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PAGE 1 OF 8

Protein Sciences Wins \$35M HHS Pact; Fends Off Creditors

By Donna Young
Washington Editor

WASHINGTON – Privately held Protein Sciences Corp. Inc. won a \$35 million Health and Human Services (HHS) contract, which could be extended to \$147 million over five years, to support the Meriden, Conn.-based firm's recombinant baculovirus influenza vaccine technology.

However, Protein Sciences' creditors, led by Rockville, Md.-based Emergent Biosolutions Inc., which had attempted last year to acquire the company, filed a petition in federal bankruptcy court seeking to force Protein Sciences into bankruptcy and liquidation.

Protein Sciences and the government have maintained that the company has the financial stability necessary to follow through on the contract.

The contract requires Protein Sciences to establish
See Protein Sciences, Page 3

First Crohn's, Now COPD

Safety First? Prochymal Trial Gets Low Efficacy for Osiris

By Randy Osborne
Staff Writer

Almost three months after Osiris Therapeutics Inc.'s Prochymal failed in Phase III trials for Crohn's disease, news of unfavorable interim Phase II data in chronic obstructive pulmonary disease dented the stock and left some investors on edge about the next indication, graft-vs.-host disease.

Columbia, Md.-based Osiris said Wednesday that the product, made of adult mesenchymal stem cells, proved safe but did not significantly improve lung function. At the end of the trading day, the company's stock (NASDAQ:OSIR) had fallen by \$1.03, to close at \$12.90.

Partnered with Genzyme Corp., of Cambridge, Mass., Prochymal was tested in 62 COPD patients, 58 percent of
See Osiris, Page 4

'You Have to Really Nip It in the Bud'

Novel Amyloid-Beta Oligomer Effect Identified in Alzheimer's

By Anette Breindl
Science Editor

In the June 25, 2009, issue of *Neuron*, a paper added to the litany of ways in which A-beta oligomers contribute to the symptoms of Alzheimer's disease. They enhance long-term depression, a weakening in neural connections that is the physical way in which brain cells forget.

The anatomical calling cards of Alzheimer's disease are amyloid plaques, or aggregates of A-beta peptide. But a growing number of researchers believe that the real problem with plaques is not the plaques themselves, but that they provide a reservoir for A-beta oligomers – smaller aggregations of A-beta peptide that are soluble and can spread far and wide to do their damage.

In the *Neuron* paper, senior author Dennis Selkoe and
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NEW CO NEWS

Savara's NanoCluster Platform Aiming at Inhaled Drugs Market

By Jennifer Boggs
Assistant Managing Editor

With the so-called "patent cliff" looming on the horizon, the inhalable therapeutics market has become "one of the fastest growing spaces," said Rob Neville, executive chairman of 2007 start-up Savara Pharmaceuticals.

"Companies are seeking new formulations and new routes of delivery," he said, and Savara's NanoCluster formulation technology, originally developed by company founder Cory Berkland at the University of Kansas, is designed as a next-generation pulmonary delivery platform aimed at overcoming some of the limitations of ear-

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INSIDE: OTHER NEWS TO NOTE2, 5, 8
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OTHER NEWS TO NOTE

• **Atox Bio Ltd.**, a subsidiary of Yissum Research Development Company Ltd., of Jerusalem, and **Fast-Track Drugs & Biologics LLC**, of North Potomac, Md., have begun a joint R&D program to continue the development of Atox Bio's mechanism-based immunomodulator peptide, AB103, for the treatment of sepsis and septic shock. The collaboration includes advanced preclinical studies and a Phase I trial to be performed at the University of Maryland. The collaborative R&D program was awarded \$575,000 from the Israel-U.S. Binational Industrial Research and Development Fund.

• **Cell Therapeutics Inc.**, of Seattle, said it completed its new drug application submission with the FDA for pixantrone to treat relapsed or refractory, aggressive non-Hodgkin's lymphoma and has requested priority review, which if granted could lead to an approval decision by the fourth quarter. Pixantrone is a major groove binder with an aza-anthracenedione molecular structure that differentiates it from the anthracyclines – the cornerstone therapeutics for lymphoma, leukemia and breast cancer – and other related chemotherapy agents. The drug currently is available in Europe on a named-patient basis.

