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PAGE 1 OF 7

Seattle Genetics Aims at Accelerated Approval Bar

By Mari Serebrov
Washington Editor

A lot is on the line Thursday when the FDA's Oncologic Drugs Advisory Committee (ODAC) reviews Seattle Genetics Inc.'s Adcetris as a treatment for relapsed or refractory Hodgkin lymphoma and for relapsed or refractory systemic anaplastic large cell lymphoma (ALCL).

If approved by the FDA, Adcetris could be the first new Hodgkin's treatment since 1977 and the first treatment for ALK1 negative ALCL.

The agency is asking the committee to consider full or accelerated approval for both indications.

Because Adcetris is one of the first cancer drugs seeking accelerated approval since ODAC weighed in earlier this year on the evidence needed to support such approval, Thursday's meeting also could serve as a bit of a litmus test.

See Seattle Genetics, Page 3

Financings Roundup

Tarsa Pads Coffers Ahead of NDA Filing for Oral Calcitonin

By Jennifer Boggs
Assistant Managing Editor

Three months after reporting positive top-line data from its Phase III study of oral calcitonin in postmenopausal osteoporosis patients, Tarsa Therapeutics Inc. disclosed a \$24.5 million financing round that should get the Philadelphia-based firm through a new drug application (NDA) filing later this year.

The internal round is the second substantial fund raising for the company, which was formed in 2009 to develop the late-stage product in-licensed from Unigene Laboratories Inc. A Series A round that year brought in \$24 million from venture investors MVM Life Science Partners, Quaker BioVentures and Novo A/S. All three plus Unigene returned for the latest investment.

Proceeds should cover the NDA submission for

See Financings Roundup, Page 4

First in Vivo Data for HMT Inhibitors

Epigenetic Approach Works for Mixed-Lineage Leukemia

By Anette Breindl
Science Editor

Two papers published this week described a novel target for fighting mixed-lineage leukemia. By inhibiting the histone methyltransferase DOTIL, scientists were able to kill mixed lineage leukemia cells both in cell culture and in animal models.

The work, Robert Copeland told *BioWorld Today*, has implications beyond mixed-lineage leukemia. It is "the first demonstration of in vivo efficacy for a histone methyltransferase inhibitor," and "portends the success of the entire class."

Copeland is chief scientific officer of Cambridge, Mass.-based biotech Epizyme Inc., and a co-author on one of the papers, "Selective Killing of Mixed Lineage Leukemia Cells by a Potent Small-Molecule DOTIL Inhibitor."

See Leukemia, Page 5

New Co News

Madeira Seeks to Fill Pediatric Niche with Reformulation Plan

By Marie Powers
BioWorld Today Contributing Writer

Reformulations aren't exactly a novel proposition in the biotech world, but Madeira Therapeutics LLC is taking that strategy one step further. The company is one of the few biotechs focused on repositioning adult compounds for the pediatric market.

More broadly, Madeira specializes in drugs developed under the 505(b)(2) new drug application pathway – a popular route for biotechs and pharmas, enabling modification and repositioning of existing drugs for expeditious marketing clearance.

"We want to take existing small-molecule medications and find new uses for them," explained Pete Joiner, a

See Madeira, Page 6

INSIDE:

OTHER NEWS TO NOTE: 3SBIO, 4SC, BLUEBIRD BIO, AMARANTUS2
CLINIC ROUNDUP: ARENA, CERULEAN, GAMIDA CELL, CENFIT7

AHC Media

Other News To Note

- The Chinese State Food and Drug Administration approved a new dosage formulation of EPIAO for anemia associated with chemotherapy by **3SBio Inc.**, of Shenyang, China. The drug is designed to rapidly restore hemoglobin to normal levels. The approval was based on a clinical trial showing a weekly subcutaneous injection of 36,000 IU EPIAO was similar to administration of 10,000 IU three times a week.
- **4SC AG**, Planegg-Martinsried, Germany, received orphan drug designation from the FDA for resminostat in hepatocellular cancer. Resminostat is a pan-histone-deacetylase inhibitor in Phase II trials for advanced HCC, with results expected toward the end of 2011.
- **Bluebird Bio**, of Cambridge, Mass., exclusively licensed its RMCE technology for making knock-in rodents for laboratory use to **GenOway SA**, of Lyon, France. Terms were not disclosed. GenOway specializes in genetically modified rodents, while Bluebird is developing gene therapies.
- **Amarantus BioSciences Inc.**, of Sunnyvale, Calif., and **Genorex Biotechnology Inc.**, of Toronto, said they selected the development of a MANF-based therapeutic for the treatment of the beta cell destruction at the root of diabetes as the second program in their joint research collaboration disclosed in late May. The first collaboration program involves a MANF-based diagnostic to identify a subpopulation at risk for developing Type I or Type II diabetes.
- **AnaptysBio Inc.**, of San Diego, selected an anti-IL17 monoclonal antibody candidate, ANB004, generated using its SHM-XEL platform. The company's most advanced compound, ANB004 is in development for autoimmune and inflammatory conditions.

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BIO and ASCO: It's like Halloween for the health care industry vs. a birthday celebration for biotechnology ...

Tune into this week's *BioWorld Perspectives* in which BioWorld Executive Editor Michael Harris discusses the year's biggest biotech conferences.

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Stock Movers

07/12/11

Company	Stock Change	
Nasdaq Biotechnology	-\$0.72	-0.06%
Adolor Corp.	-\$0.35	-12.73%
EntreMed Inc.	+\$0.38	+18.27%
Infinity Pharmaceuticals Inc.	+\$0.74	+9.31%
RXi Pharmaceuticals Corp.	+\$0.14	+11.29%

(Biotechs showing significant stock changes Tuesday)

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Seattle Genetics

Continued from page 1

At a February meeting, the committee told the FDA that randomized, controlled trials should be the standard for accelerated approval, noting that the bar should not be lowered to move drugs to market faster through single-arm trials.

However, ODAC didn't rule out single-arm trials, saying they should be the exception – but only for drugs used in rare diseases and that demonstrate a high level of activity or a pronounced treatment effect.

Seattle Genetics' Adcetris (brentuximab vedotin) has both going for it.

Besides meeting unmet needs in both indications, it proved highly effective in the single-arm Phase II trials being used to support accelerated approval of its two biologic license applications (BLA), which were submitted a few weeks after the committee's February meeting. (See *BioWorld Today*, March 1, 2011.)

In the Hodgkin's trial, 94 percent of the 102 subjects had reductions in tumor volume and 75 percent had objective responses, including 32 percent who achieved complete remission.

The Bothell, Wash.-based company reported similar results for its Phase II ALCL trial, with 97 percent of the 58 patients experiencing reductions in tumor volume and 53 percent complete remission.

The FDA confirmed the Adcetris results in its briefing documents for Thursday's meeting, but it is asking ODAC to comment on the level of evidence presented for the efficacy results.

FDA's Discomfort: Single-Arm Trials

Seattle Genetics conducted one single-arm Phase II trial for each BLA.

The company has started Phase III trials in Hodgkin lymphoma patients after autologous stem cell transplant (ASCT) and is conducting an additional Phase II study for relapsed patients and a Phase I study for Hodgkin lymphoma front-line treatment.

While the agency raised no serious concerns about Adcetris in the run-up to the meeting, it "reiterated its discomfort with single-arm trials," Baird Equity Research analyst Christopher Raymond said.

If, as expected by most analysts, ODAC supports accelerated approval for Adcetris, single-arm trials for many cancer drugs, such as Onyx Pharmaceuticals Inc.'s carfilzomib, still would be a risky strategy, Raymond added.

ODAC has exhibited a trend of increasing caution in cancer drug applications in recent years.

In 2009, the committee voted against accelerated approval for Genzyme Corp.'s Clolar (clofarabine) and Vion Pharmaceuticals Inc.'s Onrigin (laromustine) because

the applications were based on single-arm, uncontrolled Phase II trials.

