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PAGE 1 OF 7

Targacept, AZT Depression Drug Candidate Enters Home Stretch

By Catherine Hollingsworth
Staff Writer

Targacept Inc. and AstraZeneca have enrolled the first patient in a Phase III program for depression drug candidate TC-5214, which showed positive results in Phase II testing as an add-on therapy for patients who did not respond well to prior treatment with another antidepressant, citalopram.

The Phase III program for TC-5214 includes two fixed-dose studies and two flexible dose studies as well as a placebo-controlled long-term safety study in which patients will receive TC-5214 or placebo for up to a year. All of those studies, known collectively as the Renaissance Program, are on track to initiate this year, the companies said.

Two positive Phase III trials will likely be needed to seek FDA approval, based on the history with previous depression drugs, Brett Holley, an analyst with Oppenheimer & Co. stated in a research note. "We believe four chances to

See Targacept, Page 3

Spherix Seeks Sweeter Road to Market with Sugar Drug

By Donna Young
Washington Editor

A low-calorie sweetener product, whose roots of discovery go back to the 1930s and to NASA's 1970s Mars Viking program, is headed on a new exploration path of being a potential treatment to reduce triglyceride levels.

Spherix Inc. and its Biospherics drug unit have been developing D-Tagatose, a naturally occurring simple sugar, as an oral treatment for glycemic control in patients with Type II diabetes. The product currently is in Phase III testing for the disease.

But the FDA's 2008 guidelines requiring investigational Type II diabetes drugs to undergo assessments for cardiovascular risks has created a financial roadblock for Bethesda, Md.-based Spherix in taking its tagatose product to the finish line. (See *BioWorld Today*, Dec. 18, 2008.)

"Spherix never budgeted nor assumed financial

See Spherix, Page 4

The Problems of Ineffective Schooling

Paradoxically, Autoimmune T Cells May Bind Too Weakly

By Anette Breindl
Science Editor

Two recent studies have shed some light on the molecular mechanisms of how Type I diabetes develops. And in doing so, they suggested that current ideas of how autoimmunity occurs may have it backward.

Specifically, the current theory is that autoimmunity results when T cells bind too strongly to antigens. But in two separate studies, corresponding author John Kappler and his team have shown that autoimmunity can result when T cells bind weakly to different antigens, because such weakly binding cells can escape mechanisms that are designed to weed out autoimmunity-causing T cells.

T cells are something of an underappreciated culprit in autoimmune disease. "Even though autoantibodies show up and are easy to detect," Kappler told *BioWorld Today*,

See T Cells, Page 5

New Co News

Strox in Crowded Race to Develop Antibody for *S. Aureus*

By Catherine Hollingsworth
Staff Writer

Strox Biopharmaceuticals is working to develop an antibody-based antibacterial aimed at *Staphylococcus aureus* infections that could overcome what it sees as a key hurdle facing similar pipeline vaccines and antibodies.

The company believes it may have an edge by using antibodies that can effectively target the capsular polysaccharide antigens on the outer surface of *S. aureus*, without being neutralized by a key protein, Protein A.

Protein A is a well-known research tool used to purify antibodies. But Strox Bio sees Protein A as a virulence mechanism that can bind to as well as neutralize antibodies. "And I don't believe any other anti-Staph

See Strox, Page 6

INSIDE:	OTHER NEWS TO NOTE: GENENTECH, PROSENSA, SANTARIS, SCIL.....	5
	CLINIC ROUNDUP: ANTHERA, MAP, MERSANA, SIGA	7



Appointments And Advancements

3-V Biosciences Inc., of Menlo Park, Calif., appointed Edward M. Connor Jr. chief medical officer.

AesRx LLC, of Newton, Mass, named Henry Louis Gates Jr. to its strategic advisory board.

Alnylam Pharmaceuticals Inc., of Cambridge, Mass., appointed Laurence Reid senior vice president and chief business officer and named Kenneth Koblan vice president and Distinguished Alnylam Fellow. Alnylam also formed a scientific advisory board including Daniel Anderson, Charles Cooney and Robert Langer.

Amarantus Therapeutics Inc., of Sunnyvale, Calif., named Lawrence M. Schwartz to its scientific advisory board.

