BIOWORLD™ TODAY

THE DAILY BIOPHARMACEUTICAL NEWS SOURCE

MAY 30, 2014 | BIOTECH'S MOST RESPECTED NEWS SOURCE FOR MORE THAN 20 YEARS | VOLUME 25, NO. 104

FIRM TO EXPAND MANUFACTURING

Oxford Biomedica's gene therapy pipeline bolstered by $39.6M financing

By Nuala Moran, Staff Writer

LONDON – With dwindling cash supplies and a month after Sanofi SA handed back its Retinostat gene therapy product for wet age-related macular degeneration (AMD), Oxford Biomedica plc is going to the market to raise up to £23.7 million (US$39.61 million) in a placing and open offer.

It plans to invest some £4 million of this in expanding its contract manufacturing business, capturing a wave of demand for the production of gene and cell therapy products.

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NEWS FROM WASHINGTON

FDA funding bill is intended to hold the agency's feet to the fire

By Mari Serebrov, Washington Editor

The fiscal 2015 funding bill for the FDA that's now headed to the House floor has become a bully pulpit to keep the agency from backsliding on commitments ranging from accelerated approval and abuse deterrence to science-based, data-

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FINANCINGS

Rodin closes $13M A round to target HDAC2 in Alzheimer's disease

By Cormac Sheridan, Staff Writer

Rodin Therapeutics Inc., a company co-founded by Proteros Biostructures GmbH and Atlas Venture, raised $12.9 million in a series A round to take forward two sets of epigenetic modulators that are in

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CHINA

Hutchison Medipharma hopes to break through with cancer drug Volitinib

By Shannon Ellis, Staff Writer

SHANGHAI – Hutchison Medipharma Ltd. (HMP) is set to turn a corner announcing strong early results for not one, but three of its oncology drugs at ASCO 2014 this weekend in Chicago.

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KOREA

BIO KOREA 2014

Korea sets sights on biopharma powerhouse status by 2020

By Alfred Romann, Staff Writer

SEOUL, South Korea – With one eye firmly planted on future economic growth, South Korea is taking steps to boost its biotechnology industry by

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THE BIOWORLD BIOME

MERS and SARS viruses are vulnerable to new coronavirus inhibitor

By Sharon Kingman, Staff Writer

LONDON – The discovery of a compound that can prevent replication of various coronaviruses – which cause common respiratory infections as well as rare but highly dangerous infections – has raised

See Viruses, page 8

U.S. NEWS

All together: Consortia boom as scientific complexity grows

By Michael Fitzhugh, Staff Writer

Biomedical competitors, fierce as ever, are finding complementary aid in mission-driven collaborations, according to a new survey of the largely unmapped consortia landscape. Consortia-pedia, a

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HMP

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Arguably the most exciting is the phase I data for Volitinib, a c-Met inhibitor that has shown strong results in patients with papillary renal cell carcinoma (PRCC), a rare form of cancer with no existing treatment.

HMP and partner Astrazeneca plc are hoping that Volitinib (HMPL-013/ AZD6094) will garner the much-coveted breakthrough status.

"The only study done on PRCC had an objective response rate (ORR) of 13.5 percent, while we got 50 percent. It is a huge thing," Christian Hogg, CEO of HMP, told *BioWorld Today*. "With breakthrough therapy in the U.S., if you are able to show in a rare cancer type – one that does not have any approved treatment – that you can deliver that kind of response rate then you are in a good situation," he said.

But Hogg is cautious, aware that the challenge will be to replicate those results early on in the open-label, single-arm, global multicenter phase II trial that just commenced. The firm is shooting for the same ORR of 50 percent that it saw in three of the six PRCC patients with partial tumor shrinkage of greater than 30 percent.

The other trial on PRCC was a phase II study of Fortetinib conducted by Glaxosmithkline plc in 2012 – which showed a 13.5 percent ORR, which HMP's Volitinib so far outmatches. "This is why we are optimistic on the prospects of the phase II PRCC study that we started last week with Astrazeneca," Hogg said.

The phase I conducted by HMP and Astrazeneca was a first-in-human dose-escalation study to determine the maximum tolerated dose, dose-limiting toxicities, pharmacokinetics (PK) profile and preliminary antitumor activity. Thirty-two patients were tested with the majority having PRCC, while five patients had colorectal cancer.

Patients were treated at single daily doses of 100 mg to 1,000 mg or 300 mg to 400 mg twice a day. Volitinib was well tolerated at doses of up to 800 mg, once per day.

PK analysis showed rapid absorption with Tmax at two hours and half-life at five hours. Peak concentration and area under the curve showed a dose-proportional increase and no obvious accumulation. Common adverse events included constipation, diarrhea, fatigue, nausea, vomiting, dizziness and peripheral edema.

For patients with evidence of dysregulated MET signaling, Volitnib holds promise for antitumor activity beyond the small numbers of patients with PRCC.

According to Hogg, most patients with PRCC have mutated c-Met or c-Met amplification, making a c-Met inhibitor a likely choice for approval in that indication. But c-Met is out of control in a number of other cancer types, such as non-small-cell lung cancer and gastric cancer and can be found in tumors of specific relevance to the Asian population such as lung, stomach and esophageal cancers (with EGFR mutations).

While the potential market for Volitinib is great, the first step is to prove the drug is worthy of a breakthrough designation.

The phase II study plans to enroll 100 patients but with no treatment for comparison it is not double blinded. According to Hogg, there is the potential to have the trial wrapped up quickly, within the year, with interim reporting to be done at the one-third, and two-third stages.

If granted, breakthrough designation could allow for a drug to gain approval without having gone through a phase III trial. That can mean quick progress, as evidenced by Pharmacyclics Inc.'s meteoric rise with breakthrough drug Ibruvica (ibrutinib), a case study Hogg is hoping to emulate. (See *BioWorld Today*, Feb. 14, 2013.)

What truly excites the CEO is the potential for Volitinib to be combined with other therapies.

"One of the Astrazeneca's strategies is to have a basket of targeted cancer therapies that can be combined, that can hit many cancers and many target types. And Volitinib is one in that basket basically," Hogg said.

But HMP is far from putting all its eggs in one basket, with three other promising drugs in the pipeline, and two more with strong phase Ib and phase I results to be shared at ASCO, for Fruquintinib (HMPL-013) and Sulfatinib (HMPL-012).

HMP started out as a company focused on botanicals, and it is known for its catalog of 50,000 medical substances derived from Chinese herbs, as well as its China Healthcare Division, which sells popular branded traditional Chinese medicine products across the country at a healthy profit that helps to finance the company's R&D division.

After 12 years of slow and steady nurturing of the pipeline and $200 million invested in R&D, HMP has one botanical for ulcerative colitis, partnered with Nestle SA, expected to show phase III eight-week results in August, and a line-up of self-discovered small molecules that are showing results in the clinic.

MOVE OVER NEXAVAR, HERE COMES FRUQUINTINIB

Fruquintinib, a second-generation VEGFR inhibitor, has phase Ib data that "show the efficacy of Fruquintinib in colorectal cancer is far superior to that of the existing therapies on the global market," Hogg said. He added that it is the most targeted, selective VEGFR inhibitor, requiring only low doses, leading to fewer side effects.

The phase I trial involved 40 patients with various heavily pre-treated solid tumors, including colorectal cancer. Administered at 5 mg once daily in cycles of one-week rest after three weeks of dosing, Fruquintinib was well tolerated and, given that it showed promising signs of early clinical efficacy, phase II commenced in early April.

For that asset HMP has partnered with Eli Lilly and Co., giving the Indinapolis-based pharma the China-rights license and

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