

BIOWORLD® TODAY

THURSDAY
MARCH 13, 2008

THE DAILY BIOTECHNOLOGY NEWSPAPER

VOLUME 19, No. 50
PAGE 1 OF 8

MNTX Miss in Postoperative Ileus Drops Progenics' Stock

By Jennifer Boggs
Assistant Managing Editor

Shares of Tarrytown, N.Y.-based Progenics Pharmaceuticals Inc. lost more than half their value after the company, along with partner Wyeth Pharmaceuticals, reported disappointing Phase III data of methylnaltrexone (MNTX) in postoperative ileus, casting a dark cloud of investor worry over the expansive MNTX program, which includes a pending new drug application for opioid-induced constipation.

Trading at about 25 times its normal volume, Progenics' stock (NASDAQ:PGNX) plunged 63.6 percent to close Wednesday at \$4.93, down \$8.62, while shares of Wyeth (NYSE:WYE) were barely nicked, losing \$1 to close at \$40.65.

Company executives were quick to point out, however, that the results of the trial, which failed to show a statisti-

See Progenics, Page 3

Memory Seeks a Turnaround By Focusing on What it Has

By Glen Harris
Managing Editor

Memory Pharmaceuticals attempted to pick itself up off the mat from two hard stock falls last year on bad news about an Alzheimer's product, announcing a cutback in discovery research and a new focus on developing current candidates.

"The curse of Memory is that the programs we are pursuing all have significant market potential and all require significant development activity," new President and CEO Vaughn M. Kailian said during a conference call. To free up money for that development the company announced it is eliminating 11 positions – 20 percent of its work force – and is shifting resources to current products with two partners who have notable resources, F. Hoffmann LaRoche Ltd. and Amgen Inc.

See Memory, Page 4

Receptor-of-all-Trades

TRPV1 Findings Bear on Weight Loss, Painkillers, Learning, Fever

By Anette Breindl
Science Editor

In a finding that could have implications for both painkillers under development and a weight loss drug already approved in many places, researchers from Brown University have discovered that so-called TRPV1 receptors have a role in neural plasticity.

"This is the first example of any TRP channel being involved in synaptic plasticity," senior author Julie Kauer, a professor of molecular pharmacology at Brown University, told *BioWorld Today*.

TRPV1, or transient receptor potential vanilloid 1, is best known as an inflammatory and neuropathic pain receptor that is activated by heat, and by capsaicin, the active ingredient in chili peppers. But those actions are

See TRPV1, Page 5

2008 Partnering for Global Health Forum

Voucher Senate Sponsor Seeks New Incentives for Drugmakers

By Donna Young
Washington Editor

RESTON, Va. – The likeability of the U.S. by foreign nations could increase if Americans broadened their efforts in global health initiatives, such as developing drugs to tackle diseases that affect poor populations, said Sen. Sam Brownback (R-Kan.).

Sponsoring global health programs, he told attendees at the 2008 Partnering for Global Health Forum, not only is a humanitarian obligation for the U.S. but should be a foreign policy endeavor for engaging other nations.

"The United States is like the MVP player on a team," Brownback said.

"Everybody admires you, but if the MVP player doesn't look around and thank or help the other members of the

See Global Health Forum, Page 6

INSIDE: TACERE SIGNS ONCOLYS AS ASIAN PARTNER	2
INSIDE: INVESTORS EAGER FOR RXI; SHARES SOAR.....	2



Tacere Signs Oncolys as Asian Partner in \$60M HCV Agreement

From Staff Reports

Two months after signing a potential \$145 million deal giving Pfizer Inc. rights to its preclinical hepatitis C virus candidate in all areas outside of Asia, Tacere Therapeutics Inc. added an Asian partner, signing Tokyo-based Oncolys BioPharma Inc. in a deal worth up to \$60 million in up-front and milestone payments.

The deal stems from a strategic alliance signed between San Jose, Calif.-based Tacere and Oncolys in June, which granted Oncolys an option to license TT-033 for Asian development and commercialization in exchange for an equity investment in Tacere. In addition to the potential \$60 million in payments, Tacere also would be eligible for royalties on any product sales, and if Oncolys opts to subli-

cense rights to TT-033, Tacere also would get milestones and royalties based on predetermined rates.

The companies will form a joint steering committee and will work with the Tacere/Pfizer steering committee to oversee preclinical R&D efforts for TT-033, a compound that contains three separate RNAi elements targeted against HCV inside an adeno-associated virus (AAV) protein coat.

