

BIOWORLD[®] TODAYWEDNESDAY
OCTOBER 27, 2004

THE DAILY BIOTECHNOLOGY NEWSPAPER

VOLUME 15, No. 208
PAGE 1 OF 8**HGS' Albugon For Diabetes Nets \$183M Deal With GSK****By Randall Osborne**
West Coast Editor

Human Genome Sciences Inc.'s Albugon for diabetes drew a development and commercialization deal worth up to \$183 million with GlaxoSmithKline plc, which gets worldwide rights to albumin-glucagon-like peptide-1.

"It's the first example of a very short peptide being stabilized with albumin," said Craig Rosen, president and chief operating officer of Rockville, Md.-based HGS.

The agreement sweetened HGS' stock (NASDAQ:HGSI) by 26 cents, ending the day at \$9.75.

GSK, of London, is paying an up-front fee along with clinical development and commercial milestone payments that could amount to as much as \$183 million, plus more milestones for other indications and royalties.

HGS, which created the compound using its albumin
See HGS, Page 3

Stem Cells Inc. Shares Sink On \$22.5M Placement Deal**By Randall Osborne**
West Coast Editor

Still riding high on California Gov. Arnold Schwarzenegger's endorsement of a measure to boost stem cell research, Stem Cells Inc. entered agreements with institutional investors for a placement of 7.5 million shares of stock at \$3 per share, raising gross proceeds of about \$22.5 million.

News of the sale, expected to close in the next few days, might not have terminated the Palo Alto, Calif.-based firm's recent stock run-up but did slow the pace considerably. Shares (NASDAQ:STEM) closed Tuesday at \$3.17, down 92 cents, or 22.5 percent. Company officials could not be reached.

Stem Cells' stock Monday jumped 51 percent to close at \$4.09, a week-long trend due to Schwarzenegger's
See Stem Cells, Page 3

Kai Advances First Clinical Product With \$28M Series A**By Karen Pihl-Carey**
Staff Writer

An additional \$11 million raised in a Series A financing started in December extended the runway for Kai Pharmaceuticals Inc. into 2006.

The South San Francisco-based company completed its second closing of the round this week, bringing the total raised since inception to \$28 million. The bulk of that – \$17 million – was raised late last year in the first part of the round. (See *BioWorld Today*, Dec. 5, 2003.)

Kai intends to use proceeds to fund the ongoing Phase I/II trial of the fast-track drug KAI-9803, to treat reperfusion injury following acute myocardial infarction. That clinical trial was initiated in late September. KAI-9803 targets a specific protein kinase C (PKC) isozyme, delta-PKC, which is known to activate certain events that cause cell

See Kai, Page 4

EntreMed Partners TFPI Program With Affymax**By Aaron Lorenzo**
Senior Staff Writer

To further develop its tissue factor pathway inhibitor (TFPI) program, EntreMed Inc. tapped Affymax Inc. as a collaborative partner.

The companies entered a research collaboration for the synthesis and development of peptides that mimic certain fragments of TFPI, a naturally occurring anticoagulant protein that in preclinical models has been shown to inhibit tumor growth and the formation of new blood vessels. Terms call for EntreMed and Affymax to combine their capabilities in peptide design and drug development to identify lead candidates for cancer.

"TFPI has been an interest of ours for some time, and the goal of getting a candidate into the clinic requires somebody who is familiar with peptide synthesis and
See EntreMed, Page 5

INSIDE:

OTHER NEWS TO NOTE (BIOENVISION FILES \$90M STOCK OFFERING) ..2, 3, 5-8

THOMSON

Kai

Continued from Page 1

injury and death during reperfusion injury. It is designed to reduce reperfusion injury as an adjunct to current treatments for heart attack.

"There is no drug at the moment that is approved for reducing reperfusion injury," said Daria Mochly-Rosen, Kai's chief scientific officer and founder. "Our compound, if successful, will address this particular problem."

Money from the Series A round also will help move along Kai's preclinical programs and to expand its management team. The company has about five compounds in preclinical development and several more at an earlier stage. Kai develops therapeutics that selectively modulate PKC. It also focuses on ischemia and diseases involving chronic regulation of angiogenesis.

