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PAGE 1 OF 6

It's Deja Vue All Over Again For Adventrx's Exelbine

By Mari Serebrov
Washington Editor

Adventrx Pharmaceuticals Inc. finds itself once again requesting a meeting with the FDA so it can make its case for lung cancer drug Exelbine.

Last year, the meeting followed a refuse-to-file letter from the FDA because of manufacturing concerns. This time, it's a complete response letter, which also raised manufacturing issues and requested a repeat of a pivotal bioequivalence study conducted in Argentina.

Although Adventrx won't make a final decision about the future of Exelbine (vinorelbine injectable emulsion) until after meeting with the FDA, it hopes to find some gold in the silver lining.

"We could realize significant cost savings from delaying or discontinuing the Exelbine program, in particular as it relates to commercial activities, which would provide us

See Adventrx, Page 3

Enobia Adds \$40M for Hypophosphatasia ERT

By Jennifer Boggs
Managing Editor

Montreal-based Enobia Pharma Inc. padded its coffers via a \$40 million private placement to support ongoing work on ENB-0040, an enzyme replacement therapy for rare genetic bone disorder hypophosphatasia (HPP).

Proceeds should carry the privately held firm "well into next year," said Robert Heft, president and CEO.

It's the first private placement for Enobia, which previously raised more than \$100 million in venture capital, with the most recent round being a \$50 million Series C closed in 2009. For the latest fundraising effort, Enobia decided to tap financial institutions and pharmaceutical firms. (See *BioWorld Today*, Aug. 11, 2009.)

To date, most of Enobia's focus has been on ENB-0040 (asfotase alfa), a recombinant fusion protein version of alkaline phosphatase, an enzyme involved in bone

See Enobia, Page 4

Immunology "Right at the Front"

GWAS More than Doubles Known MS Risk Genes

By Anette Breindl
Science Editor

A multinational team reported results yesterday from the largest genomewide association study to date looking at genetic risk factors underlying multiple sclerosis (MS). The study, which looked at nearly 10,000 individuals with multiple sclerosis and more than 17,000 healthy controls, has confirmed most of the 26 potential risk genes identified to date, and found an additional 29 variants that correlate with risk. The results were published in the Aug. 11, 2011, issue of *Nature*.

The fact that MS has a genetic component has long been clear, but identification of the specific genes involved has been slow in coming.

After an association with HLA genes was identified in 1972, senior author Alastair Compston, professor of

See MS, Page 5

From Dyslipidemia to Cardiac Risk Prevention

With New SPA for Fish Oil Drug, Amarin is on its Way

By Catherine Shaffer
BioWorld Today Contributing Writer

Amarin Corp. plc and the FDA have reached an agreement on a special protocol assessment (SPA) for the design of a cardiovascular outcomes study (REDUCE-IT) of AMRIOI. The drug, a prescription-grade fish oil, has already turned in impressive results for dyslipidemia in two previous Phase III trials.

A successful outcome in REDUCE-IT may allow Amarin, of Dublin, Ireland, to market the drug for prevention of cardiac events in an at-risk population. The trial will enroll approximately 8,000 patients and will take around six years to complete. Patients with cardiovascular risk factors will receive an optimized statin regimen plus AMRIOI or statins alone, with the goal of measuring outcomes.

Leerink Swann analyst Joseph Schwartz commented,

See Amarin, Page 6

INSIDE:

OTHER NEWS TO NOTE: AFFYMAX, AVILA, GENESIS, IRONWOOD2
CLINIC ROUNDUP: ADOLOR, GLENMARK PHARMACEUTICALS.....2



Other News To Note

- **Affymax Inc.**, of Palo Alto, Calif., received a \$10 million milestone payment from **Takeda Pharmaceutical Co. Ltd.**, of Osaka, Japan, triggered by the acceptance and filing of a new drug application for peginesatide by the FDA. The companies are seeking approval of peginesatide as a once-monthly erythropoiesis stimulating agent for anemia associated with chronic kidney disease patients on dialysis. (See *BioWorld Today*, June 1, 2011.)