In early studies, TT-033 demonstrated an ability to penetrate hepatocytes at high levels following a single intravenous administration, and was able, in animal studies, to target and cleave the hepatitis C virus itself at three different sites without toxicity. Those data were promising enough to land Tacere the early stage deal with New York-based Pfizer. Terms of that collaboration called for an undisclosed up-front payment, plus up to \$145 million in milestone payments and royalties on product sales. Pfizer also will pick up the tab for development work. (See *BioWorld Today*, Jan. 8, 2008.) ■

Investors Eager for RXi; Shares Soar on First Day of Trading

From Staff Reports

If there's any doubt that the RNAi space is hot these days, one look at RXi Pharmaceuticals' opening day stock activity should put that firmly to rest.

Shares of the Worcester, Mass.-based company (NASDAQ:RXII), which filed for a public listing in October to become independent of its parent firm, CytRx Corp., opened Wednesday at a modest \$6.01 before skyrocketing in morning trading – at one point as high as \$23.95. The stock closed Wednesday at \$10.50, up \$4.50, or 75 percent.

According to RXi's filing, the Nasdaq listing was intended to provide liquidity to shareholders and to allow the firm to raise money publicly in the future, but it was not accompanied by an immediate financing. To date, the company, which was spun out as a "pure-play" RNAi subsidiary in January 2007, has supported operations with a \$15 million investment from CytRx. (See *BioWorld Today*, Jan. 11, 2007, and Oct. 31, 2007.)

Originally holding an 85 percent stake in RXi, CytRx later reduced its ownership as part of RXi's licensing deal for intellectual property and product candidates from the University of Massachusetts Medical School. RXi's preclinical pipeline includes programs for familial amyotrophic lateral sclerosis, obesity, diabetes, oncology and cytomegalovirus-related disorders. ■

FINANCINGS ROUNDUP

- **EyeGate Pharma**, of Waltham, Mass., secured \$15 million in a Series C venture financing round for two Phase II clinical studies using its EyeGate II delivery system and its formulation of a corticosteroid. In the first half of this year the company plans to begin a Phase II trial in severe uveitis, and in the second half, it plans to initiate a Phase II trial in dry eye. New investor Medicis Capital joins existing investors Ventech, Innoven Partenaires and the Nexus Group. The funding brings the total venture investment in EyeGate to \$31 million to date.

BioWorld® Today (ISSN# 1541-0595) is published every business day by AHC Media LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305 U.S.A. Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. BioWorld® and BioWorld® Today are trademarks of AHC Media LLC, a Thompson Publishing Group company. Copyright © 2008 AHC Media LLC. All Rights Reserved. No part of this publication may be reproduced without the written consent of AHC Media LLC. (GST Registration Number R128870672).

ATLANTA NEWSROOM: Managing Editor: **Glen Harris**. Assistant Managing Editor: **Jennifer Boggs**. Senior Staff Writer: **Karen Pihl-Carey**. Staff Writer: **Tiffany Turner**. Senior Production Editor: **Ann Duncan**. Editorial Coordinator: **Daria Theodora**.

WASHINGTON BUREAU: Washington Editor: **Donna Young**. Staff Writer: **Catherine Hollingsworth**.

WEST COAST BUREAU: Staff Writer: **Trista Morrison**.

EAST COAST BUREAU: Science Editor: **Anette Breindl**.

BUSINESS OFFICE: Senior Vice President/Group Publisher: **Donald R. Johnston**. Senior Marketing Product Manager: **Chris Walker**. Marketing Coordinator: **Sonia Blanco**. Account Representatives: **Bob Sobel, Chris Wiley**.

DISPLAY ADVERTISING: For ad rates and information, please call **Stephen Vance** at (404) 262-5511 or email him at stephen.vance@ahcmedia.com.

REPRINTS: For photocopy rights or reprints, call our reprints department at (404) 262-5479.

PRESS MATERIALS: Send all press releases and related information to newsdesk@bioworld.com.

SUBSCRIBER INFORMATION

Please call **(800) 688-2421** to subscribe or if you have fax transmission problems. Outside U.S. and Canada, call **(404) 262-5476**. Our customer service hours are 8:30 a.m. to 6:00 p.m. EST.

Glen Harris, **(404) 262-5408**

Jennifer Boggs, **(404) 262-5427**

Anette Breindl, **(304) 296-1160**

Trista Morrison, **(858) 901-4785**

Donna Young, **(202) 739-9556**

Catherine Hollingsworth, **(301) 576-0667**

Senior Vice President/Group Publisher:

Donald R. Johnston, **(404) 262-5439**

Internet: <http://www.bioworld.com>



AHC Media LLC

Progenics

Continued from page 1

cally significant reduction in time to recovery of gastrointestinal function compared to placebo in patients with postoperative ileus (POI) recovering from segmental colectomy surgical procedures, were drastically inconsistent with prior Phase II data, and they await further data from that and several ongoing studies of MNTX.