• **Cepheid Inc.**, of Sunnyvale, Calif., said an article in the June 2009 issue of the *New England Journal of Medicine* concluded that rapid, PCR-based testing at the time of admission for delivery may improve the accuracy of Group B streptococcal (GBS) screening over the normal antepartum testing done at 35-37 weeks of gestation. Cepheid said its Xpert GBS test is designed to run on a STAT basis, returning positive results in as little as 32 minutes.

• **Cerulean Pharma Inc.**, of Cambridge, Mass., entered an exclusive, worldwide license agreement with **Calando Pharmaceuticals Inc.**, of Pasadena, Calif. Calando will receive an up-front payment as well as development and sales milestones and sales royalties but financial terms were

Will This CME Program Violate Off-Label Promotion Law?

There's a thin line between legitimate continuing medical education (CME) and illegal off-label promotion of a drug or device. Even with proper credentials, sales and marketing staff can place their companies on the wrong side of the law.

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"CME and Off-Label Promotion: Find and Fix Noncompliance Before the Feds Do" is just \$325 per listening site. Scheduled for June 30, 1-2:30 p.m., E.T., it includes presentation handouts and a Q&A session with the speakers. A conference CD (MP3 format) also is available. Please call 800-688-2421 or 404-262-5474 and mention conference code **T09566**.

not disclosed. Under the terms of the agreement, Cerulean has acquired worldwide exclusive rights to Calando's cyclodextrin co-polymer-based drug delivery technology to develop and commercialize products. Additionally, Cerulean has acquired worldwide exclusive rights to develop and commercialize Calando's clinical stage anticancer product candidate, IT-101, a camptothecin nanoparticle with a highly differentiated and promising preclinical foundation that successfully progressed through a Phase I trial.

• **Compugen Ltd.**, of Tel Aviv, Israel, said it will receive grants of approximately \$400,000 from the Office of the Chief Scientist of Israel to support its FPRLI and TP programs. The funds will support the testing of the therapeutic potential of selected novel peptides and proteins discovered through the use of four of the company's 10 discovery platforms.

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Protein Sciences

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domestic manufacturing capability to provide a finished vaccine within 12 weeks of onset of an influenza pandemic and to produce at least 50 million doses of the vaccine within six months of pandemic onset.

The award was in response to a 2007 solicitation from the government for advanced development of recombinant influenza vaccines for seasonal and pandemic purposes, said Robin Robinson, director of the Biomedical Advanced Research and Development Authority (BARDA), the office that is administering the contract.

Recombinant baculovirus technology, Robinson said, "has the promise of being able to deliver vaccines sooner than the traditional egg-based and maybe even cell-based" influenza vaccines.

Robinson noted that he was one of the inventors of baculovirus technology when he worked in industry before joining BARDA.

Companies responding to the HHS solicitation had to have completed Phase I trials, or proof of concept, to apply for the contracts, Robinson said.

BARDA received the proposals from firms in early 2008 and notified companies that met the competitive range a few months later, he added.

Protein Sciences officials said they were notified in March 2008 that they had met the competitive range.

When the government and the company entered into negotiations, "we had numerous technical and business questions about their proposal," Robinson said.

He noted that Protein Sciences already was in advanced development of its seasonal influenza vaccine, known as FluBlok, and had submitted a biologics license application to the FDA at that point.

The product currently is under review, with the FDA expected to make a decision by late October, said Protein Sciences CEO Daniel Adams.

Protein Sciences also is developing a H1N1 pandemic influenza vaccine, known as PanBlok using the same technology, in which flu virus genes are extracted and placed into an insect virus called baculovirus.

Robinson said that as part of BARDA's due-diligence process in reviewing potential contract offers, "we always look at the financial stability of a company."

During that process, Protein Sciences had entered into an asset purchase agreement with Emergent.

Under the terms of the proposed transaction, Emergent had extended \$10 million to Protein Sciences in the form of a bridge loan. The loan, said Daniel Abdun-Nabi, president and chief operating officer at Emergent "was secured by all assets."

"We had a security agreement in place. They pledged as collateral for the loan all assets of the company," he said.

But, he charged, once Protein Sciences obtained the funds from Emergent, "senior management of the company

solicited shareholders to oppose the transaction in violation of the contractual commitment."

Abdun-Nabi said Protein Sciences had initially issued a proxy statement to their stockholders, which "identified and described in detail the history of their efforts to raise money, that they had no alternatives but to secure some funding from Emergent and complete the transaction because there were no other viable transactions available to the company."

