

BIOWORLD™ TODAY

THE DAILY BIOPHARMACEUTICAL NEWS SOURCE

OCTOBER 15, 2015

BIOTECH'S MOST RESPECTED NEWS SOURCE FOR MORE THAN 20 YEARS

VOLUME 26, NO. 197

A GREENFIELD WITH MORE DEALS TO COME

J&J banks up to \$686M on Canadian innovation in dual option deals

By Michael Fitzhugh, Staff Writer

Johnson & Johnson Innovation LLC's ongoing investment in Canada's drug discovery and development space has yielded two early stage deals for the company, both securing access to potential new assets for J&J unit Janssen Biotech LLC. A newly formed blood cancer drug developer, Novera Therapeutics Inc., stands to earn milestones of up to C\$450 million (US\$346 million) in one deal, while Engene Inc. could see up to C\$441 million in milestones should Janssen embrace its non-viral vector for gene delivery to cells lining the intestine.

[See J&J, page 3](#)

CRACKER JACK JAK DATA FOR INCYTE/LILLY DRUG

An 'upside surprise' as baricitinib bests RA market leader Humira

By Jennifer Boggs, Managing Editor

Incyte Corp.'s decision to buy into the costly phase III development of baricitinib in rheumatoid arthritis (RA) looked even smarter Wednesday, upon release of top-line data showing the oral JAK1/2 inhibitor superior to top-selling drug

[See Incyte, page 4](#)

FINANCINGS

ORAL CRPS PHASE III UNDER WAY

'Axsome' if they care: IPO seeks \$57.5M to advance ZA despite roster of rivals

By Randy Osborne, Staff Writer

With would-be competition in the wings from Thar Pharmaceuticals Inc. in complex regional pain syndrome (CRPS), Axsome Therapeutics Inc. filed for an

[See Axsome, page 5](#)

REGULATORY

ON STRIKE

India's 800K pharmacies shut down over lack of online drug sales regs

By T.V. Padma, Staff Writer

NEW DELHI – Claiming that the unregulated proliferation of online sales of pharmaceuticals in India could put lives at risk and threaten their

[See India, page 6](#)

EUROPE

UK IS A 'STANDOUT STORY'

European biotechs finally on sustainable financial footing

By Nuala Moran, Staff Writer

LONDON – Biotech executives gathering for the Bioindustry Association's (BIA) annual forum in London Thursday will hear the cheery news that 2014 was the

[See BIA, page 7](#)

FINANCINGS

No radiation 'Galera' as \$37M series B speeds oral mucositis drug

By Marie Powers, News Editor

Galera Therapeutics Inc. completed a \$37 million series B designed to propel its pipeline of selective dismutase mimetics and move lead candidate, GC4419, into a randomized, double-blind phase IIb trial

[See Galera, page 8](#)

REGULATORY

Social media is a breeding ground of threats for clinical trials

By Mari Serebrov, Regulatory Editor

An ounce of prevention could be worth several pounds of cure when it comes to protecting clinical trials from the dangers lurking in social media.

Increasingly viewed as a great tool for

[See Social media, page 9](#)

FINANCINGS

LOUD AND CLEAR

Third Rock hears music in \$52M Decibel launch

By Marie Powers, News Editor

In an ambitious scheme to develop a pipeline of drug therapies targeting hearing loss, Third Rock Ventures backed Decibel Therapeutics with a \$52 million series A to advance "disruptive

[See Decibel, page 10](#)

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Social media

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recruiting patients and helping to manage a trial, social media also can be a breeding ground of threats to the health of a blinded trial – from disgruntled employees to overzealous investigators to anxious analysts to engaged patients and their families.

The best way to thwart such threats is to prevent them up front, said Leslie Tector, a partner at Quarles & Brady LLP. That has to encompass the entire clinical trial spectrum, as it requires heightened awareness among the sponsor, contract research organization (CRO), institutional review board (IRB), site personnel and study participants.

A patient who participated in a completed drug trial tipped *BioWorld Today* off to some of the threats from a participant perspective.

The informed consent form for the trial had a paragraph cautioning all people involved in the research study not to speculate about the results.

“If there are rumors about how many patients have side effects, or about whether the medication is working or not working, it may affect the study,” the form said. “If the information from the study might be affected by early conclusions, it could cause the study to have to be repeated and may slow down the development of new drugs.”

However, when site personnel reviewed the consent form with the patient, who asked not to be identified for privacy reasons, they didn’t mention that paragraph or elaborate on how social media references to the trial could delay development of new treatments.

The site did take precautions to preserve the blinding of the study, ensuring participants weren’t scheduled when a sponsor rep was there and trying to keep patients from interacting with each other when they inadvertently had appointments on the same day.

SEEKING COMMUNITY

Despite the precautions and the informed consent language, another participant approached the patient about exchanging email when they were at the site at the same time. The patient later discovered the person was blogging about living with the condition and included information about participating in the trial.

The potential repercussions of that were driven home when the patient saw a note from a prominent analyst, who was bearish on an experimental combination drug in a different trial. The note cited published preclinical data and commented on the fact that no anecdotal success stories from the trial were making the rounds.

Social media is an important outlet for people suffering with rare diseases, the patient said, as it may be the only way for

them to connect with others suffering with the same condition. It’s even more so for young people who live their lives online, the patient pointed out. Thus, sponsors need more than a paragraph in a lengthy informed consent form to deal with the issue.

Tector agreed, noting that many informed consent forms don’t caution against social media slips. Her advice to drug and devicemakers is to make sure the issue is addressed in consent forms, as well as in assent forms used in some pediatric trials. Training also is necessary, she said, especially in trials involving Internet-savvy age groups. In addition to the patients and their families, the training should include IRBs at children’s hospitals.

Sponsors have to deal with patient leaks before they occur. Once the information is out there, a sponsor’s hands are tied as it can’t risk unblinding the trial results and violating the Health Insurance Portability and Accountability Act’s privacy rules, Tector said.

SITE THREATS

Other social media threats come from the health care professionals involved in the trials. Disgruntled employees could spout off about trial “deviations” or an investigator excited about the product could reveal too much information. Both could sink a trial, Tector told *BioWorld Today*.

The first step in avoiding such problems is to address them in the contract with the CRO or the site itself by making sure that the confidentiality provisions extend to everyone who works in the trial. That gives the sponsor an enforcement tool to rein in staff, if necessary, Tector said.

If an investigator or staff violates the clause, the sponsor will have to discuss the problem with them. These are hard conversations to have, Tector said, but they have to be held. There’s too much at stake.

Confidentiality concerns are not just with social media. Tector noted an instance in which an analyst posed as a patient looking to enroll in an ongoing clinical trial. To encourage the potential subject, the enthusiastic investigator revealed far more information than permissible, and that information became public.

Her concern about disgruntled employees “revealing deviations” has to do with the nature of clinical trials. “It’s not cookie cutter like people want it to be,” Tector said. For instance, a cancer study can have more than 40 protocol amendments, which can relate to minute details such as the exact timing of a response to a change in a patient’s blood level.

A deviation also can be a small paperwork slip-up that’s corrected or a patient who changed an appointment.

Putting out information about a so-called deviation with no context could condemn a trial before there’s an opportunity to see what an experimental drug or device can do, Tector noted. //