At this time, “we haven’t any explanation for why these results occurred, especially in light of the Phase II data,” said Richard Kraweic, Progenics’ vice president of corporate affairs, though he added that the companies will continue to analyze those results.

The trial, conducted by Wyeth, tested intravenously administered MNTX, an opioid receptor antagonist, in doses of 12 mg or 24 mg every six hours vs. placebo. In addition to missing the primary endpoint, the study also failed to meet secondary endpoints, including time to discharge eligibility.

Even as they review those data, the partners also await results from a second similarly designed Phase III POI trial, expected in midyear. That study is being run by Progenics, and the “only real difference is that the Wyeth trial had a larger number of foreign sites,” Kraweic said, though he added, “but that shouldn’t be” what threw the Wyeth study off.

“From time to time, there are setbacks,” he told *BioWorld Today*, “but we think the future for methylnaltrexone is a very positive one.”

And that includes the upcoming April 30 PDUFA date regarding an application for the subcutaneous formulation of MNTX in opioid-induced constipation (OIC), an indication Kraweic described as “very, very different” from POI. He said the company does not expect the latest POI data to affect the FDA’s review of the drug in OIC.

“There were no safety concerns that came out” of the POI Phase III study, he said, adding that opioid-induced constipation in a palliative care setting – a market of about 1.5 million people in the U.S. – is a “significant unmet medical need.”

But some analysts were concerned that the discouraging POI results could taint the FDA’s view of the drug in OIC.

Analyst Joel Sendek, of Lazard Capital Markets LLC, who downgraded Progenics’ stock from “buy” to “hold,” wrote in a research note that while he thinks MNTX has “better than 50 percent change of approval” in opioid-induced constipation, there’s a good chance the “increasingly conservative FDA” could delay the approval to review POI safety data.

Cowen and Co.’s Leland Gershell anticipates an approvable letter at best, probably with a request for additional clinical work “given the limited database on patient exposures with” the subcutaneous formulation, he said in a note.

But Jonathan Aschoff, an analyst at Brean Murray, Carret & Co., who maintained a “buy” rating on Progenics,

wrote that the pending FDA review is for a different formulation of MNTX in a different indication than POI, and “we anticipate the company will . . . receive approval for subcutaneous MNTX in terminally ill patients” by the PDUFA date.

In the POI market, estimated to comprise about 2 million patients undergoing surgical procedures in the U.S., Progenics’ and Wyeth’s chief competitor is Exton, Penn.-based Adolor Corp., which is developing Entereg (alvimopan) in collaboration with GlaxoSmithKline plc. Despite being nearly derailed by reported links to increased cardiovascular risks, Entereg received a thumbs-up from an FDA advisory panel in January for use in POI following partial large or small bowel resection surgery with primary anastomosis and has a May 10 PDUFA date. (See *BioWorld Today*, Jan. 24, 2008.)

News of MNTX’s Phase III miss boosted shares of Adolor (NASDAQ:ADLR) 9.1 percent Wednesday, closing at \$4.68, up 39 cents.

For Progenics and Wyeth, mid-2008 likely will mark a decisive point in MNTX’s development. In addition to data from the second POI study, the companies are expecting results from two Phase II trials testing an oral formulation of the drug in OIC and from a Phase II study evaluating subcutaneous MNTX in an orthopedic rehabilitation setting.

A Phase III program is ongoing with the IV formulation in patients suffering POI following surgical repair of large abdominal hernias. Results from that study are expected in early 2009.

“We’re also looking at the chronic pain setting,” said Dory Lombardo, senior manager of corporate affairs. That program includes a Phase III trial of subcutaneous MNTX in patients with chronic noncancer pain.

“The key here,” Kraweic said, “is that we have a lot of shots on goal with methylnaltrexone.”

Under the terms of the 2005 collaboration, Wyeth gained exclusive rights to MNTX in exchange for \$60 million up front and milestones up to \$356.5 million. Progenics retains co-promotion rights in the U.S. and is eligible for royalties on sales ex-U.S. product sales.