But Protein Sciences said it terminated the agreement because of "multiple breaches" by Emergent, including disclosure and mischaracterization of Protein Sciences' material confidential information obtained from the firm during due diligence and Emergent's failure to fulfill its obligation to provide adequate funding to the company.

Abdun-Nabi said his firm has twice extended its deadline for Protein Sciences to repay the loan, most recently to May 31. He said his firm filed the petition Monday to get its money back.

Protein Sciences' Adams charged that his firm has attempted over the past year to repay it. But Abdun-Nabi responded that the offer Emergent received was from a third-party that offered to buy the loan note for a "substantial discount," which he called "a low-ball" offer.

Adams said the petition to the bankruptcy court was a "desperate attempt to stop us" from getting the BARDA contract.

Because of the ongoing dispute between Protein Sciences and Emergent, the government conducted "two extra audits of the firm's business model and its financial stability," Robinson said.

"The results of those audits, which take a very long time to do, revealed that while there may be some minor problems, the company could perform the tasks that were asked in the contract," he insisted.

BARDA was able to resolve "most of the problems to the point that we felt it was worthwhile to award the contract," Robinson said.

The five-year contract is funded only for the first 18 months, with options for further development aspects, such as scale-up of the manufacturing facility, validation of the manufacturing process and development of the pandemic vaccine, he noted.

If Protein Sciences reaches its early milestones, the government would then consider exercising the options of the contract, which ultimately could provide the company access to \$147 million, Robinson said.

He noted that the award is a "cost-reimbursement contract," where the firm must submit an invoice on the work it has done, which must undergo a review process. If BARDA deems that work acceptable, the firm is reimbursed.

One thing that makes Protein Sciences contract different from other advanced development awards is that the government added an option to buy the firm's H1N1 vaccine, Robinson said. ■

Osiris

Continued from page 1

them male, ranging in age from 47 to 80 and suffering disease levels that ranged from moderate (23 patients) to severe (39). Patients had been afflicted for an average of 7.8 years, and those who also had asthma were excluded from the trial.

All participants took their four infusions with no evidence of related toxicity. Oxygen saturation levels showed no events either, and adverse event rates were comparable for patients receiving Prochymal and placebo.

Prochymal did, though, knock down c-reactive protein levels to a significant degree compared to placebo in patients who had elevated CRP (>4 mg/L) when they entered the study. The difference was clear at 10 days after the first infusion, and stayed low during treatment and follow-up.

CRP is often higher in such diseases as Crohn's, where Prochymal failed in late March. The trial was tainted by a higher-than-expected placebo response and the possibility of bias in patients' reporting, Osiris said, and the trial was starting over. (See *BioWorld Today*, March 30, 2009.)

In GvHD, too, elevated CRP is an important factor. September is expected to bring data from two pivotal Phase III trials in that indication. One study randomized 244 steroid-refractory patients, and the other randomized 190 patients with newly diagnosed GvHD.

Signed in late 2008, the deal between Genzyme and Osiris provided the latter with \$130 million up front and as much as \$1.25 billion in milestone payments. Also included in the deal is Chondrogen, a Phase I/II mesenchymal adult stem cell candidate for osteoarthritis of the knee. (See *BioWorld Today*, Nov. 5, 2008.)

Company officials were traveling and not available Wednesday, as analysts debated the meaning of the latest results. "Prochymal fails again," wrote Lazard Capital Markets' Joel Sendek in a same-day research report, adding that efficacy in the refractory GvHD indication would not be enough to drive profitability. Sendek had a "sell" rating on Osiris' shares.

At the opposite end of the spectrum was Charles C. Duncan, of JMP Securities, who rated Osiris "market outperform" and wrote that the good safety data lowered the risk for approvability. "Although not statistically significant nor an observation that we are basing our bullish view on, treatment with Prochymal did demonstrate positive trends in improving pulmonary function, including the six-minute walk test," in Duncan's view.