- **Avila Therapeutics Inc.**, of Bedford, Mass., relocated to a 23,000-square-foot facility in Bedford.

- **Genesis Biopharma Inc.**, of Los Angeles, inked a five-year cooperative research and development agreement (CRADA) with the National Cancer Institute to develop adoptive cell immunotherapies designed to destroy metastatic melanoma cells using a patient's tumor infiltrating lymphocytes. Specifically, the CRADA will support the in vitro development of improved methods for the generation and selection of tumor infiltrating lymphocytes with antitumor reactivity from melanoma patients, develop approaches for large-scale production of those lymphocytes and allow the conduct of clinical trials.

- **Ironwood Pharmaceuticals Inc.**, of Cambridge, Mass., and **Forest Laboratories Inc.**, of New York, submitted a new drug application to the FDA for linaclotide for the treatment of irritable bowel syndrome with constipation and chronic constipation. The guanylate cyclase type-C agonist was evaluated in a Phase III program comprising more than 2,800 patients in four double-blind, placebo-controlled trials and more than 3,200 patients in ongoing open-label, long-term safety studies. Ironwood and Forest plan to co-promote linaclotide in the U.S. Ironwood out-licensed the drug to **Almirall SA**, of Barcelona, Spain, for European development. Tokyo-based **Astellas Pharma Inc.** will develop and commercialize linaclotide in Indonesia, Japan, Korea, the Philippines, Taiwan and Thailand. (See *BioWorld Today*, Nov. 3, 2010.)

Stock Movers

08/10/11

Company	Stock Change	
Nasdaq Biotechnology	-\$45.96	-4.92
Arena Pharmaceuticals Inc.	-\$0.16	-11.03%
NeurogesX Inc.	-\$0.30	-14.63%
Osiris Therapeutics Inc.	-\$0.80	-13.84%
Protalix BioTherapeutics Inc.	-\$0.63	-12.30%
Telik Inc.	-\$0.17	-41.78%

(Biotechs showing significant stock changes Wednesday)

Clinic Roundup

- **Adolor Corp.**, of Exton, Pa., reported top-line data from two randomized, double-blind, placebo-controlled Phase II trials of ADL5945 for opioid-induced constipation. When dosed twice daily, high-dose ADL5945 significantly increased the weekly number of spontaneous bowel movements vs. placebo (3.4 SBMs vs. 1.4 SBMs; $p = 0.0003$). The difference for the low-dose group (2 SBMs) was not significant. High-dose ADL5945 also significantly improved SBMs with once-daily dosing. The drug, a peripherally acting mu opioid receptor antagonist, was well tolerated.

- **Glenmark Pharmaceuticals Ltd.**, of Mumbai, India, initiated two Phase IIb dose-ranging trials of Revamilast (GRC 4039) for asthma and rheumatoid arthritis. Revamilast is an oral phosphodiesterase 4 inhibitor.

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Adventrx

Continued from page 1

with additional cash runway as we continue to advance our ANX-188 and -514 programs," CEO Brian Culley said in an investors call Wednesday.

With a Sept. 1 PDUFA date, the San Diego-based company had been gearing up for a fourth-quarter launch of Exelbine as a treatment for non-small-cell lung cancer. All of that was put on hold when the biotech received the complete response letter this week.

If the FDA won't back down on its request for another bioequivalence study, Adventrx will look to out-license Exelbine, Culley said. That would save the company the cost of another trial, as well as launch expenses.

While the cost of running the trial is relatively low, about \$1 million to \$2 million, and the company has the capital; time is an issue. Culley estimated such a trial could stretch out 18 to 24 months.

"Our resources and focus are on ANX-188 and ANX-514, which we believe are the long-term value drivers for our company," Culley said. "Our cash and equivalents of \$40.7 million at July 31, plus cost savings from delaying or potentially discontinuing the Exelbine program, will provide us the capital to continue to advance both of these programs."