Beyond MNTX, the company has PRO 140, an HIV drug that successfully completed Phase Ib testing and has fast-track status in the U.S., and a prostate cancer program that includes vaccines and antibodies targeting prostate-specific membrane antigen. ■

CLINIC ROUNDUP

• **Avexa Ltd.**, of Melbourne, Australia, said updated data from its Phase IIb clinical trial of apricitabine (ATC) for HIV showed that 90 percent of patients achieved undetectable viral loads. The 48-week data also showed increased CD4 cell count, which doubled in patients switched from 3TC to ATC.

Memory

Continued from page 1

Company officials explained during the conference call that the cutbacks and reallocations will affect R&D efforts the most, especially early discovery programs. They also will realize a \$3 million reduction in the annual burn rate.

One of the chief beneficiaries will be MEM 3454, the lead compound in its nicotinic alpha-7 receptor agonist collaboration with Roche. The product demonstrated a statistically significant effect on multiple measures of cognition in a Phase IIa study in Alzheimer's disease, and Memory is evaluating it as a treatment for cognitive impairment associated with schizophrenia in a Phase IIa trial. Topline data from that trial are expected in the fourth quarter.

Kailian said if Roche decides to exercise its option for MEM 3454 – a decision expected in the second quarter this year – it would mean an immediate milestone payment to Memory, plus another milestone to maintain the license, with those milestones totaling more than \$20 million.

Kailian said he would not conjecture on whether Roche will pick up the option, but added that “we remain impressed by their enthusiasm and commitment to the program...”

The company also said Roche will fund a biomarker study for MEM 3454 in schizophrenia this summer, with results expected in early 2009.

Kailian also said the company has expanded its collaboration with Amgen on its PDE10 inhibitor, looking at it for neurological and psychiatric disorders. Memory will be increasing its own funding for preclinical research and provide more access to its screening technologies to the collaboration over the next 12 months. In exchange, he said, Memory will be eligible for increased milestone payments. The revised pact also expanded the scope of compounds eligible for higher-tier royalties. Detailed financial terms were not disclosed.

Internally, Memory said it plans to proceed on its own with its PDE4 inhibitor program, which includes MEM 1414 and MEM 1917, both being investigated in cognition-related central nervous system disorders and inflammatory diseases. MEM 1414 has demonstrated efficacy in a broad range of preclinical cognition and anti-inflammatory models, and Phase I studies have demonstrated a favorable safety profile for the compound overall and particularly in nausea and vomiting, which has limited the development of other PDE4 compounds, the company said. Memory plans to move MEM 1414 into a Phase IIa trial by the end of 2008.

Last June Memory regained all worldwide rights to its PDE4 inhibitor back from Roche and agreed to make unspecified milestone payments and pay royalties on worldwide sales of marketed products from the program. (See *BioWorld Today*, June 20, 2007.)

Another program benefiting from the company refocus is its 5-HT6 antagonist program being developed for

Alzheimer's, schizophrenia, attention deficit disorder and obesity. The company is evaluating several lead compounds as potential development candidates, and said it plans to advance the program into clinical trials by the end of 2008.

Meanwhile, the compound that caused Memory so many problems last year, MEM 1003, has been sent to the company's development officer for possible assignment to someone else, Kailian said. The compound first failed a Phase IIa trial in bipolar disorder, and then in October missed in a Phase IIa trial in Alzheimer's disease. (See *BioWorld Today*, March 6, 2007, and Oct. 16, 2007.) The latter failure sent Memory's stock plunging 39 percent.

On Wednesday's news investors apparently decided to remain on the sidelines, with Memory shares (NASDAQ:MEMY) closing at 55 cents, down 2 cents. ■

CLINIC ROUNDUP

• **Biolex Therapeutics Inc.**, of Pittsboro, N.C., and **OctoPlus NV**, of Leiden, the Netherlands, said results of a Phase I clinical trial of Locteron, a controlled-release interferon alfa in development for the treatment of chronic hepatitis C, were published in the *Journal of Interferon & Cytokine Research*. In the randomized trial, the administration of Locteron showed bioactivity over a two-week period and resulted in flu-like side effects that were less frequent, milder and of a shorter duration than with PEG-Intron, the standard of care used as the control arm in the trial.

• **Celsion Corp.**, of Columbia, Md., said two clinical sites currently are screening patients after an institutional review board (IRB) granted approval of a Phase III study of ThermoDox (thermally sensitive liposomal doxorubicin) for liver cancer. The IRB approval is for the U.S. and Hong Kong. Celsion's clinical trial authorization application for the Phase III protocol has been accepted by China's FDA, with authorization to enroll patients expected in August, the company said.

