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Medicure Acquires Marketed CV Drug Aggrastat From MGI

By Karen Pihl-Carey
Senior Staff Writer

As a complement to its lead cardiovascular drug, MC-1, Medicure Inc. acquired rights to its first marketed product, Aggrastat, a glycoprotein IIb/IIIa inhibitor to treat acute coronary syndrome.

Taking over all U.S. sales responsibilities from MGI Pharma Inc. means Winnipeg, Manitoba-based Medicure will have its own contracted sales force and begin to post its first revenues since its 1997 founding.

"It's a perfect fit with the strategic goal of getting a product that is complementary to our lead drug, MC-1, in the acute cardiovascular space," said Albert Friesen, Medicure's president and CEO. "So the target market is one that we are developing with an existing drug."

Terms call for Medicure to pay MGI Pharma $19 million

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HGS Outlines LymphoStat-B's Phase III Plan; Riquent Returns

By Aaron Lorenzo
Washington Editor

Late-stage lupus drug development is moving forward for Human Genome Sciences Inc. and La Jolla Pharmaceutical Co., both of which unveiled Phase III plans Wednesday.

HGS will begin patient enrollment over the next few months in a two-trial pivotal program to test systemic lupus erythematosus patients' response to LymphoStat-B (belimumab), a drug designed to treat an underlying cause of the chronic, life-threatening disease. Already the Rockville, Md.-based company has received positive feedback on the studies' major components from U.S. and European regulatory authorities, including a primary efficacy endpoint based on an innovative composite measure, and plans are in the works to soon submit the final Phase III designs to the FDA for a special protocol assessment.

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For Toll-Like Receptors, Anatomy Is Destiny

CpGs Tweak Cells Toward Innate, Adaptive Immunity

By Anette Breindl
Science Editor

As an infection progresses, the body's arsenal for fighting it changes.

The body's first batter up is the innate immune system, which is fast but fairly nonspecific. The adaptive immune system, which is more specific but takes time to gear up, comes later in the game.

But while the body's response team changes during the course of an infection, some of the players don't. One cell type involved in both the innate and the adaptive immune response is the plasmacytoid dendritic cell. And in the July 24, 2006, issue of *Journal of Experimental Medicine*, scientists from Berkeley, Calif.-based Dynavax Inc. and the University of Michigan at Ann Arbor have pub-

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Altor Moving To Clinic With T-Cell Receptor-Based Drug

By Jennifer Boggs
Staff Writer

Though it has maintained a relatively low profile since its founding four years ago, Altor BioScience Corp. has made steady progress with its T-cell receptor program and anticipates filing its first investigational new drug application later this year.

The company recently garnered attention with news of a Phase II Small Business Innovation Research grant to develop a method of producing antibodies in transgenic lettuce, as part of President Bush's order to encourage innovation in manufacturing. That transgenic lettuce technology, licensed from Sunol Molecular Corp., previously was the subject of Phase I SBIR funding, and has shown an ability to produce therapeutically relevant antibodies.

"We've been getting quite a bit of response since we

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Altor

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released news of the [Phase II grant]," said Hing Wong, chairman and CEO of the Miramar, Fla.-based firm that was spun out of Sunol, also of Miramar, in August 2002.

Wong is happy his firm is one of the leaders in plant-produced antibody technology – expected to be far more economical manufacturing method than the existing mammalian-cell production – but much of Altor's work to date has focused on its T-cell receptor (TRC)-based protein therapeutic program. Its soluble T-cell antigen receptor (STAR) technology, along with its single-chain major histocompatability complex receptor (MHC) platform, also came from Sunol, a company founded by Wong in 1996 as a spin-out of Deerfield, Ill.-based Baxter International.

"We carried a lot of technology from Baxter [covering] targeted immunotherapies," Wong said. "What we're focusing on at Altor is how to manipulate and use the TCR and MHC molecules to create therapies for cancer and viral infections."

The company's lead compound is designed to target the TRC antigen on p53, an oncogene expressed in more than 50 percent of tumors.

"But the antigen is not placed on the cell surface, so an antibody approach would not work," Wong told *BioWorld Today*. "The only way to recognize the antigen is by using TCR, and then we can use that to carry the cytokine to the tumor site."

Altor is in the late stages of preclinical work on the compound and is finishing up GMP manufacturing procedures, and Wong said an IND is expected before the end of the year.

"It's pretty exciting for us, and there's a lot of data," he said. "The key thing is moving into the clinic and getting proof of principle [needed to] convince everyone that the TCR approach will work."

TCR-based protein drug development is a fairly young field. Oxford, UK-based Avidex Ltd. is focused on the area, and has started a Phase I program for its lead product, RhuDex, a TRC drug targeting CD80 in rheumatoid arthritis. It has several other early programs in inflammatory disease and cancer.

In addition to its lead program in cancer, Altor is investigating the use of TCRs in infectious diseases, largely through grants and collaborations with research institutions, and expects to "be moving into preclinical with those soon," Wong said.

Last year, the company agreed to work with Massachusetts General Hospital and the Howard Hughes Medical Institute on viral-specific TCRs for research, diagnosis and treatment of HIV and hepatitis C infections. And in 2003, Altor received a grant from the National Institute of Allergy and Infectious Disease for developing an antiviral against cytomegalovirus.

Altor received its initial funding from Sunol, and later conducted an undisclosed Series B round led by San Mateo, Calif.-based Sanderling Ventures. Wong expects the next VC round to be a "modest" one of "$10 million to $15 million, max."

"We do not need a whole lot of capital," he said, adding that the company would prefer to "rely on non-dilutive cash, which is better for shareholders."

The next round, combined with existing cash plus revenue from collaborations and 14 SBIR grants "should take us through Phase II proof of concept" with the lead program.

Many of Altor's collaborations stem from its reagents business. Using its STAR technology, the company developed products for detecting disease targets presented on the surface of cells and tissues. Those products are designed to evaluate the presence of peptides in the context of MHC molecules on cancer and virally infected cells, and are intended to assist with the discovery of diagnostic and therapeutic approaches.

Wong said Altor is a small company, and "we intend to keep it that way."

Once the lead candidate has progressed through proof-of-concept studies, Altor plans to seek a partner for late-stage development and commercialization.

"For the other molecules, we have not made up our minds yet," he said. "But our strategy is always to get into late stage before partnering." ■

OTHER NEWS TO NOTE

• **BioCryst Pharmaceuticals Inc.**, of Birmingham, Ala., saw its shares drop 15 percent Wednesday after reporting a net loss of $10.1 million, which came to 35 cents per share for the quarter ending June 30. Analysts predicted a loss of 29 cents per share. BioCryst attributed the wider loss to costs associated with its peramivir and Fodosine trials. The company ended the quarter with a cash position of $74.7 million. Shares of BioCryst (NASDAQ:BCRX) closed at $8.96, down $1.79.

• **Introgen Therapeutics Inc.**, of Austin, Texas, reached an agreement with the FDA to incorporate the use of Introgen's biomarkers in the analysis of Advexin clinical data in support of the drug's approval as a p53 cancer therapy. Advexin is in Phase III trials in head and neck cancer.

• **Lipid Sciences Inc.**, of Pleasanton, Calif., closed a private placement of common stock and warrants with institutional and accredited investors, raising $6.3 million in gross proceeds. The almost 5 million shares of common stock were priced at $1.26 each, and the warrants are exercisable for a period of five years beginning Feb. 9, 2007. If all of the warrants are exercised, the company has the potential to raise about $2.3 million in additional gross proceeds. Lipid Sciences plans to use the funds for product development efforts, including the completion of its human clinical trial for HDL Selective Delipidation.