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Clinical Data to Earn up to \$252M

CombinatoRx Gains Adenosine Agonist Rights in Surprise Deal

By Catherine Hollingsworth
Staff Writer

Clinical Data Inc. entered a collaboration and licensing agreement with CombinatoRx Inc. to develop an adenosine A2A agonist compound in a combination therapy for multiple myeloma and other B-cell cancers, but the deal might be more strategic than lucrative.

Under the terms, Clinical Data licensed ATL313 to CombinatoRx in exchange for up to \$252 million in clinical, regulatory and commercial milestones, as well as royalties on product sales.

There is no apparent up-front payment coming from Cambridge, Mass.-based CombinatoRx, which is low on cash and has its own set of programs that need funding. At the end of June, CombinatoRx reported having just \$30.6

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Dmab OK for Treatment, Not Prevention

FDA Panel Hands Amgen Mixed Bag in Osteoporosis, Cancer

By Donna Young
Washington Editor

GAITHERSBURG, Md. – An FDA panel Thursday said Amgen Inc.'s denosumab should be approved to treat osteoporosis in postmenopausal women, but rejected the drug as therapy to prevent the disease in that population because of safety issues and concerns about the unknown risks of using the drug long term.

In addition, the FDA's Reproductive Health Drugs Advisory Committee voted against denosumab as a therapy to treat or prevent bone loss associated with hormone ablation therapy in patients with breast cancer.

But the panel split on the same indication for bone loss associated with hormone ablation therapy in prostate cancer, backing it as a treatment but rejecting it as a preven-

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Third-time Prochymal Charm?

Osiris: No Subjective Endpoint, but Placebo Danger Still Looms

By Randy Osborne
Staff Writer

Braced for a potential third strike or an over-the-fence hit with Prochymal in the first week of next month – when two Phase III trials are due to report data – investors in Osiris Pharmaceuticals Inc. are understandably edgy about a potentially high complete response rate in the placebo arm of the study, which is testing the mesenchymal stem cell product in graft-vs.-host disease.

It's been a problem before. Prochymal sputtered out this spring in a Phase III trial against Crohn's disease. Osiris, of Columbia, Md., quit the study 60 patients away from the 270-subject enrollment goal, blaming an interim analysis that found a higher-than-expected placebo effect, as well as possible bias in patient reporting. (See

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NEW CO NEWS

Sorrento Finds More Ways to Skin CAT in RNA Method

By Trista Morrison
Staff Writer

Sorrento Therapeutics Inc., with a patented platform for generating fully human monoclonal antibodies, is hoping to fill the void created over the last few years by big pharma's antibody acquisition spree.

There are a "limited number of gateway technologies" for the creation of human antibodies, Sorrento president and CEO Antonius "Toni" Schuh explained, adding that most of those technologies have been "locked up."

Cambridge Antibody Technology Group plc was bought by AstraZeneca plc for \$1.3 billion, Domantis Ltd.

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FINANCINGS ROUNDUP

• **BioSante Pharmaceuticals Inc.**, of Lincolnshire, Ill., said it received commitments from three institutional investors to purchase \$12 million of securities in a registered direct offering. The company will sell an aggregate of 6 million shares of stock and warrants to purchase up to 2.4 million shares. Each unit, consisting of one share and a warrant to buy 0.4 of a share, will be priced at \$2. The firm expects to receive net proceeds of about \$11.1 million, which will be used to advance its late-stage LibiGel program for female sexual dysfunction. Rodman & Renshaw LLC acted as exclusive placement agent.

• **Seattle Genetics Inc.**, of Bothell, Wash., said underwriters exercised in full their option to purchase an additional 1.65 million shares of common stock, bringing the total shares sold in the public offering to 12.65 million. Gross proceeds will be about \$136 million. The offering, set to close Aug. 17, is expected to fund R&D efforts, including manufacturing activities and clinical trials, the buildout of commercial infrastructure and for general corporate purposes. (See *BioWorld Today*, Aug. 13, 2009.)

APPOINTMENTS AND ADVANCEMENTS

Advanced Cell Technology Inc., of Worcester, Mass., named Edmund Mickunas vice president of regulatory matters.

aTyr Pharma Inc., of San Diego, named Bruce Beutler to its scientific advisory board.

Benitec Ltd., of Melbourne, Australia, appointed Peter French chief scientific officer.

Bioceros BV, of Utrecht, the Netherlands, appointed Mark Treherne chairman of the supervisory board.

DxS Ltd., of Manchester, UK, appointed Dave Clennell director of quality.

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EGEN Inc., of Huntsville, Ala., promoted Jason Fewell to vice president of preclinical research and development.

Nuon Therapeutics Inc., of San Mateo, Calif., appointed Paulette Dillon chief business officer and Tito Serafini chief scientific officer.

Progenitor Cell Therapy LLC, of Hackensack, N.J., appointed Daryl LeSueur vice president of manufacturing operations.

Topica Pharmaceuticals, of Palo Alto, Calif., elected G. Kirk Raab chairman.

Xanodyne Pharmaceuticals Inc., of Newport, Ken., appointed Natasha Giordano as chief commercial officer, Rita O'Connor as chief financial & information officer, and Peter Wentworth as senior vice president for human resources.

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AHC Media LLC

Clinical Data

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million in cash and equivalents, compared to \$39.2 million the previous quarter.

So while it may look “a little weird” for a company hurting for cash to be entering such a deal, no dollars are changing hands at this point, analyst Gregory Wade, of Wedbush PacGrow Life Sciences, told *BioWorld Today*. “It’s all about getting the ball down the field a little bit.”

CombinatoRx will be responsible for the preclinical and clinical development of ATL313 as a potential treatment for B-cell malignancies. Such cancers include non-Hodgkin’s lymphoma, chronic lymphocytic leukemia, multiple myeloma and other malignancies commonly treated by stem cell transplantation.

Although oncology development is expensive, Wade said promising early data could boost the company’s valuation. CombinatoRx also could be reimbursed for expenses under the deal, he said.

Research thus far has shown that a combination drug approach using adenosine A2A agonists has broad activity in multiple myeloma cell lines and synergy with multiple myeloma standard-of-care therapies, according to Newton, Mass.-based Clinical Data. In addition, results so far have demonstrated potent induction of apoptosis, selectivity and safety.

As for funding its own pipeline of midstage programs, including Synavive for arthritis pain, CombinatoRx has a few possible options, such as partnering, securing additional equity and picking up potential milestone payments

stemming from Exalgo, a product it acquired through a merger with Canadian drugmaker Neuromed Pharmaceuticals Inc. (See *BioWorld Today*, July 2, 2009.)

Exalgo is under FDA review as a potential once-daily hydro-morphone treatment for chronic pain, and an agency action date is set for Nov. 22. Approval would trigger a \$30 million milestone, which potentially could increase up to \$40 million, plus tiered royalties on Exalgo net sales after U.S. approval.

Vancouver, British Columbia-based Neuromed recently sold the U.S. rights to Exalgo to Mallinckrodt Inc., a subsidiary of Dublin, Ireland-based Covidien plc, in a deal worth potentially \$71 million, including \$15 million up front, and tiered royalties.

As for Clinical Data’s cash, the company’s balance sheet is “in OK shape,” Andrew Vaino, an analyst with Roth Capital Partners told *BioWorld Today*. He estimated that the company’s cash could last through the first or second quarter of next year. Vaino said he was not expecting a deal on ATL313 and that he does not see how it helps the company short term. “It wasn’t a particularly rich deal,” he said. Still, he added, he likes the stock solely because of depression drug candidate, vilazodone.

Clinical Data has reported positive results from a confirmatory Phase III trial of lead drug candidate vilazodone in depression. Those results will contribute to a new drug application that is expected to be submitted to the FDA by year-end.

Shares in CombinatoRx (NASDAQ:CRXX) gained 9 cents to close Thursday at \$1.14. Shares in Clinical Data (NASDAQ:CLDA) fell 2 cents, to close at \$15.14. ■

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Denosumab

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tive therapy for those patients.

The committee also said in a 12-to-1 vote that the FDA should require denosumab to have a risk evaluation and mitigation strategy consisting of a patient-friendly medication guide and a communication plan for health care providers. Some also backed a patient registry under the REMS program.

The committee tabled a vote on whether Amgen should be required to provide data evaluating the effects of denosumab on skeletal-related events in advanced cancers, though Richard Pazdur, director of the FDA's Office of Oncology Drug Products, hinted that the agency may seek new studies or further data from the Thousand Oaks, Calif.-based biotech.

Denosumab, which is designed to target RANK ligand, a primary regulator of the formation, function and survival of osteoclasts, has been shown to be effective in reducing the incidence of fractures in postmenopausal women with osteoporosis and in increasing bone mineral density in postmenopausal women with low bone mass and in patients undergoing hormone ablation therapy for breast or prostate cancers.

However, there were higher rates of serious adverse skin, ear and urinary tract infections, new malignancies, tumor metastases, endocarditis and dermatologic reactions in study participants administered denosumab than in the placebo groups.

Drug regulators also had raised concerns that the long-term use of denosumab could result in delayed fracture healing, atypical fracture or osteonecrosis of the jaw.

While the panel voted 15 to 0 that there was a population of postmenopausal women with osteoporosis in which the benefit of treatment with denosumab is likely to outweigh its risk, most of the experts said the drug should be restricted to only those women at high risk of fracture or who have failed other therapies.

In a 12-to-3 vote, the committee said denosumab should not be marketed as a therapy to prevent osteoporosis.

"This treatment, while it may be effective, is related to unknown risks, which may not make the benefit worthwhile," said panel chairwoman Sandra Carson, a professor of obstetrics and gynecology at Brown University.

While the committee voted 9 to 4, with one abstention that denosumab's benefits outweighed its risks in treating bone loss associated with hormone ablation therapy in men with prostate cancer, it voted 11 to 3 that Amgen had failed to demonstrate a favorable risk-benefit profile for the drug as a preventive therapy in that indication.

Amgen also failed to demonstrate a favorable risk-benefit ratio for denosumab as a therapy to treat or prevent bone loss associated with hormone ablation therapy in women with breast cancer, the experts said, voting 13 to 2 and 14 to 0, with one abstention, respectively.

Amgen is seeking to market denosumab under the

brand name Prolia as the first biologic and human monoclonal antibody in the U.S. to treat or prevent postmenopausal osteoporosis and the first medication to treat and prevent bone loss associated with hormone ablation for prostate or breast cancers.

The FDA is not required to take the advice of its advisory committees but does so in most cases.

There currently are 10 products approved in the U.S. to treat postmenopausal osteoporosis, a market that is dominated by bisphosphonates. The medications range in dosing regimens from once-daily tablets to once-yearly injections. Several of those products also are approved as preventive therapies for osteoporosis, a systemic skeletal disorder that affects about 8 million women in the U.S. and 2 million men, with an estimated 34 million Americans at risk of developing the disease.

As a twice-yearly subcutaneous injection, said Ethel Siris, an osteoporosis specialist at Columbia University, denosumab would be considerably more convenient to patients and also would aid doctors in knowing their patients are adhering to their medication regimen.

She noted that most patients stop taking oral osteoporosis drugs within a year of receiving a prescription. "One of the biggest problems in our field is adherence," Siris told panelists.

Shares of Amgen (NASDAQ:AMGN) closed at \$60.86, down \$1.30. ■

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Osiris

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BioWorld Today, March 30, 2009.)

Part of the endpoint used the Crohn's Disease Activity Index, which lets patients report their responses. Osiris theorized that some might have exaggerated their answers on a questionnaire so they would be eligible for continued therapy in a second study. The trial started over.

Subjective accounting by trial participants has its downside but also potential upside as, for example, Auxilium Pharmaceuticals Inc. may discover in its Phase IIb study with Xiaflex, a formulation of collagenase enzyme, in a completely different indication: Peyronie's disease.

Malvern, Pa.-based Auxilium, which also has Xiaflex pending FDA review for Dupuytren's contracture, is using a subjective endpoint in the Phase IIb study, the Peyronie's Patient Reported Outcomes questionnaire. Savvy patients know collagenase injections can cause bruising, so those with no bruising (or beneficial drug effect) may figure out that they are on placebo. That could serve to keep the drug-arm score high – or even raise it, if some drug patients happen not to bruise. Unlike with Osiris' Crohn's trial testing Prochymal, all patients in the Xiaflex study are allowed to continue into an open-label extension study and get the drug.

Patient-reported outcomes are regarded as iffy by researchers, who still avoid them when possible, said Harris Kaplan, CEO of the consulting firm Healogix. "There's pushback and resistance about including them, because [scientists] don't want that subjectivity clouding the hard, tangible data," he said. "Physicians tend not to like this stuff because it's touchy feely."

But "more and more drugs have a highly patient-centric component," Kaplan said, especially in gastrointestinal therapies such as those for Crohn's and irritable bowel syndrome. PROs become important not only in clinical trials but in marketing the drugs later, he noted.

"Co-payments are rising, and you've got to be able to have a message that resonates with patients, in order to get them to come up with their portion," he told *BioWorld Today*. The PRO issue is "affecting every category of drugs, including oncology products," Kaplan said. While becoming more important, PROs still are difficult to refine for reliability.

"This is still an art, and it's a long way from a science," Kaplan said.

After Prochymal's failure in Crohn's came a disappointment in chronic obstructive pulmonary disease. Osiris in June reported that the drug, partnered with Cambridge, Mass.-based Genzyme Corp., proved safe but did not significantly improve lung function. (See *BioWorld Today*, June 25, 2009.)

The COPD failure seemed more straightforward than the outcome in Crohn's, and Osiris-watchers are mulling whether results from either of the studies can be extrapolated into the ongoing GvHD trials. Though of course

there's no subjective questionnaire, the placebo danger looms. Never before have placebo-controlled trials been done in GvHD as large as those by Osiris, which has a total of more than 430 patients in two trials: one in steroid-refractory disease and one in acute.

Enrolling patients with two weeks of onset in the refractory study and keeping background-therapy changes to a minimum in the acute trial could help keep the placebo effect in check. In the "hopeful" column of the ledger is the fact that the acute trial is 90 percent powered to show a 25 percent improvement in complete response – and Prochymal gained a 77 percent CR rate in the Phase II study. The refractory study is 80 percent powered to show a 20 percent improvement over the historic 20 percent CR rate. Osiris has gained a 58 percent rate in an expanded-access program in pediatric patients.

The drug has orphan drug status from the FDA and European authorities, and a rolling biologics license application has begun. ■

CLINIC ROUNDUP

• **BioSante Pharmaceuticals Inc.**, of Lincolnshire, Ill., reported that there have been no deaths and five cardiovascular events so far, according to data from its ongoing LibiGel Phase III development program, which has enrolled more than 1,250 women (almost 825 women-years of exposure). The company said development will continue as planned and is targeting a new drug application submission by mid-2011. LibiGel, a transdermal testosterone gel, is being tested under a special protocol assessment for the treatment of female sexual dysfunction. Shares of BioSante (NASDAQ:BPAX) rose 15.7 percent, or 28 cents, to close Thursday at \$2.06. The firm also is raising \$12 million. (See *Financings Roundup* in this issue.)

• **Hana Biosciences Inc.**, of South San Francisco, achieved its enrollment goal of 56 evaluable subjects in a pivotal Phase II trial of Marqibo (vincristine sulfate liposomes injection) in adult acute lymphoblastic leukemia in second relapse. Hana expects the final patient data to be available by year-end and, assuming positive results, plans to file a new drug application seeking accelerated approval in the first half of 2010. Marqibo has orphan drug and fast-track designations for ALL in the U.S. and orphan designation in Europe.

• **Oncogenex Pharmaceuticals Inc.**, of Bothell, Wash., said the first patient was dosed in a Phase I trial of OGX-427, administered directly into the bladder in patients with bladder cancer. The trial will enroll up to 36 patients and, in addition to safety, will measure the direct effect of the second-generation antisense drug on expression of heat-shock protein 27 in bladder tumor cells. A separate ongoing Phase I study is testing OGX-427 in solid tumors.

Sorrento

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got snapped up by GlaxoSmithKline plc for \$454 million, MorphoSys Inc. signed an extensive billion-dollar deal with Novartis AG, Abgenix Inc. was bought by Amgen Inc. for \$2.2 billion and the list goes on. (See *BioWorld Today*, Dec. 15, 2005, May 16, 2006, Dec. 11, 2006, and Dec. 4, 2007.)