The biotech is finalizing the protocol for a Phase III pediatric sickle cell trial for ANX-188 that's expected to begin next year. ANX-514, also in late stage, is a detergent-free reformulation of Sanofi SA's blockbuster cancer drug Taxotere, which recently went off patent.

In light of these other products, "our goal is to make a decision regarding the future of the Exelbine program as rapidly and with as little capital outlay as possible," Culley said.

The majority of the issues the FDA raised in the complete response letter dealt with product quality. Adventrx had already responded to all of the issues, which have been raised in the past. Culley noted that the agency's complete response letter did not take into consideration the responses the company made this past spring and summer.

In the refuse-to-file letter issued last year, the FDA said Adventrx's commercial manufacturing site was insufficient to support a commercially viable expiration dating period for Exelbine. The agency requested 12 months of site-specific, real-time stability data from the intended commercial manufacturer. That letter set the Exelbine program back several months. (See *BioWorld Today*, March 2, 2010.)

Sites Discarded Study Samples

This week's complete response letter also raised concerns about the pivotal bioequivalence study conducted in Argentina under the 505(b)(2) pathway that compared Exelbine with GlaxoSmithKline plc's Navelbine. Based on inspections at two of the seven clinical sites this year, the

FDA said it could not verify the authenticity of the drug products used in the trial, placing the results of the trial into question.

FDA regulations require clinical sites to maintain reserve samples of the drugs used in a trial so its inspectors can ensure that no alterations or substitutions were made. But the two sites inspected were not able to produce the reserve vials.

Culley explained that the study used commercially approved vials of Navelbine, which expired in March 2008. Following the expiration date, the sites removed the samples from refrigerated storage and then destroyed them. Given that the samples would have been expired for more than three years, they would have been difficult to authenticate at the FDA's June inspection.

Culley acknowledged mistakes were made. But since the study was not blinded and the study and reference drugs had different packaging, preparation procedures and physical characteristics, sites would not have confused the two products, he said.

It would be like confusing skim milk with water, Culley added, noting that Navelbine is transparent and colorless, while Exelbine is semitransparent and white to off-white.

"For these reasons, we stand by the authenticity of the study drugs used in the Exelbine pivotal study and the integrity of our data," he said.

Should Adventrx decide to out-license Exelbine, it would conjure more *deja vu*. The company out-licensed its folate-based cancer drug CoFactor to Theragence Inc., of San Diego, last year. Adventrx had shelved the drug for a few years following disappointing Phase IIb data so the company could focus on Exelbine. (See *BioWorld Today*, June 11, 2010.) ■

Appointments and Advancements

- **Palatin Technologies Inc.**, of Cranbury, N.J., added Alan W. Dunton to its board.
- **PharmacoFore Inc.**, of San Carlos, Calif., appointed Joseph Stauffer chief medical officer and vice president of corporate strategy and named Narinder Banait vice president of intellectual property.
- **PharmAthene Inc.**, of Annapolis, Md., elected Mitchel Sayare chairman.
- **Portola Pharmaceuticals Inc.**, of South San Francisco, added Michael M. Kitt as senior vice president and chief medical officer.
- **Pozen Inc.**, of Chapel Hill, N.C., formed a digital advisory board that includes Raj Amin, John Bax, Bonin Bough, Marc Monseau, Daniel Palestrant and Meredith Ressi. The company also appointed Tomas S. Bocanegra executive vice president of development.
- **Prime Therapeutics**, of St. Paul, Minn., added Michael Showalter as chief marketing officer.

Enobia

Continued from page 1

mineralization. HPP, which has been estimated to affect potentially 1 in 100,000 newborns, results from mutations in the gene for alkaline phosphatase and, depending on those mutations, the disease runs from mild conditions that affect the teeth to more severe forms that result in rickets and osteomalacia and, in the most severely affected can lead to death.

ENB-0040 is designed to replace the deficient enzyme, with modifications aimed at improving the pharmacokinetics compared to the natural enzyme while targeting the drug specifically to bone, Heft said.

