedimed lost more than three percent; Benitec, Bionomics, Osprey and Starpharma shed more than two percent; Medical Developments, Nanosonics, Orthocell, Paradigm, Polynovo, Prescient, Resmed, Telix and Volpara were down one percent or more; with Clinuvel and Cochlear down by less than one percent.

BIOCELECT

Biocelect managing-director Karl Herz says the Australian Therapeutic Goods Administration has approved tafenoquine as a prophylaxis for malaria.

Mr Herz told Biotech Daily the Sydney-based Biocelect and Biointelect (formerly part of BTC Health) were advisers to the Washington DC-based 60 Degrees Pharmaceuticals which developed the drug with the US Walter Reed Army Institute of Research.

Biocelect said that tafenoquine was discovered by Walter Reed scientists and with 60 Degrees conducted 21 clinical trials with more than 3,100 trial subjects, to develop tafenoquine as a weekly drug for the prevention of malaria.

Mr Herz said tafenoquine had been approved for patients aged 18 years and older for up to six months continuous dosing, was the first new malaria prevention drug to be approved "in more than two decades" and would be marketed in the US as Arakoda and in Australia as Kodatef.

"Kodatef kills the malaria parasites in both the blood and liver stages, including the dormant liver phase seen with Plasmodium vivax," Mr Herz said.

Biocelect said that people traveling to areas with potential for contracting malaria should take two of the 100mg tablets once daily for three days prior to departure, and once in the area take 200mg once weekly, with the final 200mg dose after leaving the area.

Mr Herz said that Biointelect had provided "full biotechnology advice including in relation to the regulatory pathway, commercialization, sales and marketing".

Biocelect said the World Malaria Congress in Melbourne in July 2018 reported that progress in eliminating malaria had slowed and there was a threat that malaria would return in areas where it was eradicated and drug resistance was a growing concern.

The company said the approval was "the first step in developing novel manufacturing of the drug including new indications … [for] the global goal of eliminating malaria".

Biocelect said it and Biointelect would play "a significant role in this elimination goal".

The company said that malaria was widespread in many countries including Papua New Guinea, Vanuatu, Solomon Islands and South East Asian countries.

Biocelect said that each year more than four million Australians traveled to areas where malaria was present.

Biocelect is a private company.

MESOBLAST

Mesoblast says that 38 of 55 children (69%) in its open-label, phase III trial of remestemcel-L for acute graft versus host disease have survived to 180 days.

Mesoblast said that 33 of the 38 children (87%), who responded to its mesenchymal stem cell treatment at day-28 were alive at day-100 and the treatments was well-tolerated.

The company said that 30 of the 38 children (79%) were alive at day-180, with 38 of the 55 children (69%) surviving to day-180 compared to historical survival rates of 10 percent to 30 percent.

In June, Mesoblast said that 41 children survived to day-100 with 33 of the 38 children (86.8%) who responded to treatment at day-28, alive at day-100 (BD: Jun 21, 2018).

Today, the company said the US Food and Drug Administration had stated that to be considered successful its trial should achieve both the primary endpoint of day-28 overall response and also demonstrate overall survival benefits at 180 days.

Mesoblast said that, having met the advised endpoints, it would meet with the FDA "in the next few months" to discuss a biologics licence application for remestemcel-L for acute graft versus host disease.

Mesoblast was up nine cents or 5.3 percent to $1.78 with 2.15 million shares traded.

GI DYNAMICS

GI Dynamics says it has commitments for a $6,944,445 placement, is considering a consolidation and has lowered the conversion price for its 2017 convertible note.
GI Dynamics said it had commitments for a $6,944,445 at 2.0 cents per Chess depositary instrument (CDI) with 347,222,250 CDIs to be issued in two tranches.
The company said that the first tranche of 150,000,000 CDIs for $3,000,000 would be issued by September 25 and the second tranche of 197,222,250 CDIs for $3,944,445 was subject to shareholder approval.
GI Dynamics said the funds would be used for the development of its Endobarrier duodenal insert for obesity and type 2 diabetes, prepare for a US Endobarrier trial and for working capital.
The company said it proposed to consolidation its shares to list on the Nasdaq, the London Stock Exchange or another exchange, with the consolidation ratio to be decided.
GI Dynamics said that it had lowered the exercise price of its 2018 $US1,750,000 ($A2,332,140) warrant with major shareholder Crystal Amber from 1.8 US cents (2.5 Australian cents) to 1.44 US cents (2.0 Australian cents) to match the placement price (BD: May 2, 2018). [The ASX notice included an incorrect US conversion amount.]
The company said its $US5,000,000 ($A6,883,250) convertible note with Crystal Amber from 2017 could be converted into CDIs at any time prior to maturity on December 31, 2018 at a conversion price equal to the volume weighted average closing price per CDI on the ASX over the five trading days prior to conversion (BD: Jun 16, 2017).
GI Dynamics was untraded at two cents.

IMAGION BIOSYSTEMS

Imagion says it hopes to raise $4.3 million through a non-renounceable, one-for-two rights issue at four cents a share.
Imagion said the funds from the rights issue would be used for a first-in-human study of its nanoparticles for the detection of cancer to be conducted at the Houston, Texas-based MD Anderson Cancer Centre in early 2019 (BD: Sep 10, 2018).
The company said the record date would be September 28, the offer would open on October 3 and close on October 17, 2018.
Imagion was untraded at 7.4 cents.

OSPREY MEDICAL

Osprey says it will collaborate with GE Healthcare to sponsor educational programs and seminars for its US Be Kind to Kidneys campaign.
Osprey said the campaign aimed to increase awareness of guidelines issued by the American College of Cardiology and American Heart Association to help address acute kidney injury following heart imaging procedures in patients with chronic kidney disease.
The company said its campaign would begin in September with a series of two-day educational programs for nurses and technicians focusing on strategies to reduce the amount of contrast dye used while using Osprey's Dyevert Plus kidney imaging system.
Osprey fell half a cent or 2.3 percent to 21.5 cents.