• **Unigene Laboratories Inc.**, of Fairfield, N.J., said it successfully completed a Phase I/II study of oral calcitonin, which met all of its planned objectives, including showing the ability of the company's oral delivery technology to significantly reduce the levels of an established biochemical marker that correlates with bone loss. All of the 22 subjects who completed the study demonstrated reduction in that marker. The study also showed a dose-dependent increase in calcitonin blood levels.

• **Urogen Pharmaceuticals Inc.**, of Burlingame, Calif., said painful bladder syndrome/interstitial cystitis (PBS/IC) was reduced significantly with a single dose of URG-101, in a Phase II clinical trial of URG-101. Few IC treatments exist and no approved therapies are available for PBS, conditions that affect an estimated 10.5 million people in North America, the company said.

TRPV1

Continued from page 1

mediated by TRPV1 receptors on pain-sensing peripheral neurons. "Anatomical papers had localized TRPV1 receptors in the brain," Kauer said, "but no specific cellular function has been reported for them."

Using a variety of pharmacological agents and studying brain slices, Kauer and her team found that stimulating TRPV1 receptors induced long-term depression, a form of synaptic plasticity that makes neurons less responsive to stimuli, in inhibitory interneurons. Such interneurons, Kauer said, can simultaneously inhibit large groups of excitatory neurons, and so are important in timing and synchronization of brain rhythms.

When Kauer and her team blocked TRPV1 receptors in brain slices, and found that long-term depression also was blocked. In TRPV1 knockouts, interneurons had a greatly reduced capacity for long-term depression.

Synaptic plasticity is "a basic building block that the brain uses in all sorts of situations where it wants to adapt to changes in its environment," Kauer said. Long-term potentiation, where neurons become more responsive to stimuli, is a neural mechanism of memory storage. Long-term depression also has been implicated in memory formation, and is possibly related to a host of other behaviors, though Kauer said that it is experimentally "hard to connect synaptic plasticity to behavioral events."

The research may have implications for the use of TRPV1 agonists such as NeuroGesX Inc.'s NGX-4010. That drug has been successful in two Phase III trials to treat postherpetic neuralgia (PHN), a painful nerve complication related to shingles, though it failed a third trial. NeuroGesX plans to file its U.S. approval application later this year for NGX-4010 as a treatment for PHN, and several other companies also are developing TRPV1 antagonists. (See *BioWorld Today*, Feb. 28, 2008, and Dec. 27, 2007.)

NGX-4010 is administered in the form of a skin patch, making it somewhat unlikely that the compound significantly affects central receptors. Indeed, the more direct clinical relevance of the study may be for another drug that also can affect TRPV1 receptors: Sanofi-Aventis group's rimonabant, approved under the brand name Acomplia for weight loss in the European Union. Rimonabant has yet to gain FDA clearance, partly because of the agency's concern over its psychiatric side effects.

Acomplia was one of the TRPV1 receptor blockers that Kauer and her colleagues used in their study. It's been clear for some time, Kauer said, that endocannabinoids in general and Acomplia specifically affect TRPV1 receptors. But with her team's new discovery that such receptors play a role in neural plasticity, means that "some of the effects of Acomplia could be occurring through effects on TRPV1."

Kauer noted that her discovery is not necessarily bad news for either TRPV1 antagonists or Acomplia. The effect

of the drugs on central receptors "may be bad, or may be good [therapeutically] – we just don't know right now," she said. But "the fact that there are central receptors there, and that they have pretty potent effects on synapses, is something that needs to be taken into account."

On the basic science side, the group's findings potentially could implicate the receptor in yet another event: febrile seizures. In separate animal studies, researchers found last year that rimonabant affected brain physiology after the induction of such seizures, which can occur during high fevers. Kauer and her colleagues wrote that "our data suggest that the blockade of TRPV1 receptors could contribute to the anticonvulsant effect of [rimonabant]."

Kauer did stress that in the periphery, the channel is active at temperatures of 43 degrees Celsius or higher, a temperature that would be fatal in the brain. But recent studies also have shown that in the brain, TRPV1 can be influenced by other cellular denizens, making it possible that central TRPV1 receptors are active at slightly lower temperatures. And mechanistically, the link certainly makes sense: after all, the channel's "job in the periphery is to sense noxious heat." ■

OTHER NEWS TO NOTE

• **Amgen Inc.**, of Thousand Oaks, Calif., said the FDA's Oncologic Drugs Advisory Committee unanimously voted to recommend approval of romiplostim, its investigational thrombopoietin mimetic peptibody, in thrombocytopenia in adult patients with chronic immune thrombocytopenic purpura. While the FDA is not bound by advisory panel recommendations, the agency usually follows them. Amgen said it anticipates an FDA decision in the second quarter.