Following promising preclinical studies, which showed that ENB-0040 significantly increased survival, prevented hypomineralization associated with HPP and appeared to heal bones that had been severely weakened by the disease, Enobia launched clinical programs. So far, there has been "a lot of excitement" around early data from two six-month Phase I/II studies, one in infants and one in pediatric patients ages 5 to 12, Heft told *BioWorld Today*, adding that updated results are expected this fall at the Society for the Study of Inborn Errors of Metabolism meeting in Geneva and at the American Society for Bone and Mineral Research meeting in San Diego.

Patients in both studies were rolled over into an extension

trial. Those in the infant study include patients who have been on ENB-0040 for more than 2.5 years, Heft said.

Data from an ongoing Phase II trial in 19 adult and adolescent patients are expected in the second quarter of next year. That study is measuring the effect of ENB-0040 on HPP-related osteomalacia using trans-iliac crest bone biopsy as the primary endpoint.

Pending positive data from that trial, there's a chance Enobia could seek approval. Heft said the firm is in "multiple discussions" with regulatory agencies in the U.S. and Europe. "Our hope is that we will have a data package" that will be sufficient. For now, the firm holds all rights to the drug and has not yet finalized its strategy. But Enobia could easily take ENB-0040 into the market on its own in the main U.S. and European markets, as other small biotechs have done with ultra-orphan products.

ENB-0040 has orphan designation in both areas. And it recently added \$1.2 million through an FDA Orphan grant for long-term treatment of infants and young children with severely debilitating or life-threatening HPP. That study currently has about 10 patients enrolled. Besides HPP, Enobia is hoping to build a pipeline of drugs for other rare bone disorders, and funds from the latest financing also will go toward an undisclosed preclinical program.

BofA Merrill Lynch acted as exclusive placement agent for the financing. ■

Other News To Note

- **Marina Biotech Inc.**, of Bothell, Wash., reported in vivo data showing that a single-stranded oligonucleotide construct, modified with the company's conformationally restricted nucleotide (CRN) technology, demonstrated high potency and good tolerability in inhibiting microRNA-122. The CRN modified antagonist was highly effective at a dose of 10 mg/kg, while demonstrating good tolerability with repeat dosing.

- **Medivation Inc.**, of San Francisco, expects to report interim analysis data this year from its Phase III AFFIRM trial, which is evaluating MDV3100 on overall survival in 1,199 men with advanced prostate cancer who have previously been treated with docetaxel-based chemotherapy. Medivation is partnering with **Astellas Pharma Inc.**, of Tokyo, to develop the androgen receptor antagonist across the spectrum of advanced prostate cancer disease states. (See *BioWorld Today*, March 19, 2009.)

- **Paladin Labs Inc.**, of Montreal, made an offer to acquire all existing and outstanding shares of **Afexa Life Sciences Inc.**, of Edmonton, Alberta, for 55 cents per share. Afexa derives most of its income from its cold and flu remedy, Cold-Fx, marketed in Canada to reduce the frequency, severity and duration of cold and flu symptoms. In July, Paladin purchased 15,421,300 shares of Afexa stock, to achieve beneficial ownership of 14.94 percent of shares

in the company. The offer follows failure of previous acquisition discussions between Paladin and Afexa.

- **Pharmacyclics Inc.**, of Sunnyvale, Calif., signed a five-year cooperative research and development agreement (CRADA) with the National Cancer Institute (NCI) for the development of PCI-32765, a Bruton's tyrosine kinase inhibitor for treatment of blood cancers. Under the agreement, the NCI will sponsor Phase I and II trials of the drug for various types of cancers, including non-Hodgkin lymphoma and multiple myeloma.

- **Prolor Biotech Inc.**, of Nes-Ziona, Israel, will receive a grant from Israel's Office of the Chief Scientist for the development of its long-acting human growth hormone, hGH-CTP. It will use the \$1.7 million grant to advance hGH-CTP into Phase III trials following positive results from a Phase II trial in adults with growth hormone deficiency.