Although incorporated in 2002, the company really got its start in mid-2003, when its founder, Leon Chen, now Kai's manager of preclinical sciences, became the company's first employee, working out of investor Skyline Ventures' office. The company received its first funding in October, and then moved into its own facility in December. Kai has since grown to 19 employees, including a new president and CEO, Steven James, who started last week. James most recently was senior vice president of commercial operations at Exelixis Inc., of South San Francisco.

"What really makes this company quite special, especially nowadays with what investors are looking for in a biotech company, is the fact that this company comes with a ready-made pipeline of therapeutic products," James told *BioWorld Today*.

The Phase I/II trial of KAI-9803 is expected to be completed near the end of next year, when the company plans to begin a pivotal trial. If all goes well, the drug could reach the market in early 2008. Kai also plans to bring one or two more candidates into the clinic within the next few years.

The company's science is based on the work of Mochly-Rosen, who is on leave as chair of the department of molecular pharmacology at Stanford University. She discovered a method of making the approach to modulating PKC more specific. Mochly-Rosen found that PKC consists of 10 different isozymes in the body, each of which moves within cells during certain activities.

Researchers have long known that abnormal PKC signaling is associated with various diseases, but they faced a major roadblock for drug discovery. Because each of the isozymes is similar, researchers have been hindered by a lack of selectivity in their attempts to develop therapeutics.

"Targeting protein kinase C has been a major effort in the last 16 years," Mochly-Rosen said. "It has failed because of the approach that they've taken."

However, Mochly-Rosen was able to discover specific peptides composed of short chains of amino acids to either block individually or to activate each of the isozymes. Once PKC isozymes are activated, each isozyme is differentially

localized within the cell and anchored by receptors for activated C-kinases (RACKs). It is possible to modulate PKC isozyme activity through enhancement or inhibition of the isozyme's interaction with RACKs.

"Using an approach that was very much against the dogma in the field, there was plenty of time to do it well," Mochly-Rosen said. "I was very blessed that nobody was paying attention to what we were doing."

The randomized, double-blind, placebo-controlled trial of KAI-9803 will enroll about 150 patients at 30 clinical sites and will evaluate increasing doses. Clinical endpoints include heart failure and death, as well as surrogate measures of infarct size, myocardial function and myocardial perfusion. The trial is being performed in collaboration with the Duke Clinical Research Institute.

In preclinical animal models, KAI-9803 showed its ability to cause a 30 percent inhibition in infarct size and to dramatically improve heart function, Mochly-Rosen said.

Aside from KAI-9803, the company is developing another drug designed as a prophylactic agent in patients at risk for ischemic injury. The isozyme-selective PKC activator mediates preconditioning, a protective process that can eliminate ischemic reperfusion injury.

Kai also is researching selective PKC modulators to reduce ischemic injury to the brain during stroke, to reduce reperfusion injury during coronary artery bypass grafting and to reduce ischemic-induced injury before and during abdominal aortic aneurysm repair surgery. The company intends to develop therapies that selectively modulate PKC isozymes known to participate in the pathogenesis of age-related macular degeneration, diabetic retinopathy and tumors expressing VEGF.

James said the company plans to take its products as far through the clinic as possible before partnering. It also might choose to market some of its products on its own.

"I think we'd like to do that," he said, "because some of these products would be used in an acute-care setting where there would be a high need and not a substantial barrier in terms of marketing."

Participants in the recent Series A included Skyline Ventures, of Palo Alto, Calif.; InterWest Partners, of Menlo Park, Calif.; Intersouth Partners, of Research Triangle Park, N.C.; Delphi Ventures, of Menlo Park, Calif.; Thomas Weisel Venture Partners, of San Francisco; and MDS Capital, of Toronto. All but Thomas Weisel and MDS Capital also participated in the \$17 million closing last year. ■

BIOWORLD TODAY ONLINE ARCHIVES!

Your own personal BioWorld library! Search for any company, product or person written about in *BioWorld Today* over the past 14 years!

Only available at www.BioWorld.com!