Landing in the middle was Edward A. Tenthoff, analyst with Piper Jaffray, who pointed to the CRP data and its meaning for GvHD. Tenthoff wrote that he was "optimistic we'll see positive results" from that trial in the fall, with potential fast-track approval in that indication in the first half of next year. ■

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Oligomers

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his team showed that adding A-beta oligomers to brain slices – in the sorts of concentrations that might naturally be present in an aging brain – “quite strongly facilitates” long-term depression, a weakening of neural connections. Whether the effects identified in the paper are technically toxic “depends on your definition of toxicity,” Selkoe told *BioWorld Today*. A-beta oligomers do not kill neurons outright, though in high concentrations they do ultimately damage them physically. And after all, forgetting is a normal, necessary and helpful part of brain function.

But in one way, that is precisely what makes the changes in neural communication that Selkoe and his colleagues described typical of Alzheimer’s disease.

“I can hardly point to an event in the entire [disease] process that is truly unique to Alzheimer’s,” Selkoe said. Instead, what happens in Alzheimer’s is “too much of a normal thing,” he said.

Neurons communicate through electrical signals, and the connection between two neurons can be altered permanently if one neuron fires multiple times in a row. Whether such stimulation is able to permanently alter the connection, and whether an altered connection will be strengthened or weakened, depends on the strength and patterning of the pulses. In the most simple terms, strengthening of neural connections or long-term potentiation is thought to be the way in which neurons store memories, whereas a permanent weakening or long-term depression is a way for memories to be erased.

In their paper, Selkoe, who is co-director of the Center for Neurologic Diseases at Brigham and Women’s Hospital, and his colleagues, from Harvard Medical School and University College Dublin, used isolated brain slices to test how neural transmission was altered by exposure to A-beta oligomers, and used a variety of receptor blockers to tease out the transmitter systems underlying the changes.

They found that A-beta increased the effectiveness of stimulation patterns that weaken neuronal connections, making it easier to induce long-term depression. That finding is complementary to earlier work that had shown that A-beta oligomers make it harder to strengthen neural connections.

Mechanistically, A-beta appears to increase glutamate concentrations in the synapse by hindering its recycling. When Selkoe and his colleagues added a glutamate scavenger to the brain slices before stimulation, regular long-term depression was not altered. But the increases in long-term depression due to A-beta were reversed by the scavenger, showing that the increased long-term depression results from increased levels of glutamate.

In their paper, Selkoe and his colleagues wrote that their findings “have both mechanistic and therapeutic implications for the initiation of hippocampal synaptic failure in AD and in more subtle forms of age-related A-beta accumulation.”

Selkoe said that a specific lesson from the work is that A-beta oligomers could be targeted therapeutically. “If you could find a small molecule that coats the A-beta oligomer or prevents its binding to the cell membrane . . . chances are that you would get less loss of synapses, and therefore improved learning.”

Elan Pharmaceuticals, of which Selkoe is a co-founder, currently is developing one candidate, as are others in the field.

More generally, Selkoe said, the work argues that an aggressive approach to early stage Alzheimer’s will be necessary to make a dent in the disease, which is the most common neurodegenerative disorder and on the increase as the population ages.

Instead of focusing on what delivers the final blow to kill a cell, the focus should be on “what suddenly impairs the function of neurons, long before they die,” Selkoe said.

“To treat Alzheimer’s, you have to really nip it in the bud,” he added. ■

OTHER NEWS TO NOTE

- **Cougar Biotechnology Inc.**, of Los Angeles, announced the voluntary dismissal by the plaintiff of a class-action complaint filed in May in California, which sought to block Cougar’s purchase by a wholly owned subsidiary of **Johnson & Johnson**, of New Brunswick, N.J. (See *BioWorld Today*, May 26, 2009.)

- **DiaGenic ASA**, of Oslo, Norway, signed an option agreement with **Merz Pharmaceuticals GmbH**, of Frankfurt, Germany, to gain access to biomarkers for mild cognitive impairment (MCI), increasingly considered a transitional stage to Alzheimer’s disease. The biomarkers are intended to be used to identify patients with MCI prone to converting to Alzheimer’s disease for inclusion into Merz’ clinical trial programs. Merz also will receive an option for nonexclusive rights to further biomarkers. Financial details were not disclosed.

- **GPC Biotech AG**, of Princeton, N.J., said its shareholders approved the adoption of the merger agreement with Diagenix GmbH, which will be renamed Agennix AG and converted into a stock corporation. German investment firm dievini Hopp BioTech holding GmbH & Co KG, one GPC’s largest shareholders, contributed €15 million (US\$20 million) under the deal. The merger, which was announced in February, is expected to close by year-end. (See *BioWorld Today*, Feb. 19, 2009.)