Since then, biotechs have tended to go the full nine yards with large, randomized Phase III trials. For instance, Sunesis Pharmaceuticals Inc. opted not to attempt accelerated approval for its first-in-class quinolone derivative, vosaroxin, despite good results in two separate Phase II studies in acute myeloid leukemia. It began Phase III trials instead. (See *BioWorld Today*, Dec. 22, 2010.)

One exception was Celgene Corp.'s Istodax (romidepsin), which received accelerated approval last month as a treatment for peripheral T-cell lymphoma, based on two small single-arm Phase II trials. Istodax had already been approved to treat cutaneous T-cell lymphoma. (See *BioWorld Today*, June 20, 2011.)

"It is clear that the bar for trials in first- and second-line disease will be set higher and that safety will be a larger issue," said J.P. Morgan analyst Cory Kasimov.

In addition to the evidence questions Thursday, the FDA will ask ODAC to consider the acceptability of Seattle Genetics' confirmatory trial design for the Hodgkin's BLA. A confirmatory trial is needed to move a drug from accelerated approval to full approval.

The agency also will ask the committee whether accelerated approval should be granted for the ALCL BLA without an ongoing confirmatory trial.

In the briefing documents, the FDA emphasized that the Hodgkin's trial evaluated only patients who had previously received an autologous stem cell transplant.

That could lead to a more restrictive label than the broader relapse/refractory label that has been widely anticipated, according to Kasimov.

Should it get accelerated approval by its Aug. 30 PDUFA date, Seattle Genetics is in a strong position to launch its lead antibody-drug conjugate (ADC), which was developed through a partnership with Millennium, of Cambridge, Mass., a unit of Takeda Pharmaceuticals Co. Ltd.

In exchange for global rights outside North America, Millennium paid half the development costs and gave Seattle Genetics \$60 million up front with more than \$230 million in milestones, Seattle Genetics Chief Operating Officer Eric Dobmeier told *BioWorld Today*. The company also stands to get royalties from the mid-teens to mid-20s on Millennium's sales.

The European Medicines Agency accepted Millennium's filing of marketing authorization applications for Adcetris for both indications last month, and Dobmeier expects European approval next year.

Seattle Genetics has three other ADCs in Phase I, two of which are being developed in collaboration with Astellas Pharma Inc., and 11 others being developed by partners. (See *BioWorld Today*, March 23, 2011.)

Adcetris is "sort of the tip of the iceberg using this technology," Dobmeier said. ■

Financings Roundup

Continued from page 1

Tarsa's oral recombinant salmon calcitonin in osteoporosis treatment, as well as advance further clinical work in osteoporosis prevention, and support general corporate purposes.

Amid the crowded osteoporosis treatment market, dominated by bisphosphonates such as Merck & Co. Inc.'s Fosamax (alendronate), with competition from selective estrogen receptor modulators, human parathyroid hormone drugs and Amgen's Inc. RANK ligand inhibitor Prolia (denosumab), calcitonin has commanded only about 3 percent to 4 percent share – about half a billion globally.

Part of that is due to the fact that it hasn't been promoted over the past several years, noted David Brand, Tarsa's president and CEO, though he added that physicians continue to prescribe it for its "well-known record of safety."

But the other limiting factor to calcitonin's use has been administration. While it's available as an injectable, it's more widely used nasally, a formulation that has not lent itself to good patient compliance, Brand said.

But an oral version could prove a solid option for patients, especially as safety issues on existing drugs continue to come to light. Only last fall, the FDA ordered makers of bisphosphonates to include label warnings about the possible risk of femoral fracture. Infrequent cases of osteonecrosis of the jaw also have been linked to bisphosphonates, as well as Amgen's Prolia. (See *BioWorld Today*, Oct. 14, 2010.)