• **Anadis Ltd.**, of Melbourne, Australia, signed a final agreement with **ImmuCell Corp.**, of Portland, Maine, under which Anadis licensed from ImmuCell a portfolio of issued patents, IND filings, clinical data and manufacturing plans related to several human health product lines. The deal will enhance development work for *Clostridium difficile*, *E. coli* and immune deficiency-related opportunistic infections, the company said. The licensed technologies all are related to the usage of hyperimmune bovine colostrum to provide immediate-acting passive immunity against infectious diseases. The intellectual property Anadis obtains under the agreement includes two issued U.S. patents, and Anadis will provide ImmuCell with access to manufacturing infrastructure and know-how for their veterinary applications. No financial terms were disclosed.

• **Arcadia Biosciences Inc.**, of Davis, Calif., and **DuPont**, of Wilmington, Del., signed a research and commercial agreement to improve nitrogen use efficiency in corn. Under the terms, DuPont business Pioneer Hi-Bred has exclusive rights to Arcadia's technology. Financial details were not disclosed.

Global Health Forum

Continued from page 1

team to be better, then everybody gets resentful of the MVP," he noted.

Industry, Brownback said, must work with lawmakers and government to conceive new incentives for firms to get involved in global health issues, such as the FDA priority-review voucher, which was created under the FDA Amendments Act Of 2007. (See *BioWorld Today*, March 12, 2008.)

Brownback co-sponsored the voucher legislation with Sen. Sherrod Brown (D-Ohio), which was based on a proposal from a group of Duke University economics professors.

Under the provision, a manufacturer that receives U.S. approval of a treatment for a neglected disease – diseases that are infectious or parasitic and typically affect large populations in poor developing nations – could receive a voucher from the FDA for the expedited review of a second product of the firm's choice.

The law allows for the bearer of a voucher to sell or barter it to another company with no restrictions on how often it can be transferred.

The voucher measure passed swiftly through both chambers of Congress, in as little as 18 months from the time it was proposed by the Duke professors in March 2006 to when it was enacted in September, Brownback noted.

One reason the provision passed so quickly, he said, was that it had little political value.

The greater the political payoff, Brownback contended, the more difficult it is to get a bill passed in Congress. However, measures with little political value have an easier path forward, he said.

"If there was a political payoff on it, there would be competition for the two parties probably fighting each other about it," he said.

Brownback said he looks for issues to tackle that do not have "a lot of political value but have a high human value," such as the priority-review voucher.

"We had no resistance on this," Brownback said.

The intention of the voucher provision, he said, is to use the U.S. marketplace "to get the dollars to put forward to be able to develop drug treatments for Third World diseases."

The Duke professors estimated that the voucher could be worth between \$300 million and \$1 billion to the firm awarded it, which could be a huge financial boost to any company, but is especially valuable to small firms.

Now that Congress has passed the law creating the vouchers, the next step is ensuring the FDA implements the measure as lawmakers intended, Brownback said.

"I want to see that this has as much free-market value as possible," he said. "I want to see this fully tradable and have as high of value as possible."

"That's determined in the regulatory process, and we'll make sure that that happens," he added.

At least one member of an FDA committee that is working out the details of implementing the voucher program has suggested that the transferability of the vouchers be restricted to one time only.

Venture capitalists attending the forum insisted that the transferability of the vouchers be preserved to ensure they retain their potential for the highest possible value.

The FDA, Brownback told *BioWorld Today*, does not have the legal authority to restrict the vouchers "because we built into the language that this was transferable, and it's in the statute itself.

"We said transferability, and we meant transferability, total transferability," he stressed.

Brownback said he will reach out to the FDA to ensure that the agency implements the voucher program as Congress intended.

"Congressional intent is to have some weight, you would hope, in a regulatory process," he said.

One conference attendee noted that the priority-review voucher program is limited to human drugs and does not include products to treat animals.

Addressing animal health, he told Brownback during an audience Q&A session, is vital to developing nations. One of the main causes of malnutrition in Africans, the attendee said, is diseases that affect and kill animals used as food sources.

Brownback acknowledged that he and his colleagues had failed to consider animal drugs in the legislation, but said he would consider it for future amendments.

The audience applauded a suggestion by Brownback that the National Institutes of Health's budget be increased to allow for more research into therapies for neglected diseases.