- **ImmunoCellular Therapeutics Ltd.**, of Los Angeles, said it signed an agreement with **Formatech Inc.**, of Andover, Mass., for the manufacture of IMUC’s cancer stem cell vaccine candidate, ICT-121, for an upcoming Phase I trial. That study, set to start early next year, will target glioblastoma. Financial terms were not disclosed.

Savara

Continued from page 1

lier inhaled products.

The company can take compounds – both marketed drugs and new chemical entities – and formulate them using the NanoCluster technology, which engineers particles out of the drug itself, negating the need for excipients. The concept is based on natural examples of aerosols such as spores from molds and fungi.

“We tried to mimic that, with something that looked like a spore” by changing the molecular structure of the drug, Neville said.

The goal is to create particles small enough to ensure adequate deposition of the drug into the lung. In most existing inhaled products – inhaled asthma drugs, for example – only 15 percent to 30 percent of the drug actually gets into the lungs, he said, and of that, only a fraction makes it into the deep lungs, the rest going into the throat and stomach where it can result in systemic effects.

With the NanoCluster technology, “we’ve been able to dial in the drug at between 1 and 3 microns,” Neville told *BioWorld Today*. “That’s the perfect range of those particles.”

Best of all, he added, the technology “is very reproducible and scalable,” and data to date have demonstrated a “high dose-to-dose repeatability.”

Savara is working on a couple of programs on its own, namely in lung cancer prevention and lung cancer staging, using grant money, but most of its business development centers around partnerships in which it will apply the NanoCluster technology to other companies’ compounds.

Those deals typically start with a feasibility phase, with Savara formulating the drug and returning it to partners. “Then they evaluate it, and we enter into licensing negotiations,” Neville said.

Savara, which raised seed funding in August, recently closed a Series A round. Though the company did not disclose the amount raised, an SEC filing indicated that the firm pulled in \$833,000 of a \$1.4 million round, with a total of 13 investors. The individual investors were not disclosed.

Neville said the Series A funding should take the firm through the end of 2010. He added that Savara also has revenue coming in from out-licensing its particle engineering technology services to other companies for drug development purposes.

“That’s the value of having a platform technology,” he said. “We have a number of areas” to potentially pursue.

The company initially is focusing on indications “involving infections in the lung,” he said, such as asthma, chronic obstructive pulmonary disease, pulmonary bacterial infections and is working on ways to deliver tuberculosis therapy to the lungs.

Savara also had some early positive data in cancer. An upcoming issue of *Pharmaceutical Research* is expected to highlight preclinical data showing that a chemothera-

peutic agent could be delivered directly to the lungs using a NanoCluster-based formulation at a much lower dose, suggesting a method of possibly treating lung cancer without the usual systemic side effects, Neville said.

But is Savara going to get into the inhaled insulin space, which, after some notable failures, seems to have been reignited by positive data from MannKind Corp.’s Afresia (insulin human [rDNA origin]) inhalation powder?

“We do have a 100 percent insulation formulation” that’s available for licensing, Neville said, though the company does not intend to pursue that product on its own.

For now, Savara is using its technology to develop dry powder inhaled therapeutics, though the company would like to expand into the nebulizer and propellant markets as well. “Those are both very big markets, and we believe our technology is applicable,” he said.

Savara operates with five full-time employees, plus another 12 to 15 part-time workers and consultants, though Neville said the latest financing will allow the firm to hire at least three new business development people.

The company is based in Austin, Texas, though its wet-lab and technical operations are in Lawrence, Kan. ■

CLINIC ROUNDUP

- **Addex Pharmaceuticals**, of Geneva, said partner **Ortho-McNeil-Janssen Pharmaceuticals Inc.**, of Raritan, N.J., started Phase I testing of ADX71149, a metabotropic glutamate receptor 2-positive allosteric modulator, triggering a €1 million (US\$1.4 million) milestone payment to Addex. ADX71149 is believed to have potential in schizophrenia, anxiety, depression and other central nervous system disorders.

- **Conatus Pharmaceuticals Inc.**, of San Diego, said it started a second Phase II trial of CTX-1027, a small-molecule matrix metalloproteinase inhibitor in development for liver disease associated with hepatitis C virus infection. The study is expected to enroll about 70 patients for whom treatment with standard of care is not advised and will test CTS-1027 alone or in combination with ribavirin. Dosing will last up to 24 weeks.