Calcitonin, on the other hand, "has very few side effects," Brand told *BioWorld Today*. As an analogue of human calcitonin, Tarsa's drug is about 30 times more potent, and in prior studies was able to deliver sufficient blood levels of calcitonin and reduce levels of biomarkers of bone resorption.

"So it's well proven, with few safety concerns," he added.

The 565-patient Phase III ORACAL trial, conducted under a special protocol assessment, hit its primary endpoint, showing that Tarsa's drug was significantly superior to placebo and noninferior to a calcitonin nasal spray in increasing lumbar spine bone mineral density after one year of treatment in postmenopausal women with osteoporosis. Detailed data from the study will be presented at the American Society for Bone and Mineral Research meeting in September. (See *BioWorld Today*, March 25, 2011.)

If Tarsa wins a first-pass approval at the FDA, its product will be the first oral calcitonin on the market. Coming up is another oral calcitonin from Novartis AG. The Swiss pharma firm's candidate uses a drug delivery technology from Cedar Knolls, NJ.-based Emisphere Technologies Inc. and manufacturing technology from Unigene. Tarsa also plans a European application in early 2012.

For now, the small biotech holds worldwide rights to its oral calcitonin, excluding China, under its agreement with Boonton, NJ.-based Unigene. "And we have a number

of options" going forward, Brand said. Tarsa might consider commercializing the product on its own, or seek a partner or partners. "We look forward over the next couple of months to strategic discussions," he said.

The firm also is testing its drug in a Phase II study in preventing osteoporosis. That trial, designated TAR01-201, is comparing Tarsa's oral calcitonin to placebo in about 120 postmenopausal women with osteopenia. Patient enrollment was recently completed, and Brand said six-month data are expected early next year.

In other financing news:

- **Cytori Therapeutics Inc.**, of San Diego, is pulling in gross proceeds of \$6 million through an equity purchase agreement with Seaside 88 LP. Under the terms, Seaside completed the purchase of about 1.3 million common shares of Cytori priced at \$4.52 each. It also committed to purchase an additional 5 million shares over a nine-month period beginning Aug. 12. Proceeds are expected to help fund the ADVANCE European pivotal trial, designed to test adipose-derived stem and regenerative stem cells processed by the Celution system in patients with acute heart attacks. Funds also will go toward starting a U.S. cardiac clinical trial, a European indication-for-use for the Celution system in treating nonoption chronic myocardial ischemia patients, Celution regulatory approvals in additional countries and a strategic partnership. Shares of Cytori (NASDAQ:CYTX) gained 1 cent Tuesday to close at \$5.22. ■

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Leukemia

Continued from page 1

The other paper, which was published by a partially overlapping team of scientists and also includes authors from both Epizyme and academic co-authors, is titled “MLL-Rearranged Leukemia Is Dependent on Aberrant H3K79 Methylation by DOTIL.”

Both appeared in the July 11, 2011, online edition of *Cancer Cell*. The papers are “complimentary,” in their approach, Copeland said.

While his team developed a pharmacological inhibitor, the other paper described experiments investigating DOTIL’s role in leukemia by using genetic methods to knock out DOTIL expression.

Mixed-lineage leukemia – which gets its name, Copeland said, because it seems to “bridge” the acute myelogenous and acute lymphoblastic leukemia populations in terms of its underlying genetic error – results from a chromosome shuffling, or translocation in the MLL gene.

The cancer, which can appear in both children and adults, is difficult to treat. While the remission rates for some other forms of pediatric leukemia now approach 80 percent to 90 percent, less than half of all children with mixed-lineage leukemia are helped by standard chemotherapies.

The underlying chromosomal trouble is somewhat similar to the BCR-ABL or Philadelphia chromosome that is Gleevec’s target, though with a subtle but important difference: The enzyme that is the net cause of trouble is not part of the translocation.

The MLL gene normally encodes for a histone methyltransferase – but not DOTIL, which is ultimately the troublemaker in mixed-lineage leukemia. It consists both of the active site of the enzyme, and binding sites that direct the enzyme to the right histones.