- **Salix Pharmaceuticals Ltd.**, of Raleigh, N.C., said in its second quarter earnings update that it will continue to develop Xifaxan (rifaximin) 550-mg tablets for irritable bowel syndrome (IBS). The drug is approved for traveler's diarrhea and hepatic encephalopathy, but received a complete response letter for IBS earlier this year. Salix said an FDA advisory committee will be convened in November to help finalize the plans for a retreatment study. Salix anticipates starting the study late this year or early 2012, and expects it would take two years to complete the trial and reach an FDA decision. (See *BioWorld Today*, Feb. 25, 2011.)

MS*Continued from page 1*

neurology at the University of Cambridge, told reporters at a press conference announcing the findings there was “complete radio silence for 35 years, where nothing else was learned” about the genetic underpinnings of the disease until 2007.

In 2007, two more risk genes were identified; and since then, there have been “a trickle of studies” identifying 26 possible risk genes in all. The study now published in *Nature*, Compston said, brings that number “from 26 possibles to 57 certainties.”

The team estimated that the variants they have identified account for 20 percent of all genetic risk. It’s a fuzzy number, since it’s unclear just how much of the total risk for developing MS is genetic.

But the study’s value does not come from the number of genes, or the percentage of total risk, it has identified.

For one thing, it allows researchers to look directly at patients to better understand the disease. The MS research agenda, Danny Altmann, of the Wellcome Trust, told reporters, has to some extent been driven by mouse models. “A paper like this marks a shift, where we can start to get insights from human patients themselves.”

For another, Compston said, the pathways that are implicated by the 57 genes “tell a very coherent story,” and it is a story that “puts immunology” – and in particular, T cells – “right at the front end of the disease, unambiguously.”

Over time, there are clearly several different things that go awry in multiple sclerosis. The disease is characterized by inflammation, degeneration and a lack of repair processes. One of the major current scientific debates, though, is which of those aspects originally goes wrong.

The current debate is around “which is more important: inflammation or degeneration,” Compston said. His team’s results strongly favor the idea that “This disease begins with inflammation, and everything else follows.”

The findings do not revolutionize the concept of what multiple sclerosis is. “Is this brand new; is this a Eureka moment? The answer to that is no,” Compston told reporters, with refreshing honesty.

But, he added, the work is still much more than “just a catalog” of variants that amount to little more than a list of unvalidated drug targets.

Peter Donnelly, of the Wellcome Trust, added that, “a somewhat overused analogy, but not unhelpful,” would be to think of the study as providing more pieces of a large and complex jigsaw puzzle. “They don’t give you the whole picture from the jigsaw. But there are enough of them that if you look carefully” one can draw out the key role of some of the biology.

One piece of that biology is how MS relates to other autoimmune diseases. More than a third of the genes identified in the new study are also known to be involved in other autoimmune diseases.

Those relationships, Donnelly told reporters, will be “a pretty exciting story to develop over the years ahead. . . . We’re just at the relative early stage . . . in understanding the similarities and the differences between each of those diseases in terms of the genetic part of their risk.”

The primary motivation behind the study was not to find new drug targets, but rather to gain a deeper understanding of what’s going on in MS that can then drive further research. But the findings do validate the current treatment approaches, which are focused on the immunological component of the disease.

Compston said that over time, MS treatments have become more effective, but can also have more severe side effects. This in turn has led some to argue that targeting the degenerative or repair aspects of the disease offers a better chance at developing more effective and safer treatments.

“What this study does,” Compston said, “is to say, ‘Yes, this is the right approach . . . press on in this direction.’” ■

Other News To Note

• **XenoPort Inc.**, of Santa Clara, Calif., and London-based **GlaxoSmithKline plc** submitted a supplemental new drug application seeking FDA approval of Horizant (gabapentin enacarbil) extended-release tablets for postherpetic neuralgia. Horizant is approved for restless legs syndrome. (See *BioWorld Today*, April 8, 2011.)