- **Crucell NV**, of Leiden, the Netherlands, said results of a second Phase II trial of its monoclonal antibody combination for rabies showed that it was safe and well tolerated when administered with a rabies vaccine vs. the marketed rabies immune globulin (HRIG) product in 48 healthy children and adolescents in a high endemic area of metro Manila, Philippines. Neutralizing activity levels were similar in the subjects administered the antibody product or with HRIG, and all study participants reached adequate immunity levels. Crucell is collaborating on that program with Sanofi-Pasteur, the vaccines division of Paris-based **Sanofi-Aventis Group**, which is providing the rabies vaccine, Verorab, for post-exposure prophylaxis.

CLINIC ROUNDUP

• **Cytos Biotechnology Ltd.**, of Zurich, Switzerland, said results from a biochemical analysis from a Phase IIa (Study 02) trial of CYT006-AngQb in hypertension, which involved an accelerated treatment regimen compared to an earlier Phase IIa trial (Study 01), showed on average a fivefold higher antibody titer, though much lower blood pressure reductions vs. Study 01. Those data indicated that patients whose antibodies had a higher affinity and which bound angiotensin II for a longer period of time showed a larger blood pressure reduction. No such correlation was detected between individual antibody titers and blood pressure reductions. Cytos has a third trial (Study 03) ongoing, evaluating the vaccine in the same treatment regimen but at higher doses.

• **Glenmark Pharmaceuticals Ltd.**, of Mumbai, India, reported Phase IIb data from a 12-week trial in 494 patients with Type II diabetes mellitus, showing that its Melogliptin, a dipeptidyl peptidase-4 inhibitor improved glycemic control, and patients receiving the drug experienced low incidence of hypoglycemia and neutral effect on body weight. Melogliptin significantly reduced HbA1c from baseline as compared to placebo with a mean average reduction of 0.75 percent in patients receiving 50-mg twice-daily doses and 0.60 percent in patients receiving 100-mg once-daily doses. In a subgroup of patients with higher baseline HbA1c of 8.5 percent to 10 percent, Melogliptin reduced levels compared to placebo with a mean average of 0.88 percent and 1.05 percent in the 100-mg and 50-mg dose regimens, respectively. Glenmark anticipates Phase III trials to start by the end of this year.

• **Living Cell Technologies Ltd.**, of Sydney, Australia, said its Phase I/IIa trial of Diabecell for insulin-dependent diabetes was authorized by the New Zealand Minister of Health. The trial started in Russia with a low dose of Diabecell, with preliminary data showing sustained long-term clinical benefit, with no remarkable adverse events. The New Zealand study allows the company to extend the trial with eight patients, four of whom are to receive double the initial dose used in the Russian trial, followed by four patients who will receive triple the dose. Diabecell comprises encapsulated porcine insulin-producing cells and is designed to normalize blood glucose levels in Type I diabetes.

• **Mesoblast Ltd.**, of Melbourne, Australia, reported results from the first five patients in a Phase I/II trial who underwent bone marrow transplantation with hematopoietic stem and progenitor cells expanded by its allogeneic mesenchymal precursor cells (MPCs). Successful bone marrow reconstitution and engraftment was achieved in all five who received MPC-expanded cells from cord blood, with no cell-related adverse events. The median time to engraftment was 15 days, about two weeks faster than expected without MPC expansion. The trial is expected to involve a total of 30 patients and is being funded through a grant

from the National Institutes of Health.

• **MorphoSys AG**, of Martinsried, Germany, said it submitted an application for a Phase Ib/IIa trial of MOR103, a fully human HuCAL-derived monoclonal antibody directed against granulocyte macrophage-colony stimulating factor, in rheumatoid arthritis. The study is expected to enroll 135 patients beginning in the second half of the year. The company also reported positive results from a Phase I study of MOR103 in healthy volunteers, showing that the drug is generally safe and well tolerated at all doses administered.

• **Oculus Innovative Sciences Inc.**, of Petaluma, Calif., said preliminary results from its U.S. 40-patient feasibility study, in which an enhanced formulation of the company's Microcyn Technology-based hydrogel was used in the treatment of acne, demonstrated elimination of secondary infection and inflammation and reduction of new scarring. The firm said the results warrant further research of the possible long-term impact of the formulation to determine whether the effects are sustainable. The company said it plans to use the information to evaluate the potential of near-term market opportunities while exploring longer-term partnerships with a number of prospective companies.

