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BLUNT PINS

Has biotech's bubble burst? No, fundamentals remain sound

By Peter Winter, BioWorld Insight Editor

It is alliteratively satisfying to combine "biotech" with "bubble," and the two words have been bandied around frequently for the past couple of days causing massive trading in biotech shares that has resulted in the largest two-day declines that biotech indices have experienced since early 2012. The selloff trigger was attributed to concerns in U.S. government circles over the price of a hepatitis C drug treatment from Gilead Sciences Inc.

While this negative sentiment did not cause a full-scale panic among investors, it

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FDA not excited about serelaxin efficacy data from single trial

By Mari Serebrov, Washington Editor

If the Cardiovascular and Renal Drugs Advisory Committee (CRDAC) follows the lead of FDA reviewers Thursday, it will send Novartis AG's serelaxin back for more testing.

Unimpressed with the efficacy data from a single phase II/III trial that evaluated the breakthrough biologic in dyspnea

See FDA, page 4

FINANCINGS

It's 'GAIM' on for Neurophage with $17M series D

By Marie Powers, Staff Writer

Neurophage Pharmaceuticals Inc. moved one step closer to an investigational new drug filing and the initiation of human studies for lead candidate, NPT088, with the completion of a $17 million series D.

See Neurophage, page 5

BIOWORLD ASIA

$3.2B AVAILABLE FOR R&D PROPOSALS

China renews efforts to spur innovation; HIV/AIDS a top priority

By Kristine Yang, Staff Writer

HONG KONG – Over the next year, health authorities in China plan to renew their focus on biotech development and continue funding research and

See AIDS, page 2

DEALS AND M&A

Genable deal taps into Spark's gene therapy expertise

By Cormac Sheridan, Staff Writer

DUBLIN – Genable Technologies Ltd. is dipping into Philadelphia's deep pool of gene therapy expertise by entering a collaboration agreement with Spark Therapeutics LLC, under which the

See Genable, page 6

IN THE CLINIC

AM-Pharma opts for adaptive design route after successful phase I

By Nuala Moran, Staff Writer

LONDON – AM-Pharma has cleared the way to getting its alkaline phosphatase product back into patient trials after reporting positive results in a phase I study in 50 healthy volunteers.

See AM-Pharma, page 7

THE BIOWORLD BIOME

Bones yield their secret ingredient: a messy, sticky gel

By Sharon Kingman, Staff Writer

LONDON — A vital component of our bones has turned out to be a viscous gel that allows bone crystals to slide over one other. The gel, a combination of water and citrate that also bonds

See Bones, page 8

NEWCO NEWS

Kindex brewing diabetes drug with hops-derived humulone; $5M series A

By Randy Osborne, Staff Writer

It's only $5 million in series A funding, but enough to move start-up Kindex Pharmaceuticals Inc. into a phase II trial with lead compound KDT 501, a hops-derived candidate for type 2 diabetes

See Kindex, page 9

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Kindex

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that regulates the cross-talk between macrophages and adipocytes to influence the complex of proteins that regulate inflammation, also known as the inflammasome.

Among the investors in Seattle-based Kindex is the venture capital firm Polaris Partners, and at the helm of the company is Jeffrey Bland. Some may recognize the CEO's name from Metagenics Inc., of Aliso Viejo, Calif., where he was president and chief scientific officer. That firm specializes in medical foods. Bland also founded the not-for-profit Personalized Lifestyle Medicine Institute and Healthcomm International Inc., of Gig Harbor, Wash. Metagenics and Healthcomm merged in 2000.

Kindex's work focuses on humulone, an alpha acid in hops. Brewers of beer have long known about alpha acids, which lend bitterness to beer and which make up a group that also includes cohumulone, regarded as particularly harsh, as well as the less-studied adhumulone. Cohumulone also gets credit for providing the foamy head on beer, by way of cross-linked proteins. But the star of the group – and the focus of research at Kindex – is humulone, said by brewers to provide the pleasant bite to beers such as India pale ale. The name for the chemical comes from the plant species of hops from which oils are extracted, *Humulus lupulus* (a member of the family Cannabinaceae, which also contains another news-making medicine: cannabis).