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Amarin

Continued from page 1

“We are impressed with AMRN’s ability to obtain a third SPA so rapidly, for a CV outcomes study, which is rare.”

AMRI01 performed better than expected in Amarin’s Phase III (ANCHOR) trial by hitting both primary and secondary endpoints at all of the doses tested. The drug lowered triglyceride levels by 21.5 percent at a dose of 4 g per day, and 10.1 percent at the 2 g per day dose. (See *BioWorld Today*, April 19, 2011.)

Even better, AMRI01 did not show elevation in low-density lipoprotein-cholesterol (LDL-C). In fact, patients in both dose groups showed a decrease in LDL-C. At 4 mg per day, the reduction of 6.2 percent was statistically significant.

The LDL cholesterol data is a key differentiator from the Japanese drug Epadel (Mochida Pharmaceutical Co. Ltd.), which has been marketed there for more than 20 years. AMRI01 and Epadel share the same active ingredient eicosapentaenoic acid (EPA)-rich fish oil. AMRI01, however, does not contain docosahexaenoic acid (DHA), which is associated with undesirable increases in LDL-cholesterol.

AMRI01 had already done well in the earlier MARINE study, which enrolled patients with triglyceride levels higher than 500 mg/dL. ANCHOR enrolled patients with triglycerides higher than 200 mg/dL. (See *BioWorld Today*, Nov. 30, 2010.)

Because about 1 in 50 adults in the U.S. have triglyceride levels above 500 mg/dL, and 1 in 5 have levels above 200 mg/dL, the market opportunity for AMRI01 is easily in the 10-figure range. Adding prevention of cardiac events to the label via the REDUCE-IT trial could multiply that many-fold.

AMRI01 will go toe to toe with Lovaza (omega-3-ethyl esters; GlaxoSmithKline plc). The advantage is expected to go to AMRI01 in that match, because Lovaza lacks AMRI01’s LDL-C-lowering activity. In fact, Lovaza raises LDL-C.

Schwartz wrote, “Based on our prior analysis and positive Epadel outcomes data, we believe AMRI01 will be able to demonstrate an outcomes benefit and thus be on track to become the only non-statin lipid-lowering agent to demonstrate an outcomes benefit.”

Schwartz also noted that “usually no SPAs are granted for outcomes studies.”

The six-year, 8,000-patient study is expected to cost between \$100 million and \$125 million total, with about \$25 million incurred by the end of 2012, at which time Amarin expects to have achieved 50 percent enrollment, and plans to file for approval in the mixed dyslipidemia (ANCHOR) indication.

Joseph Pantginis, of Roth Capital Partners, also liked Amarin’s prospects under the REDUCE-IT SPA: “We also believe the SPA helps to incrementally further de-risk the story in the company’s ongoing discussions with potential partners. . . . The goal of this study is to pursue a broad label expansion of AMRI01 encompassing cardiovascular event

reduction. Based on current enrollment projections for this study, we remain comfortable with our 2013 projection for sNDA approval based on the ANCHOR study.”

Thomas Wei, an equity analyst with Jefferies and Co., wrote, “We are encouraged that AMRN has completed SPA negotiations with the FDA in a timely fashion to enable a 4Q11 start to REDUCE-IT. Although we still need to see the specifics of the trial design, the details shared to date do not raise concerns about enrollment or the ability to demonstrate a positive outcomes benefit.”

With all of the pieces falling into place for approval of AMRI01 with a later expanded label, the next logical step for Amarin is partnership or acquisition. The company has been in partnership discussions, with ANCHOR results conferring a most-eligible status. Stakeholders are hoping to hear wedding bells in the near future. ■

Appointments and Advancements

- **ProtAffin AG**, of Graz, Austria, appointed Frank Walsh chairman and named Tim Edwards to the board.

- **Provectus Pharmaceuticals Inc.**, of Knoxville, Tenn., added Stuart Fuchs to its corporate advisory board. It also appointed Alfred E. Smith IV to its board.

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