• **OncoGenex Pharmaceuticals Inc.**, of Bothell, Wash., reached an agreement with the FDA via a special protocol assessment process on an amendment to the design of a Phase III registration trial of OGX-011 in castrate-resistant prostate cancer. The FDA agreed on modifications to the study population featuring survival as the primary endpoint. The study population has been modified to evaluate patients receiving first-line chemotherapy, rather than those receiving second-line chemotherapy. The news cheered Wall Street which sent OncoGenex shares (NASDAQ:OGXI) up \$2.63, or 13.5 percent, to close at \$22.05.

• **PepTcell Ltd.**, of High Wycombe, UK, said it received approval to start a Phase Ib trial of its HIV vaccine in the UK. The study is expected to involve 55 HIV-positive volunteers and is designed to assess both safety and tolerability, as well as the effectiveness of the vaccine by monitoring blood levels of the virus and CD4-positive T-cell count. The study is expected to run for a year. The HIV-v vaccine aims to generate both B-cell and T-cell responses from the immune system against regions of the virus that do not change from variant to variant.

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FINANCINGS ROUNDUP

- **AEterna Zentaris Inc.**, of Quebec City, said it completed its registered direct offering of \$10 million of units comprising common shares and warrants. The company received net proceeds of about \$9.25 million, which are expected to support general corporate purposes, including clinical development of its oncology and endocrinology compounds.

- **BioMimetic Therapeutics Inc.**, of Franklin, Tenn., said the offering period of its rights offering expired. The preliminary results indicated that the offering has been oversubscribed and, accordingly, the company will issue a total of 2 million shares to stockholders that exercised their basic subscription privileges and their oversubscription privileges. The offering will produce gross proceeds of approximately \$17 million. The company intends to use the proceeds for general corporate purposes.

- **Cel-Sci Corp.**, of Vienna, Va., entered a definitive agreement for a registered direct offering with an unnamed institutional investor, which will raise approximately \$5 million gross. The company will sell 12.5 million units, with each unit consisting of one common share and 0.67 war-

rants to purchase one share of stock. The investor has agreed to purchase the units at 40 cents per unit. The warrants, which grant the right to acquire up to 8.375 million shares, will be exercisable on or after 181 days from the closing date at 50 cents per share. The company said it will use the funds for a variety of purposes, including acceleration of its H1N1 swine flu work.

- **Intrexon Corp.**, of Blacksburg, Va., said it received an additional \$10 million of Series C-2 financing from New River Management V LP, an investment fund managed by Third Security LLC. Proceeds will be used to expand pre-clinical studies of the firm's modular inducible cancer immunotherapeutic platform to include many different modular combinations. Intrexon recently initiated a Phase Ib study in melanoma.

- **Taris Biomedical Inc.**, of Lexington, Mass., said it secured \$15 million in a Series A financing co-led by Flagship Ventures, Flybridge Capital Partners and Polaris Venture Partners. Taris was founded based on technology developed at the Massachusetts Institute of Technology, which is designed to enable local sustained delivery of drug directly to the target tissue through drug-device convergence. Proceeds are expected to support development of the firm's first product in bladder disease, and Taris anticipates entering Phase II studies next year.

OTHER NEWS TO NOTE

- **Neuralstem Inc.**, of Rockville, Md., said it entered into a sponsored research agreement with the China Medical University & Hospital of Taiwan to prepare for a human clinical trial using Neuralstem's human spinal cord neural stem cells to treat stroke patients. The therapy will focus on patients whose post-stroke symptoms, including complete or partial paralysis, have stopped improving more than six months after an ischemic stroke.

- **Novavax Inc.**, of Rockville, Md., reported preclinical results showing that its virus-like particle vaccine against H3N2, H1N1 and B influenza strains induced HAI antibodies against all three strains represented in the vaccine and against a variety of drifted strains in mice and ferrets that received intramuscular injections. All of the ferrets who received a dose of 15 mcg/strain developed HAI titers greater than or equal to 1:40, the level of antibody shown to be important for protection against flu in human studies of flu vaccines. Novavax's VLP vaccine contains three VLPs mixed together in a single formulation. Data were published in the June 24, 2009, online issue of *PLoS One*.

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