Research on humulone has been published in the likes of *PLoS One*, in which scientists detailed work showing that KDT 501 normalized glucose metabolism and body weight in rodent models of diabetes, and *Angewandte Chemie International Edition*, where a team at the University of Washington in Seattle got a Kindex-funded better look at humulone side chains by deploying X-ray crystallography. The crystallography work was important because it discovered that the structure of the humulone molecule – how its five carbon atoms are placed – has a bearing on whether it will show efficacy against disease. KDT 501 apparently influences how cells differentiate in brown fat, and Kindex is exploring the idea that its approach may not only improve glucose homeostasis, but also modify total cholesterol and triglycerides and – "beer gut" to the contrary – reduce weight gain.

The compound is still preclinical as an anti-inflammatory agent. Behind KDT 501 are KDT 600 and others, still at the discovery and candidate selection stage.

Humulone research is not new. A study in 2012 at Sapporo Medical University in Sapporo, Japan, cited promise with the chemical against respiratory syncytial virus. Some investigators have examined the possibility that it could protect against osteoporosis, too.

Kindex plans to push its work farther. Among the scientific advisors for the company is Paul Schimmel, co-founder or co-founding director of biotech firms such as Alkermes Inc., Alnylam Pharmaceuticals Inc., Sirtris Pharmaceuticals Inc., Cubist Pharmaceuticals Inc., Momenta Pharmaceuticals Inc. and Repligen Corp.

With the series A, Kindex Pharmaceuticals was formed by the reorganization of Kindex Therapeutics LLC, the company said. //

CLINIC ROUNDUP

ZS Pharma Inc., of Coppell, Texas, said it started enrolling patients in its second phase III trial, ZS004, testing ZS-9 in hyperkalemia. The study is designed to confirm, over a longer treatment period, the positive results previously reported for ZS003, a phase III trial in which a once-daily dose of ZS-9 maintained potassium levels within the normal range with safety and tolerability similar to placebo. The study is enrolling patients with hyperkalemia, including those with chronic kidney disease, heart failure, diabetes and those on renin angiotensin aldosterone system inhibitor therapy. About 275 patients in the open-label induction phase will receive 10 g of ZS-9, administered three times daily for 48 hours, and those who achieve normokalemia are eligible for randomization in a double-blind fashion to one of three doses or placebo, administered once-daily for 28 days. The primary endpoint is mean serum potassium level of each ZS-9 treatment group vs. placebo.

PHARMA: CLINIC ROUNDUP

Pfizer Inc., of New York, reported that PROFILE 1014, a phase III study testing anaplastic lymphoma kinase (ALK) inhibitor Xalkori (crizotinib) met its primary objective of significantly prolonging progression-free survival in previously untreated patients with ALK-positive advanced nonsquamous non-small-cell lung cancer (NSCLC) when compared to standard platinum-based chemotherapy regimens. PROFILE 1014 is the second positive phase III study testing Xalkori against chemotherapy. The drug first gained approval in 2011 through the FDA's accelerated approval program and received regular approval last year in previously treated ALK-positive advanced NSCLC patients.

U.S. PATENT DISCLOSURES

Agenebio Inc., of Carmel, Ind., was issued U.S. Patent No. 8,604,075, "Methods and compositions for improving cognitive function," and No. 8,510,055, "Methods for characterizing and treating cognitive impairment in aging and disease." Both cover the company's programs for Alzheimer's disease and other cognitive disorders: '075 for the use of levetiracetam, and '055 for the use of positive allosteric modulators selective for the GABA-A alpha5 receptor.

Antigen Express Inc., of Worcester, Mass., part of Generex Biotechnology Corp., was issued U.S. Patent notice of allowance for applications related to therapeutic vaccines targeting human papilloma virus-caused cancers as well as to potentially pandemic strains of influenza virus.

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