During the translocation, Copeland explained, “the active site of that enzyme is lost, and the remainder fuses to other protein partners.”

DOTIL gets recruited to the sites by binding to the fusion protein, and “acts on genes that it normally wouldn’t act on” by adding methyl groups to specific histones. Addition of such methyl groups tends to activate genes, and in the case of the MLL fusion gene, the genes that are activated include two leukemia genes: HOXA9 and MEIS1.

In their experiments, Copeland and his colleagues designed a small molecule, EPZ004777, which inhibits DOTIL.

That inhibitor was able to take out cells with the MLL translocation in cell culture, as well as in animal models of mixed-lineage leukemia, and is the first time, Copeland said, that evidence of the effectiveness of inhibiting DOTIL in animals has been published.

On the other hand, there’s “really not much” of an effect of the DOTIL inhibitor on cells without the MLL translocation. Although DOTIL activity is blocked by the inhibitor in the

cells as well, “the cells continue to grow and proliferate just fine.”

Copeland said that MLL cells’ dependency on the enzyme is an example of oncogene addiction, where cancer cells become dependent on one particular cell signal – often a kinase – for survival.

Epizyme’s program – like all others targeting histone methyltransferases – is still in the preclinical stage. The company has partnerships with GlaxoSmithKline plc and Eisai Co. Ltd. to develop other histone methyltransferase inhibitors. (See *BioWorld Today*, March 11, 2011.)

Copeland said the company is “progressing very aggressively” toward the clinic. “We are optimistic that we will be the first to enter clinical trials with a histone methyltransferase inhibitor.”

It won’t be EPZ004777, though. The compound has poor pharmacokinetics and, in the experiments described in *Cancer Cell*, had to be administered via implanted pumps.

Epizyme scientists consider EPZ004777 to be a “very interesting tool compound,” Copeland said. “But we have much better compounds that we are pursuing for the clinic.” ■

Other News To Note

- **Gilead Sciences Inc.**, of Foster City, Calif., granted new licensing terms to India-based **Hetero Drugs Ltd.**, **Matrix Laboratories Ltd.**, **Ranbaxy Laboratories Ltd.** and **Strides Arcolab Ltd.** for three HIV/AIDS drugs currently in late-stage clinical development. Gilead also entered a licensing agreement with the Medicines Patent Pool Foundation, the first biopharmaceutical company to do so. The licensing terms grant the pool and Gilead’s Indian partners future rights to elvitegravir, an integrase inhibitor; cobicistat, an antiretroviral boosting agent; and the “Quad,” which combines four Gilead HIV medicines in a once-daily, single-tablet regimen. Gilead licensed rights to commercialize elvitegravir from **Japan Tobacco Inc.**, of Tokyo, which is working with Gilead to ensure future access to elvitegravir in the developing world.

- **Hybrigenics SA**, of Paris, said preclinical results demonstrated that its inecalcitol was 11 times more potent than calcitriol in inhibiting the growth in vitro of the LNCaP human hormone-dependent prostate cancer cell line. In vivo mice results also showed that inecalcitol, a vitamin D receptor agonist, was 480 times less toxic than calcitriol, the naturally active metabolite of vitamin D. Hybrigenics is developing inecalcitol for the first-line treatment of metastatic hormone-refractory prostate cancer in combination with Taxotere and for treatment of severe psoriasis. The results were published online in the *International Journal of Cancer*.

Madeira

Continued from page 1

retired Sanofi SA veteran who now serves as Madeira's CEO.

Although plenty of drugs are approved for conditions that traditionally affect children – asthma and allergy, attention deficit hyperactivity disorder and head lice, to name a few – along with childhood vaccines, a dearth of compounds exists for diseases that traditionally affect adults, Joiner said. Those indications include lipid control, hypertension and diabetes – diseases that are filtering down into the pediatric population, largely driven by obesity.

"As far as I'm aware, Madeira is the only company that's focusing on the obesity area, including cardiovascular issues, in children," Joiner told *BioWorld Today*.

The need is great, he added, since the National Institutes of Health has identified as many as 400 compounds for pediatric drug trials. And the market for such products is likely to grow since the American Academy of Pediatrics updated its guidelines on lipid screening and cardiovascular health in 2008, advising physicians to screen children after age 2 if one or both parents have a history of elevated lipids and to treat children pharmacologically beginning at age 8 if they show signs of LDL \geq 190 mg/dL – even lower in the presence of other risk factors.

Although pediatrics is a sweet spot for the company, "eventually we will have as many sales in the geriatric area as we do in the pediatric market," Joiner predicted. "If we can take an existing compound and teach an old dog new tricks, we certainly will."

Joiner had quickly tired of retirement when, in 2005, he joined several former Sanofi colleagues at Alliant Pharmaceuticals Inc., an Alpharetta, Ga.-based pediatric specialty pharma that was acquired for \$109 million in 2007 by Sciele Pharma Inc. (now Shionogi Pharma Inc.), of Atlanta.

Although Joiner was now twice retired, he was smitten by drug development. He approached Ken Phelps, president and CEO of Cincinnati-based Camargo Pharmaceutical Services LLC and an industry expert in 505(b)(2) FDA submissions. In 2008, Phelps helped co-found Leawood, Kan.-based Madeira and currently serves as chief scientific officer while retaining his post at Camargo.

Initially, Madeira – which alludes to the grape-like flavor prized for pediatric syrup compounds – is developing liquid statin and pain products. Both will be easily titrated and lend themselves to the pediatric and geriatric markets.

"We think we have a very nice niche there," Joiner said, adding that the company will have intellectual property protection around its delivery systems.

Madeira, which operates with just two full-time employees, has completed its pre-investigational new drug application (NDA) for the liquid statin and is following guidance from the FDA on the next steps in the process, including additional formulation work. The company expects to file the NDA this year and launch a stability trial by the first quarter of 2012, which will run concurrently

with a clinical trial. "We expect to have FDA approval for the statin product by late fourth quarter of 2012 and to launch the product in the first quarter of 2013," Joiner said.

Although development will take longer, a new pain management compound is equally desired in pediatrics, he added. Tylenol with codeine is the current drug of choice but, in many cases, a child's liver is too immature to metabolize the active ingredient.

"We plan to bring to market a more potent analgesic in a liquid format with a synthetic opioid as our active ingredient," Joiner said. "We feel very confident about the safety profile."

Starting a company at the height of the U.S. recession has made fundraising "a chore," Joiner admitted, "but we've made some progress." To date, the company has raised \$2.2 million from angel investors and grants, with the Maverick Angels representing the firm's largest investor group. Last year, Madeira received \$400,000 through the federal Qualifying Therapeutic Discovery Project, which funded its applications both for the liquid statin and pain products.

Earlier this year, SC Launch, an affiliate of Columbia, S.C.-based research and commercialization organization SCRA, provided the company with a \$200,000 convertible note.

The process of applying for the funding opened additional doors for Madeira, which subsequently added a research site in Charleston, where it can work closely with the Medical University of South Carolina Children's Hospital.

"We need to raise another \$1.5 million to gain FDA approval of our first product," Joiner said, adding that the company expects to secure those funds this year, but will not build infrastructure.

The pain management compound will come down the road, once revenues start to flow.

"We've started our pre-IND work, and we expect to submit that to the FDA by August," Joiner said. "We'll then go out for a Series B to finance the additional dosing trials needed for that product."

Ultimately, the company is open to partnering opportunities as well as the prospect of building a sales force.

"As we get closer to market, we'll make a final decision as to whether we want to team with somebody or go out on our own," Joiner said. ■

Other News To Note

• **PharmAthene Inc.**, of Annapolis, Md., demonstrated 36-month stability of its recombinant protective antigen anthrax vaccine, a technical milestone under its Biomedical Advanced Research and Development Authority contract. Stability has historically been a stumbling block for recombinant anthrax vaccine programs, the company said. (See *BioWorld Today*, Feb. 24, 2010.)