Amylin Pharmaceuticals Inc., of San Diego, appointed Christian Weyer senior vice president of R&D and named Orville Kolterman senior vice president and chief medical officer.

Anaphore Inc., of La Jolla, Calif., named Russell G. Greig executive chairman.

Angiochem Inc., of Montreal, appointed David Scheer to its board.

Anthera Pharmaceuticals Inc., of Hayward, Calif., promoted Colin Hislop to chief medical officer.

ATyr Pharma Inc., of San Diego, named Catharine E. Johnson senior vice president of business development.

Benitec Ltd., of Melbourne, Australia, appointed Iain Ross to its board.

Biocortech, of Paris, elected Andre Choulika to its board.

Biodel Inc., of Danbury, Conn., appointed Donald M. Casey Jr. to its board.

Celsion Corp., of Columbia, Md., appointed Jeffrey W. Church vice president and chief financial officer.

CombiMatrix Corp., of Mukilteo, Wash., named Mark McGowan interim president and CEO, effective July 1.

Cyntellect Inc., of San Diego, appointed Saiid Zarrabian president and CEO.

DBV Technologies, of Paris, named N. Franklin

Stock Movers

06/23/10

Company

Stock Change

NASDAQ Biotechnology	+0.09%
AVEO Pharmaceuticals Inc.	+12.43%
Emisphere Technologies Inc.	-8.71%
Rexahn Pharmaceuticals Inc.	+7.51%

(Biotechs showing significant stock changes Wednesday)

Adkinson Jr. and Jonathan M. Spergel to its scientific advisory board.

Dendreon Corp., of Seattle, named David C. Stump to its board.

Eurand NV, of Amsterdam, the Netherlands, appointed Jean-Louis Anspach president of Eurand Pharmaceuticals Inc.

Genstruct Inc., of Cambridge, Mass., named David de Graaf chief scientific officer.

Genzyme Corp., of Cambridge, Mass., nominated Dennis M. Fenton to its board.

Gilead Sciences Inc., of Foster City, Calif., added John G. McHutchison as senior vice president, liver disease therapeutics.

Girindus America Inc., of Cincinnati, appointed Edward Huber as director of analytical development and quality control.

Ikaria Inc., of Clinton, N.J., appointed Douglas Greene executive vice president of R&D. It also named Geoffrey Nichol chief medical officer.

Jazz Pharmaceuticals Inc., of Palo Alto, Calif., appointed Paul L. Berns to its board.

Marshall Edwards Inc., of San Diego, appointed Thomas Zech chief financial officer.

MediciNova Inc., of San Diego, added Michael Coffee as chief business officer.

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Targacept

Continued from page 1

produce two positive trials further mitigates the program's risk," he wrote.

Given the dazzling data seen in the Phase IIb study, expectations are high for stellar results in the Phase III trials. "We expect meaningful data from essentially all of [the Targacept] clinical programs in the next 18 months," Holley wrote.

While the endpoint will differ from the Phase IIb flexible dose study, the overall goal will remain the same in Phase III – to evaluate whether patients do better with an add-on depression treatment, J. Donald deBethizy, president and CEO of Targacept, told *BioWorld Today*.

The primary measure used in the Phase IIb study was the Hamilton Rating Scale for Depression, but in the Phase III program the Hamilton scale will be used for enrollment purposes only, and a similar scale, the Montgomery-Asberg Depression Rating Scale, will be used as the primary endpoint in the Phase III program.

The studies will be submitted as part of the U.S. regulatory filing for TC-5214 planned for the second half of 2012. A marketing authorization application in Europe is projected for 2014. Specifically, Targacept and AstraZeneca are seeking approval of TC-5214 as an adjunct treatment for patients with major depressive disorder who have not responded well to first-line therapy with a selective serotonin reuptake inhibitor (SSRI) or serotonin/norepinephrine reuptake inhibitor (SNRI).

SSRIs and SNRIs are the most commonly prescribed classes of drugs for depression, but in many cases, patients fail to respond adequately. In the large-scale study (STAR*D) by the National Institute of Mental Health, about two-thirds (63 percent) of patients did not achieve remission with first-line treatment with the SSRI citalopram hydrobromide.