Just last month, Bristol-Myers Squibb Co. moved to take Medarex Inc. off the market with a \$2.4 billion buyout. (See *BioWorld Today*, July 24, 2009.)

Since biotech and pharma companies can no longer turn to those antibody players for library screening, San Diego-based Sorrento is “responding to a market need,” Schuh said.

According to Schuh, Sorrento’s approach is similar to and “at least as good as” that used by Cambridge Antibody Technology. CAT combined known science in a new process, leveraging the properties of leukocytes, used PCR for gene amplification and then applied a display system to obtain a library.

Sorrento’s chief scientific officer, Henry Ji, recognized that PCR wasn’t the ideal amplification technology for the job. It worked well for individual gene sequences but ran into problems when aggressively multiplexed. Ji decided RNA transcription would be better, and set out to get a patent on his version of the process.

That patent was granted in mid-2008, and Schuh came on board a few months later. He was perhaps best-known for his tenure as president and CEO of Sequenom Inc., but he later served as CEO of AviraDx Inc., which was acquired by BioMerieux SA.

Unfortunately, Schuh came to Sorrento in the fall of 2008, “one of the worst times to fundraise.” Although he got a positive response from several venture capitalists and even multiple commitments to lead a financing round, the venture firms kept running into problems and the money never materialized.

Then Opko Health, which was looking for new ophthalmology options after siRNA drug bevasiranib failed a Phase III trial in wet age-related macular degeneration, got wind of Sorrento’s story.

Opko made a \$2.3 million investment in Sorrento in exchange for one-third of the company’s shares and an exclusive license to its antibody library for ophthalmology therapeutics.

Last month, Sorrento announced plans to access another \$2 million through a reverse merger with the public shell QuikByte Software Inc. The reverse merger is expected to close in the third quarter and will give Sorrento a bulletin board listing.

Schuh noted that as a bulletin board stock, Sorrento still could represent an investment opportunity for venture capitalists, as well as attract traditional funds and investors.

For now though, Sorrento has enough money to last 18

months to 24 months. By then, the company hopes its antibody collaboration revenues will cover its operating costs.

A master antibody library for partners to screen should be up and running within 12 months, and Sorrento also is interested in generating custom libraries for clients. Schuh said such libraries might be based on a small group of SARS patients who achieved spontaneous remission, or certain cancer patients who had a good response to a particular treatment.

In the longer term, Sorrento also envisions creating its own antibody pipeline, although Schuh said it is unclear how far forward the company would advance those candidates before partnering or licensing.

What’s to stop Sorrento from being snapped up like the rest of the antibody players? Schuh said “every biotech company is essentially for sale every day,” and Sorrento’s investors would no doubt consider an acquisition at the right time.

But, he added, the company should be able to develop a “substantial” operation before that day comes. ■

OTHER NEWS TO NOTE

• **King Pharmaceuticals Inc.**, of Bristol, Tenn., said the FDA approved Embeda (morphine sulfate and naltrexone hydrochloride) extended-release capsules, a long-acting opioid analgesic for the management of moderate to severe pain when a continuous opioid analgesic is needed for an extended period of time. King anticipates launching the drug next month. Embeda is designed with an inner core of naltrexone hydrochloride aimed at making it difficult for drug abusers to extract the active ingredient, though regulators have said that clinical evidence of the drug’s tamper resistance has not been clearly established. The FDA’s approval came nearly eight months after the original Dec. 30 PDUFA date. King acquired rights to Embeda through its \$1.6 billion acquisition of Bridgewater, N.J.-based **Alpharma Inc.** last year. (See *BioWorld Today*, Nov. 25, 2008.)

• **VaxGen Corp.**, of South San Francisco, was sent a letter from some of its shareholders seeking a change in the company’s strategy and board membership, and accusing VaxGen’s board and management of “lavishly” spending money while failing to secure a partnership, merger or other transaction. The company, which has been floundering since losing an \$877 million government contract, had plans last year to merge with **Raven Biotechnologies**, a private San Francisco-based firm, but shareholder opposition scuttled that deal. As of June 30, VaxGen had about \$35.6 million in cash, equivalents and investment securities. (See *BioWorld Today*, March 31, 2009.)

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