Other News To Note

- **PharmaVentures Ltd.**, of Oxford, UK, has been engaged by **Avexa Ltd.**, of Melbourne, Australia, to find a licensing partner for apricitabine, a product in development for HIV.
- **Stem Cell Therapeutics Corp.**, of Calgary, Alberta, presented preclinical data showing that its

Wondering What You Missed in *BioWorld Insight*?

Public Biotechs Drive Funding Increase in H1 2011 vs. H1 2010

Biotech companies raised a total of \$13.3 billion in the first half of 2011, reclaiming much of the fundraising ground that was lost when the markets crashed in 2008. The bulk of the load was carried by public financings, which are expected to continue apace as an increasing number of firms prepare to transition from clinical to commercial enterprises. But on the private side, cautious optimism is still the name of the game for venture capitalists, and as venture firms face make-or-break time for raising new funds, some start-ups are searching for money elsewhere.

Cross-Listing: Foreign Biotechs Head Where the Investors Are

BioLineRx Ltd., which is publicly traded on the Tel Aviv Stock Exchange, decided to get closer to U.S. investors by listing on the Nasdaq. After choosing not to follow through with a \$40 million initial public offering, the Jerusalem-based biotech plans to establish an ADR on Nasdaq without a capital raise. *BioWorld Insight* looked at the advantages and disadvantages of foreign biotechs listing on U.S. exchanges.

Varying REMS Shape Fast-Acting Fentanyl Market

Timing is everything when it comes to risk evaluation and mitigation strategies (REMS). That's the painful lesson BioDelivery Science International Inc. learned when the FDA approved other fast-acting fentanyl products to compete with Onsolis in breakthrough cancer pain. The newcomers – Archimedes Pharma Ltd.'s Lazanda and ProStrakan Group plc's Abstral – don't have to play by the same rules as Onsolis, which was approved two years ago.

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NTx-428 regimen, comprising treatment with human chorionic gonadotropin followed by erythropoietin, significantly decreased brain matter loss and improved functional recovery of symptoms in a rodent model of fluid percussion injury. Researchers also observed a significant increase in cell count number in the dentate gyrus region and specifically CA3 neuron population. Data were presented at the National Neurotrauma Symposium in Hollywood, Fla.

- Under a new licensing agreement between the two companies, **Zogenix Inc.**, of San Diego, will undertake clinical development and commercialization of a long-acting, injectable formulation of risperidone using technology developed by **Direct Corp.**, of Cupertino, Calif. Zogenix expects to begin clinical studies of the resulting product candidate, Relday, in patients with schizophrenia in early 2012.

Clinic Roundup

- **Arena Pharmaceuticals Inc.**, of San Diego, said results from a Phase I trial of its candidate for pulmonary arterial hypertension, APD811, showed its half-life was about 20 hours with dose-limiting adverse events of nausea and vomiting at 0.2 mg. Results support going on to a Phase Ib trial.

- **Cerulean Pharma Inc.**, of Cambridge, Mass., dosed its first patients in a Phase II trial of CRLX101 for non-small-cell lung cancer. The study will assess safety and efficacy of CRLX101 in patients with advanced disease following one or two prior regimens of therapy. Patients will be randomized to CRLX101 plus supportive care, or supportive care alone. Endpoints include overall survival, progression-free survival, tumor response and pharmacokinetics.

- A data monitoring committee has given a pass to a Phase III trial of StemEx, by **Gamida Cell-Teva Joint Venture**, of Jerusalem, recommending that the joint venture continue to enroll patients. StemEx is being studied for blood cancers in adolescents and adults. That was the final required DMC evaluation of the trial.

- **Genfit**, of Lille, France, reported results of a Phase II trial of GFT505 in a group of treatment-naïve diabetic patients showing that the drug improved glucose homeostasis compared to placebo, lowered plasma triglyceride levels and improved markers of hepatic dysfunction. The trial enrolled 97 patients, and was conducted for 12 weeks.

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