The Kansas Republican said he also would explore options for creating new programs to provide student loan relief for researchers involved in investigating therapies for neglected diseases and improving existing loan pay-back programs for those working in public health.

Additionally, Brownback said, he plans to investigate potential extensions of market exclusivity for neglected disease drugs and other incentives, such as tax credits, for firms involved in R&D of those products.

The 2008 Partnering for Global Health Forum brought together more than 500 leaders and experts from the biotech industry, government, global health foundations and the medical community to explore new innovations and potential collaborations to address neglected diseases.

The conference, which ended Wednesday, was sponsored by BIO Ventures for Global Health, the Biotechnology Industry Organization and the Bill and Melinda Gates Foundation. ■

OTHER NEWS TO NOTE

• **BioInvent International AB**, of Lund, Sweden, has signed a deal with Leverkusen, Germany-based **Bayer HealthCare AG** related to the discovery and development of antibody products. Bayer will have a nonexclusive research license for the use of BioInvent's n-CoDeR library for the discovery of human monoclonal antibodies. BioInvent also will provide access to an extended antibody technology suite, including BioInvent's selection processes, streamlined robotics and immunoglobulin transient expression technology. Bayer HealthCare will fund all such activities, and BioInvent will receive license fees and additional milestone payments and escalating royalties on sales of any products commercialized. The agreement allows for up to 14 antibody products to be developed. No financial terms were disclosed.

• **Dendreon Corp.**, of Seattle, said the FDA has agreed to an amended special protocol assessment (SPA) for the Phase III IMPACT clinical trial of Provenge, its investigational active cellular immunotherapy for advanced prostate cancer. In addition, the FDA has reconfirmed it will accept a positive interim or final analysis from the IMPACT trial to amend the biologics license application for Provenge, the company said. The amended SPA accelerates the expected timing of the final IMPACT results by approximately one year. Interim results still are expected in the second half of this year, but final results now are expected in the second half of 2009 rather than 2010.

• **Endo Pharmaceuticals Holdings Inc.**, of Chadds Ford, Pa., named David P. Holveck president, CEO and director of the company, effective April 1. Holveck was most recently president of Johnson & Johnson Development Corp.

• **Genex Biotechnology Corp.**, of Worcester, Mass., said it finalized the protocol for Metcontrol, its metformin chewing gum product, and will be proceeding with application to regulatory agencies for a clinical study to compare the gum to immediate-release tablets in about 75 to 100 healthy volunteers.

• **ImaRx Therapeutics Inc.**, of Tucson, Ariz., plans to eliminate 20 jobs following a decision to put its stroke-treatment development on hold. The layoffs, included in a Security and Exchange Commission filing, would reduce its work force by about 60 percent. In January, ImaRx decided to cease development of its microbubble stroke therapy. The firm, instead, plans to focus on building the market for urokinase, an approved clot-busting agent initially acquired from **Abbott**, of Abbott Park, Ill., in 2006. The move came after the firm decided to halt enrollment in its dose-escalating Phase I/II study of SonoLysis after interim data from the second cohort indicated a greater incidence

of intracranial hemorrhage in patients receiving SonoLysis therapy.

• **Mercury Therapeutics Inc.**, of Woburn, Mass., said it exclusively licensed to **Makoto Life Sciences Inc.**, of Cambridge, Mass., rights to its lead series of activators of AMP-activated protein kinase, aimed at potentially improving glycemic control in Type II diabetes patients. Under the terms, Mercury will transfer all assets related to its MT-39 series of indirect AMPK activators, including all materials, research notes, synthetic routes and the structures of more than 40 compounds, and will advise Makoto on the continuing development of the MT-39 series. Makoto will be responsible for conducting further work and for filing patents to protect the series. Specific financial terms were not disclosed.

• **Mobidiag Ltd.**, of Helsinki, Finland, has released its Prove-it Herpes test for the identification of herpesviruses. The microarray-based test takes less than three hours to complete and enables simultaneous identification of eight different human herpesviruses.

• **Power3 Medical Products Inc.**, of Houston, has published the discovery of protein biomarkers for esophageal malignancies in the *International Journal of Cancer*. A total of 23 biomarkers were identified that have not been described before in such malignancies. The article said researchers confirmed the differential expression of six of those novel protein biomarkers in a large panel of primary tumors using Western blot, immunohistochemical and quantitative real-time PCR techniques.

• **PregLem SA**, of Geneva, said German health authorities have granted clinical trial authorization for the company's SAPHIR (safety, tolerability, pharmacokinetics and pharmacodynamic) study in healthy premenopausal women with PGL2001. The study is a Phase Ib clinical trial in healthy premenopausal women. PGL2001 is the company's lead NCE steroid sulfatase inhibitor.