There currently are few options for augmenting depression treatments. Abilify (Bristol-Myers Squibb Co.) is approved as an add-on therapy to SSRIs in patients with depression. And AstraZeneca's antipsychotic Seroquel is approved for the acute treatment of manic episodes associated with bipolar disorder, both as a monotherapy and as an adjunct to the antimanic drugs lithium and divalproex.

Abilify and Seroquel can have side effects such as the irreversible movement disorder tardive dyskinesia, deBethizy pointed out. He noted that more than half of physicians prescribe Wellbutrin off-label as an add-on treatment for depression, according to Targacept's estimate.

In the Phase II study, TC-5214 was tested in patients who did not respond well to first-line therapy with citalopram (Celexa), an antidepressant in the SSRI drug class. Study patients treated with the add-on TC-5214 saw a six-point improvement (13.75 points) over those treated with the add-on placebo (7.75 points). That result was highly statistically significant and was twice as good as other clinical data for

an add-on depression drug. (See *BioWorld Today*, Oct. 19, 2009.)

Developing TC-5214 and gaining regulatory approval of the drug as an adjunct treatment for depression is only the initial goal of the 2009 agreement between AstraZeneca and Targacept. The two firms also envision the compound as a monotherapy in the second-line setting, in which, if approved, it would likely go up against drugs like Celexa, Lexapro, Zoloft and Paxil.

A Phase II study to assess TC-5214 as a second-line "switch" monotherapy treatment for depression is targeted to start in 2010.

The TC-5214 compound modulates forms of the alpha4beta2 neuronal nicotinic receptors subtype (NNRS) thought to be involved in the increased cholinergic tone associated with depression. Recent scientific evidence suggests that depressive symptoms are associated with an overstimulation of NNRS and other receptors in the brain that are activated by the neurotransmitter acetylcholine.

Shares in Targacept (NASDAQ:TRGT) were down 12 cents, closing at \$21.07. ■

Other News To Note

- **Alnylam Biotherapeutics**, of Cambridge, Mass., a division of Alnylam Pharmaceuticals Inc., reported results describing the discovery of novel delivery lipids (NDLs) that deliver siRNAs to manufacturing cell lines with no measurable adverse effects on cell density. Those NDLs also demonstrated durable target gene silencing following a single dose, improved protein quality and scalability to at least 40 liters. Those results were presented at the Cell Line Development and Engineering conference in San Francisco.

- **BioWa Inc.**, of Princeton, N.J., entered two agreements with London-based **GlaxoSmithKline plc**. The first amended the companies' 2007 deal to provide GSK with extended access to BioWa's Potelligent Technology platform for research, development and commercialization of antibody therapeutics with enhanced antibody-dependent cellular cytotoxicity. The second license agreement provides GSK with access to BioWa's Complement Technology for enhancing the complement-dependent cytotoxicity of select GSK therapeutic antibodies. Specific financial terms were not disclosed, but BioWa will receive up-front and annual fees, development milestone payments and royalties on any marketed products.

- **Febit Holding GmbH**, of Heidelberg, Germany, cut about 60 percent of its work force in a restructuring move to shift its strategic focus to blood-based microRNA biomarker discovery and on partnerships and intellectual property commercialization. Cord F. Staehler resigned as CEO, while Hartmut Voss and Jochen Kohlhaas were appointed co-CEOs.

Spherix

Continued from page 1

requirements for a large safety study on top of what we already planned," said Leisa Dennehy, a commercial and corporate development adviser to the firm.

Because of the additional cost involved in conducting a cardiovascular safety study, which could take years and millions of dollars to complete, the company has determined it would need a partner to take the program forward, Spherix President Robert Lodder told *BioWorld Today*.

Ideally, the type of collaborator Spherix is seeking is one that has experience in the endocrine metabolic area, particularly in the diabetes space, or that is ready to make a strategic move in that direction, Dennehy said.

"If I were to wave a magic wand and create an ideal partner, it would be a partner that had a large enough sales force presence to promote to primary care as well as to specialists," she said. While the company is hoping to eventually gain the FDA's OK with its tagatose drug, she said Europe may be a more attractive and likely market for the product's first approval, "because they have not changed the requirements as the FDA has."

Results expected later this summer from Spherix's Phase III trial of tagatose, being conducted in the U.S. and India, will be the key to locking in a partner, Dennehy noted.

Meanwhile, the firm has turned its sights to the pursuit of tagatose as a triglyceride-reducing agent based on unblinded Phase II data, which showed a 21 percent reduction in triglycerides from the patients who received the 7.5-g dose compared with those who got the 2.5-g dose.

Reduction of triglyceride levels is a secondary endpoint of the ongoing Phase III trial, Lodder noted.

"We have every optimistic hope that the Phase II data are predictive of the Phase III," Dennehy said. But before Spherix begins early testing for tagatose in the triglycerides space, "we are awaiting the confirmation in the Phase III data before we push the green button to go," she said.

Spherix, which was founded in 1967 by Gilbert Levin, whose sugar-related discoveries went on to be used as part of experiments exploring life on Mars, initially developed tagatose under the name Naturlose as a reduced-calorie sugar substitute.

Lodder said he got the idea to study the product as a Type II diabetes treatment after reading a 2004 *Proceedings of the National Academies of Sciences* article about a knockout mouse model that was designed to develop atherosclerosis on a high-fat diet, which he determined "would stand to also develop atherosclerosis on a high-carbohydrate diet."

"I began to wonder if it would be possible to intervene in that process with a carbohydrate that was not metabolized normally," Lodder explained. "So I did a series of studies in a knockout mouse model, and that is why we started looking for that effect at Spherix."

The product has taken an unusual path to drug testing,

with the FDA in 2005 granting Spherix an end-of-Phase-II meeting based on the strength of its investigational new drug application and the fact that tagatose already had been declared a generally recognized as safe, or GRAS, substance for use in food and beverages.

Lodder noted that regulators later granted the firm permission to go directly into Phase II/III testing.

"It is very unusual to go in with such a wealth of toxicology and safety data and human exposure and be able to go straight into a Phase II/III study," Dennehy maintained.

She also insisted that it was "rare" for a food product to be investigated as a medication.

The closest analogous product that went from food to drug, she asserted, is London-based GlaxoSmithKline plc's Lovaza, the only-FDA approved medication made from omega-3 fish oil.

Although the triglycerides area looks promising for tagatose, Lodder noted that the company must first establish a mechanism of action through animal testing.

"We would be beginning an entirely new program, because we believe that the dose and the dose regimen would need to be different than the diabetes regimen," Dennehy said. "And so we would begin from the beginning, looking at mechanism of action, and getting some really sexy good science going behind it." Given that the safety of tagatose already has been established, the next likely step may be dose-response, she added.

To be competitive in the triglycerides space, Spherix's product would need to be a once- or twice-daily medicine, Dennehy said. Unlike the already crowded cholesterol-lowering agent market, triglyceride-reducing drugs are an area of "unmet need," she said.

Although Spherix's budget currently is unable to handle the Type II diabetes cardiovascular safety testing, as a publicly traded company, "we can always sell stock to raise money" for the triglycerides program, Lodder said, adding that such a strategy is not feasible for the diabetes program because "it would take a long time for Spherix to raise the money to do that."

He insisted that the company would "not necessarily need to partner to proceed" with the triglycerides program.

Nonetheless, said Dennehy, "Our expectation is that we would love to have a pharma partner involved in Phase III for triglycerides." ■

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T Cells

Continued from page 1

"it's not always clear that they are the primary culprits, or even mediate the pathology at all." In some diseases, such as lupus, autoantibodies are clearly a driver; but in others, it appears to be autoreactive T cells that are doing most of the damage. In Type I diabetes, T cells attack and destroy insulin-producing pancreatic islet cells.

Mature T cells recognize peptide fragments presented to them by major histocompatibility complex or MHC molecules. Before going on patrol, T cells undergo a maturation process in the thymus – a sort of T-cell school designed to weed out both T cells that bind too strongly to those antigen-MHC complexes, and those that bind too weakly.

But what is the right binding strength and what is too strong or too weak, Kappler said, is "a fuzzy line. And these cells crossed over that line and should have been deleted, but weren't."

Current wisdom holds that T cells that bind too strongly are likely to cause autoimmune problems, while those that bind too weakly will be ineffective. But in papers published in the June 15, 2010, edition of the *Proceedings of the National Academy of Sciences*, and the March 2010 print edition of *Nature Immunology*, Kappler, who is an immunologist at National Jewish Health in Denver, and colleagues looked at the details of how two different antigen fragments activate T cells, and found that too-strong T-cell binding was not the problem in either case.

"The binding in both cases is odd," Kappler said. In their studies, his team looked at peptide fragments of insulin and chromogranin A, both of which are autoimmune targets in Type I diabetes.

For insulin, it is one specific fragment of the protein that activates T cells, and that fragment can bind to MHC molecules in four different ways, depending on which amino acids of the peptide are in contact with the MHC fragment. In mice with Type I diabetes, they found only T cells that bound insulin in one particular configuration – and that configuration was the one that leads to the weakest binding, rather than the strongest one.

The work on insulin, published in *PNAS*, follows another paper by Kappler and an overlapping group of colleagues in *Nature Immunology*. Here, they reported identifying another antigen that can be a target in Type I diabetes. Kappler and his colleagues showed that chromogranin A can also be recognized by T cells – and that it also binds in an unusual way, leaving half the binding pocket unoccupied while parts of the peptide stick out beyond the pocket itself.

Kappler said that there are several possibilities for why T cells do not encounter the protein fragments in the thymus that they later attack in the pancreas. He believes that chromogranin A must be processed differently in the thymus, leading to an antigen that is different from the one that T cells see in the pancreas. "These T cells have never

seen this antigen before," he said.

For insulin, the situation is somewhat different in that T cells do clearly encounter insulin in the thymus. There are two possibilities for why T cells are not weeded out: Processing in the thymus may lead to different protein fragments than the T cells will later encounter in the pancreas, as is the case with chromogranin A. Alternately, the insulin concentration in the pancreas may be so high that the weakly binding T cells become problematic.

For now, the work is basic research. But Kappler said it gives researchers "a method" for determining which specific interactions between T cells and antigens are problematic, which is the first step toward specifically targeting them. ■

Other News To Note

• **Genentech Inc.**, of South San Francisco, a unit of the Roche Group, said the FDA approved Lucentis (ranibizumab) for macular edema following retinal vein occlusion. The approval followed a six-month priority review, based on data from the 397-patient BRAVO study and 392-patient CRUISE studies, both of which met their primary endpoints of mean change from baseline in best-corrected visual acuity at six months compared with patients receiving sham injections.

• **Prosensa BV**, of Leiden, the Netherlands, initiated two further programs under its alliance with London-based **GlaxoSmithKline plc** covering RNA-based treatments for Duchenne's muscular dystrophy. The new programs will address the development of four compounds designed to target different subpopulations of DMD patients, and will focus on the skipping of its exons – exon 45, 52, 53 and 55. GSK made two initiation payments to Prosensa, which is now eligible for further pre-option milestone payments based on research progress. Specific financial terms were not disclosed.

• **Santaris Pharma A/S**, of Hoersholm, Denmark, and **miRagen Therapeutics Inc.**, of Boulder, Colo., formed an alliance to develop microRNA-targeted medicines to treat cardiovascular disease. MiRagen will gain access to Santaris' Locked Nucleic-Acid platform to develop and commercialize single-stranded LNA-based product. Santaris will receive a minority equity interest in miRagen and is eligible for undisclosed milestone payments plus royalties.

• **Scil Proteins GmbH**, of Halle, Germany, reported preclinical data showing that its lead Affilin molecule, SPVF 2801, achieved accumulation in solid tumors in a mouse model, indicating that the picomolar binder targets the tumor cells with high specificity in vivo. Based on those results, Scil said it will continue preclinical development within its lead cancer program and proceed with screening its Affilin libraries for compounds against additional targets. Affilin molecules are scaffold proteins derived from the natural serum protein ubiquitin.

Strox

Continued from page 1

antibodies out there take that into consideration," CEO Stanley Kim told *BioWorld Today*.

In some cases, companies that tried and failed with an antibody or vaccine aimed at *S. aureus* had products that were subject to the "cloaking effect" of jelly-like polysaccharides, according to Strox. The mucus-like layers of polysaccharides form a bacterial capsule. Those capsules are expressed on the outer surface of *S. aureus* and prevent the antibody from hitting target antigens located on the cell wall, under the capsule.

As a result, the antibodies aren't able to see their jelly-coated target, Kim reasoned. "I think that could very well explain the failures," he said. "The antibody couldn't really see that antigen very well because it was covered with jelly."

Strox's product, however, is designed to address both the problem of cloaking by polysaccharides capsules and neutralization by Protein A. Saurestat, a polyclonal antibody purified from human plasma, directly targets the outside surface of the bacteria (the polysaccharide capsule) and also avoids Protein A neutralization, according to Strox.

The company already has obtained three U.S. patents that broadly cover its technology, and has two pending patent applications, one of which is specifically directed to Saurestat.

Currently, no antibody-based products are approved for treating or preventing *S. aureus* infection.

A number of published studies have shown that polyclonal immunoglobulin M (IgM) plays a critical role in controlling bacterial infections. Kenta Biotech Ltd. has presented positive Phase IIa results of its lead drug candidate, panobacumab (KBPA101), a fully human IgM monoclonal antibody, showing it is safe and well tolerated in patients with hospital-acquired pneumonia caused by *Pseudomonas aeruginosa*.

Founded in 2008, Wellington, Fla.-based Strox is developing its polyclonal IgM antibody for hospital-acquired *S. aureus* infections, including those caused by methicillin-resistant *S. aureus* or MRSA.

Antibiotics are the standard treatment for *S. aureus* infection. However, the bug is becoming increasingly resistant to conventional treatment with antibiotics. For example, MRSA has the ability to resist beta-lactam antibiotics such as penicillin and cephalosporins, and the MRSA infections rates continue on the rise.

Due to methicillin-resistance, other antibiotics – including vancomycin, daptomycin and linezolid – have been developed. Those antibiotics are used as a last resort and all of them can have serious side effects and other limitations. As antibiotics are becoming less effective to address staph infection, Strox Bio believes new approaches are needed to prevent and treat such infections. The company intends to seek fast-track designation from the FDA for Saurestat based on the significant unmet medical need.

According to Strox, the current worldwide cost of staph infections exceeds \$50 billion. In 2008, U.S. sales of Cubicin, an injectable antibiotic used to treat MRSA, were \$414.7 million. Zyvox (linezolid) for hospital-acquired *S. aureus* infection, had sales of \$1.115 billion for 2008.

Several companies are in the race to develop an antibody-based product or vaccine for *S. aureus*. And many of them are subject to either the "cloaking" or neutralization effect of Protein A, or both, according to Strox.

Swiss drugmaker Novartis AG decided not to pursue further development of Aurograb as a potential add-on therapy to antibiotics for use in treating staphylococcal infections, after Phase II data showed a lack of efficacy. Aurograb was developed by NeuTec Pharma plc, of Manchester, UK.

Inhibitex Inc.'s Veronate polyclonal antibody (IgG) failed in Phase III trials. However, Inhibitex's Aurexis humanized monoclonal IgG has completed a Phase IIa study in 60 patients with complicated *S. aureus* bacteremia.

Nabi Biopharmaceutical's Staphvax vaccine failed to meet its endpoint in its last Phase III trial, although its reformulated vaccine called PentaStaph (Staphylococcal polysaccharide conjugate and toxoid vaccine) was purchased by GlaxoSmithKline Biologicals SA and is in Phase I. Biotest Pharmaceuticals Corp., a subsidiary of Dreieich, Germany-based Biotest AG, no longer has the right of first refusal for Altastaph, which gave the company access to StaphX technology.

Nabi's previous investigational polysaccharide conjugate vaccine, StaphVAX, contained the two main capsular types, 5 and 8, found in the outer coating of more than 80 percent of *S. aureus* bacteria. The capsular polysaccharide molecules are linked, or conjugated, to a nontoxic, carrier protein derived from the bacteria *Pseudomonas aeruginosa* (Pseudomonas exoprotein A).

To enhance the efficacy, Nabi developed and added a new and patented surface polysaccharide component, 336. *S. aureus* Type 336, which accounts for the roughly 20 percent of *S. aureus* infections that do not form a polysaccharide capsule in the human bloodstream. The 336 conjugate was evaluated in a Phase I/II human trial and shown to be safe and generates antibodies in humans that are specific and mediate protection against 336 positive strains of *S. aureus*, according to Nabi.

Biosynexus' pagibaximab, a humanized IgG monoclonal antibody (mAb), was partnered with GlaxoSmithKline but was returned to Biosynexus. That antibody has completed IIa, showing promising results in preventing staphylococcal infections in very low birth weight infants. A large Phase IIb/III study has been initiated.

A Phase II/III proof-of-concept trial of Intercell AG's investigational *S. aureus* vaccine (V710), licensed to Merck & Co. Inc., is currently recruiting, with the first critical interim analysis (surpassing futility) expected in 2011.

See Strox, Page 7

Strox

Continued from page 6

Alopxx and partner Sanofi-Aventis are developing a Phase I mAb for *S. aureus* (F598). And preclinical studies of Elusys's ETI-211, which is partnered with Pfizer Inc., are nearing completion.

So far, Strox has conducted very preliminary in vitro experiments and the next step will be to raise money or enter a partnership to accelerate development of its product, said Kim, an immunologist and a registered patent attorney.

Once it has secured adequate financing, the company plans to hire additional management and scientific personnel. Although some research and development will be outsourced, Strox intends to move the bulk of its

operations to its own dedicated laboratory. Ideally, Strox would like to begin clinical trials for Saurestat in 2010-11 and complete the studies in 2012-13.

In addition to founding Strox, Kim also co-founded Nautilus Biosciences, a private Canadian company that has raised several million dollars to develop marine-derived small molecule drugs.

Paul Herron currently serves as Strox's chief financial officer. He previously served as chief financial officer at four different biopharmaceutical firms, the most recent being immunotherapeutics firm Altor BioScience, of Miramar, Fla., where he initiated a comprehensive corporate partnering effort, closed two financing rounds and negotiated several key licensing agreements. ■

Clinic Roundup

- **Anthera Pharmaceuticals Inc.**, of Hayward, Calif., started enrolling patients in its pivotal VISTA-16 (Vascular Inflammation Suppression to Treat Acute Coronary Syndrome for 16 Weeks) trial of varespladib (A-002). The study will recruit up to 6,500 high-risk ACS patients, and will be stopped after a minimum of 395 primary endpoint events have occurred. Patients will be treated with varespladib or placebo once daily in combination with Lipitor (atorvastatin, Pfizer Inc.) As per a special protocol assessment, the primary endpoint will be a reduction in major adverse coronary events defined by recent FDA draft guidance to include cardiovascular death, nonfatal myocardial infarction, nonfatal stroke or documented unstable angina with objective evidence of ischemia requiring hospitalization.

- **MAP Pharmaceuticals Inc.**, of Mountain View, Calif., presented new analyses from its FREEDOM-310 Phase III study showing that Levadex orally inhaled migraine therapy was effective irrespective of when it was administered during a migraine cycle. The post hoc analysis showed that Levadex was effective in treating a migraine attack with moderate or severe pain when administered as soon as the initial migraine onset and as late as eight hours after the start of migraine. Separately, a second post hoc analysis showed that Levadex was effective and well tolerated in migraine patients with asthma. Those data were presented at the American Headache Society meeting in Los Angeles.

- **Mersana Therapeutics Inc.**, of Cambridge, Mass., started a Phase I trial of XMT-1107, an anti-angiogenic fumagilin analogue using the company's Fleximer platform, in patients with refractory advanced solid tumors. The primary objective is to determine the maximum tolerated dose of the drug, given as an intravenous infusion once every three weeks. The trial's start triggered an undisclosed milestone payment from **Teva Pharmaceutical Industries Ltd.**, of Petach Tikva, Israel, which recently

licensed worldwide rights to the drug, excluding Japan. (See *BioWorld Today*, April 13, 2010.)

- **SIGA Technologies Inc.**, of New York, completed its fourth clinical trial testing ST-246, its lead smallpox antiviral drug candidate, with results showing that the drug likely will be found to be safe and well tolerated to treat orthopoxvirus infections. The study enrolled 107 healthy volunteers. SIGA said data also suggested an appropriate dose for completing remaining studies, along with a trial to test the pharmacologic effects on cardiac repolarization. The project was supported by funds from the Biomedical Advanced Research and Development Authority in conjunction with the National Institutes of Allergy and Infectious Diseases.

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