• **ProMetic Life Sciences Inc.**, of Montreal, Quebec, and the **Wuhan Institute of Biological Products**, of Wuhan, China, signed a license agreement in which WIBP gains exclusive access to ProMetic's Plasma Protein Purification System for the Chinese market. ProMetic will assist in implementing a product development program including training, technology transfer and scale-up. WIBP will take the lead in conducting the clinical trials to obtain regulatory approval in China.

• **Raven biotechnologies Inc.**, of South San Francisco, and **CMC ICOS Biologics Inc.**, of Seattle, have entered into an agreement under which CMC will create a production cell line for Raven's next investigational new drug candidate, RAVI8, a humanized antibody targeting the ADAM9 protein on cells. Overexpression of ADAM9 protein has been reported in pancreatic, prostate, gastric, breast and lung cancers. Raven expects to file the IND for RAVI8 in 2009.

OTHER NEWS TO NOTE

• **Sirnaomics Inc.**, of Gaithersburg, Md., and **General Research Laboratory Inc.**, also of Gaithersburg, said they are advancing their partnership, initiated in July, for development of two RNAi-based therapeutic products after successfully identifying siRNA inhibitors for multitargeted siRNA cocktail approaches via in silico and in vitro studies using Sirnaomics' Tri-Blocker technology. Under the terms, the companies will jointly focus on developing two RNAi products to improve scarless skin wound healing and to treat prostate cancer. GRL will provide Sirnaomics will research funding and access to lab and office space, and Sirnaomics will receive undisclosed milestone payments at key points in the development process, plus royalties on any product sales.

• **Spermatech AS**, of Oslo, Norway, has chosen **Evotec AG**, of Hamburg, Germany, as a partner to identify small-molecule therapeutics for a discovery project. Spermatech has identified biological targets for the development of nonhormonal reversible male contraceptives. Compounds will be identified that reduce sperm motility and will be used in the development of nonhormonal reversible male contraceptives at Spermatech. In addition, compounds that promote target activity may be evaluated as supporters of male fertility.

• **TPG Biotechnology**, of Tokyo, and **JCR Pharmaceuticals Co. Ltd.**, of Ashiya, Japan, have entered into an agreement to fund the late-stage clinical development of two drug candidates: JR-013, a recombinant human erythropoietin for the treatment of renal anemia in dialysis

patients, and Growject, a product currently approved and marketed in Japan to treat short stature in children with growth hormone deficiency and Turner's Syndrome. JR-013 is in Phase II/III clinical studies in Japan. JCR is extending Growject use to treat adult growth hormone deficiency. Clinical studies for AGHD have been applied for in Japan. TPG Biotech will fund the development of the drugs, and in return will receive milestone payments, royalties and warrants to purchase JCR's common stock.

• **VistaGen Therapeutics Inc.**, of South San Francisco, signed an embryonic stem cells research alliance with Toronto's University Health Network and its stem cell research affiliate, the McEwen Centre for Regenerative Medicine. That collaboration is expected to include research into advanced techniques to differentiate embryonic stem cells into mature cardiac, liver and pancreatic beta-islet cells. VistaGen said it anticipates using the results of that research to develop the next generation of its customized embryonic stem cell-based differentiation systems for discovering new drugs for heart disease, liver disease and diabetes.

CLINIC ROUNDUP

• **XenoPort Inc.**, of Santa Clara, Calif., said XP21279, a potential treatment for Parkinson's disease, was well tolerated in a Phase I clinical trial. This first trial in humans was designed to assess the safety and pharmacokinetic (PK) of a prototype, sustained-release formulation of XP21279 administered with carbidopa, and to compare its PK profile to that of Sinemet (L-Dopa/carbidopa).

Biotech and Pharma Companies Looking to Partner!

Find them in our new **BioWorld BioPartnering Report 2008**.

The ins-and-outs on strategy, negotiation and successful completion of partnerships are revealed in this new report. This report provides you with the best chance at a smooth and successful collaboration from start to finish.

Call 1-800-688-2421 or 1-404-262-5476 for more information!

Or go to www.BioWorld.com

10th Anniversary



C21
BioVentures

EARLY RATE
SAVE 20%

REGISTER BY APRIL 18



Register Online

WWW.TECHVISION.COM/C21

The Private Lifescience Company Conference

May 20-22, 2008 ■ Napa, CA, USA ■ The Meritage Resort

Produced by:



Powered by:

