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PAGE 1 OF 10

Sebelius, DeParle Tapped for Top Federal Health Jobs

By Donna Young
Washington Editor

WASHINGTON – As expected, President Barack Obama Monday officially announced Kansas Gov. Kathleen Sebelius as his nominee for the secretary of the Department of Health and Human Services (HHS).

Obama also nominated Nancy-Ann DeParle, who oversaw Medicare and Medicaid during the Clinton administration, as the director of the White House Office for Health Reform.

Former South Dakota Sen. Tom Daschle was nominated earlier for both jobs, but stepped aside on Feb. 3 after it was revealed he had failed to pay more than \$128,000 in taxes on time. (See *BioWorld Today*, Feb. 3, 2009, and Feb. 4, 2009.)

The nominations come just days before the presi-
See HHS, Page 3

Epistem, Novartis to Explore Training Existing Stem Cells

By Nuala Moran
BioWorld Today Correspondent

LONDON – Epithelial stem cell specialist Epistem plc agreed on a pact that will see partner Novartis AG pay \$45 million in milestones up to registration for each product emerging from the collection of 266 gene targets that is the subject of the research and development agreement.

In addition to funding all R&D for the next two years, Novartis is making a \$4 million up-front payment. In addition, there will be tiered royalties on any products that get to market. Shares in Manchester, UK-based Epistem rose 19 percent to an all-time high of £2.85 (US\$4) when the deal was announced on Monday.

The agreement is significant in terms of pharma's engagement with stem cells in that rather than developing stem cells per se (of whatever variety) as therapies
See Epistem, Page 4

Former FDA Chief von Eschenbach:

Health Care Needs to be Reformed and Transformed

By Donna Young
Washington Editor

Biotech's future is dependent on the new reality in health care of integrating the parts and pieces of product discovery, development and delivery, said former FDA Commissioner Andrew von Eschenbach, who recently joined Greenleaf Health LLC as a senior adviser.

In an environment where science and medicine have moved rapidly from simply observing the manifestations of disease to understanding the mechanisms of disease, the FDA, industry and Congress all need to make adjustments if health care is going to be reformed and transformed, said von Eschenbach, who spent 25 years at the University of Texas M.D. Anderson Cancer Center in Houston before becoming director of the National Cancer Insti-

See FDA, Page 5

NEW CO NEWS

Verus Spinout Meritage Puts a New Spin on Budesonide for EE

By Trista Morrison
Staff Writer

Less than a year after spinning out of Verus Pharmaceuticals Inc., Meritage Pharma Inc. advanced its oral viscous formulation of the corticosteroid budesonide into a Phase IIb trial for pediatric eosinophilic esophagitis.

Budesonide is the active ingredient in AstraZeneca plc's Pulmicort, an inhaled powder or suspension for asthma, and Rhinocort, a nasal spray for allergies. Together the products earned \$1.8 billion in 2008, although a licensed generic of Pulmicort is set to be launched by Teva Pharmaceutical Industries Ltd. at the end of the year.

Other formulations of budesonide are under develop-
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Pharmaxis Seeks FDA Approval for Asthma Challenge Test, Aridol

From Staff Reports

Australian biotech firm Pharmaxis Ltd. filed a new drug application for Aridol, a bronchial challenge test designed to diagnose the presence of asthma in users by detecting airway inflammation. If approved, the product would be the first dry powder test available in the U.S., where more than 34 million people are affected with asthma. Aridol was developed to help doctors determine the severity of patients' inflammation by measuring airway hyper-responsiveness, with the aim of making sure patients gets the right amount of medication and appropriate treatment to manage their asthma.

It's already approved in Australia, Europe and Korea, and in fourth-quarter 2008, Pharmaxis reported Aridol sales of A\$203,000 (US\$128,496). The U.S. application was based on data from two international Phase III trials involving more than 1,000 subjects. Sydney, Australia-based Pharmaxis also continues working on its late-stage development program, Bronchitol, an inhalable dry power formulation of a naturally occurring sugar alcohol mannitol. The product recently started testing in the second of two Phase III trial in cystic fibrosis, with patient assessments expected to include improvements in lung function, infectious episodes, antibiotic use, quality of life and health economic measures.

Bronchitol also is being tested in bronchiectasis, an obstructive lung disease, and Pharmaxis recently reached an agreement with the FDA on the design of a Phase III trial in that indication. The pivotal study is expected to enroll 350 patients randomized to receive either Bronchitol or placebo for 52 weeks, with the primary endpoints defined as a reduction in the frequency of exacerbations and improvement in quality of life.

The drug met all its endpoints in an earlier Phase III trial, with those data serving as the basis for a marketing application filed last year with Australian regulators.

Beyond Aridol and Bronchitol, Pharmaxis has an earlier-stage pipeline, including PXS25, aimed at interstitial lung

diseases such as pulmonary fibrosis, and PXS4159, a pre-clinical program for asthma. ■

CLINIC ROUNDUP

• **Aerovance Inc.**, of Berkeley, Calif., received clearance from the FDA and the UK Medicines and Healthcare products Regulatory Agency to initiate a Phase IIb trial of inhaled dry powder Aerovant in patients with uncontrolled asthma. Aerovance expects to enroll about 500 patients with moderate to severe asthma, in the U.S. and Europe, who are poorly controlled by the combination of inhaled corticosteroids and long-acting beta agonists.

• **Ariad Pharmaceuticals Inc.**, of Cambridge, Mass., said that partner **Merck & Co. Inc.**, of Whitehouse Station, N.J., is starting a Phase II trial to evaluate the safety and efficacy of oral deforolimus, Ariad's investigational mTOR inhibitor, in patients with advanced non-small-cell lung cancer. Deforolimus is being studied in multiple clinical trials, both alone and in combination with other therapies, in patients with several different types of cancer. Under the terms of the agreement, Ariad will receive a \$10 million milestone payment from Merck upon treatment of the first patient in the study.

• **Astellas Pharma Inc.**, of Tokyo, and **XenoPort Inc.**, of Santa Clara, Calif., announced preliminary top-line results from a Phase II trial of ASP8825/XPI3512 for the treatment of symptoms in moderate-to-severe primary restless legs syndrome patients. The compound demonstrated statistically significant improvements compared to placebo on the primary endpoint of the trial and was well tolerated. Treatment with 1,200 mg of the drug was associated with a statistically significant improvement in the primary endpoint compared to placebo. Statistically significant improvements over placebo also were observed on some secondary endpoints, including the investigator-rated clinical global impression of improvement scale, which achieved statistical significance for each of the 600-mg, 900-mg and 1,200-mg dosing cohorts.

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HHS

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dent's White House health care summit, where representatives from Congress, industry, labor, consumer and patient advocacy groups and other stakeholders are set to meet in a gathering similar to a larger forum convened last week by Obama to discuss fiscal challenges facing the nation, which included health reform. (See *BioWorld Today*, Feb. 24, 2009, and Feb. 25, 2009)

Sebelius, the daughter of former Ohio Gov. John Gilligan, was elected the 44th governor of Kansas in 2003 and was re-elected to a second term in 2006. Before being elected governor, she served eight years in the Kansas legislature followed by eight years as the state's insurance commissioner.

As HHS secretary, Sebelius will oversee 65,000 employees and more than 20 offices and 11 agencies, including the Centers for Medicare & Medicaid Services (CMS), the FDA and the National Institutes of Health – three agencies also awaiting permanent leadership.

The Kansas governor “embodies” a commitment to bipartisan reform that works to “rein in costs, expand access and improve the quality of health care for the American people,” said Obama, who was flanked by current and former Republican Kansas Sens. Pat Roberts and Bob Dole, Rep. Henry Waxman (D-Calif) and Sen. Max Baucus (D-Mont.) at the White House Monday.

As Kansas governor, Sebelius inherited a billion-dollar deficit, the president noted.

But, Obama said, “by eliminating waste and inefficiency, while making smart choices, she balanced the state budget without raising taxes.

“Time and again, on energy and education, jobs and health care, she's bridged the partisan divide and worked with a Republican legislature to get things done for the people of Kansas,” the president said.

Obama praised Sebelius for refusing to accept campaign contributions from insurance companies while she was state insurance commissioner and for protecting Kansans from increases to their premiums by blocking a takeover of the state's largest insurer, Blue Cross and Blue Shield of Kansas, from Indianapolis-based Anthem Inc. – a fight the governor took all the way to the Kansas Supreme Court and won.

He noted that Sebelius also helped draft the proposed National Bill of Rights for Patients and served as the president of the National Association of Insurance Commissioners.

As a governor, Obama said, Sebelius has been on the “frontlines of our health care crisis.”

“She has a deep knowledge of what the burden of crushing costs does to our families and businesses,” he said. “That's why she fought to guarantee Kansans access to quality, affordable health care, and sought to secure it for every Kansas child from birth to age 5.”

Baucus, chairman of the Senate Finance Committee –

the body that will pass judgment on whether the Kansas governor takes the reins at HHS – called Sebelius “a strong choice” to fill the secretary's job and said she would bring “solid experience” to the position.

Baucus said health care reform was his “number one priority this year,” and would work with the Kansas governor to “make it happen.” As a former insurance commissioner, Sebelius “really gets what needs to be done,” the Montana lawmaker said in a statement.

Jim Greenwood, CEO of the Biotechnology Industry Organization, noted that Sebelius is taking the helm at HHS at an important point in history when the agency will play a critical role working with the president and Congress to implement health care reform and increase federal funding for scientific research. The governor also will be facing an FDA that “badly requires additional resources and leadership stability,” Greenwood said.

DeParle, who served as administrator from 1997 to 2000 of the Health Care Financing Administration – the predecessor name for CMS – and as a former commissioner of the Tennessee Department of Human Services, saw “firsthand our health care system's impact on workers and families,” Obama said. “I have absolute confidence in her ability to lead the public and legislative effort to ensure quality, affordable health care for every American,” the president remarked.

Most recently, DeParle was a research fellow at the Kennedy School of Government and Harvard University and also taught at the University of Pennsylvania's Wharton School of Business. In addition, she was an investment adviser at JP Morgan Partners and served on the boards of Boston Scientific Corp. and Cerner Corp.

“I don't think anybody has a silver bullet when it comes to health care,” Obama said. The health care crisis in the U.S. is “punishing families, battering businesses, squeezing our states and increasingly, imperiling our own budget.” He noted that health care is one of the fastest-growing expenses in the federal budget, “and it's one we simply cannot sustain.”

Sebelius and DeParle, Obama charged, must work with Congress, the White House and other leaders to “make sure that we finally deliver health care reform that will save our federal budget and help American families for generations to come.”

Fixing health care “won't be easy,” Sebelius said, “but bringing about real change rarely is.” However, she asserted, “business and labor leaders, teachers and health care providers, policymakers at the state, local and national level, parents and children are ready to join this effort.”

Obama also announced Monday the release of \$155 million authorized by the American Recovery and Reinvestment Act that will support 126 new community health centers intended to provide primary and preventive care to U.S. residents with no health insurance and relieve the burden on emergency rooms.

The president said the construction and expansion of health centers not only provide health care to an estimated 750,000 Americans but will create 5,500 new jobs. ■

Epistem

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for injection or transplant, the aim is to develop biopharmaceuticals that modulate endogenous epithelial stem cells.

The objective is to inhibit the processes that induce epithelial stem cells to form cancer stem cells, or otherwise go awry in gastro-intestinal and dermatological diseases.

“What we are talking about is the meat and drink of what [they] do in pharma,” Matthew Walls, CEO of Epistem, told *BioWorld Today*. “We will be looking at mechanism of action, proof of efficacy, safety and so on, as [they are traditionally] assessed.”

Walls said there are two routes to translating fundamental understanding of stem cell biology into effective therapies.

The first, administering stem cells to regenerate missing or damaged tissue, is making headway, but with ethical, safety, immunological and manufacturing issues still to be overcome, is many years from leading to standardized, off-the-shelf products.

“There’s no way that big pharma will engage in regenerative medicine until all the pitfalls are removed, and dealing with the quality issues behind doing that will take many years,” Walls said.

The second avenue, which the Epistem/Novartis partnership will pursue, involves modulating and controlling

existing stem cells within the body.

“We are talking about understanding what makes stem cells tick and using that to control them,” said Walls, adding that this second route will be the fastest way to develop regulated stem cell treatments.

As yet, Epistem has not identified any leads but over the last year has expressed the proteins generated by 30 of its gene targets, some of which could be therapies in their own right. The 30 proteins have been run back through Epistem’s models, with as many as 50 percent showing good activity.

While Epistem has firm understanding of the biology of epithelial stem cells based on 30 years of research by founding scientist Chris Potten, Novartis brings in development capabilities and molecular pathway expertise. Epistem’s existing team of 10 scientists working on the project will be boosted by a similar number of Novartis researchers based in Basel, Switzerland and Boston.

“We will now collaborate to develop treatments across cancer, gastrointestinal disorders and other epithelial diseases,” Walls noted. “This is a partnering model that is seldom seen – usually [deals] are associated with specific leads or candidate drugs.” ■

CLINIC ROUNDUP

- **Bionovo Inc.**, of Emeryville, Calif., said that positive Phase II trial results of its investigational drug Menerba were published online in the peer-reviewed journal *Menopause*. The study showed that Menerba (formerly MF101) is well tolerated, safe and effective for the treatment of vasomotor symptoms (hot flashes and night sweats) associated with menopause. The study also found that there were no significant side effects and suggested that Menerba will not lead to an increased risk for breast or uterine cancers.

- **Cardio3 BioSciences SA**, of Mont-Saint-Guibert, Belgium, treated its first patient with its new cell-based treatment C-Cure. The patient is participating in a Phase II/III study to assess the second generation cell therapy in patients with heart failure. That is a first-in-man study of cardiopoietic stem cells developed to heal heart injury.

- **Chelsea Therapeutics International Ltd.**, of Charlotte, N.C., reported positive results from its Phase II trial of Droxidopa, a synthetic precursor of norepinephrine. While the study did not achieve an improvement in mean arterial blood pressure during dialysis, it demonstrated a significant benefit in limiting the severity of the drop (nadir) in blood pressure during treatment, the company said. The drug candidate was studied in patients with intradialytic hypotension, a side effect of dialysis. Patients receiving 600 mg of Droxidopa showed a mean improvement in arterial blood pressure.

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FDA

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tute in 2002 and later moving to the FDA in 2005.

Von Eschenbach noted that when he joined the FDA, his challenge was one of resuscitating the agency.

"It was like encountering a patient who was on life-support," he told *BioWorld Today*, calling the agency one that had antiquated information technology systems and a shrinking work force, with 30 percent of its personnel set to soon retire.

"My first and foremost challenge and responsibility as commissioner was along the lines of resuscitation, developing the justification and rationale for additional resources, acquiring those resources and beginning to transform the infrastructure," von Eschenbach said.

However, the agency has recently received more funds to increase its staff and improve its technology and the FDA's move to its new White Oak headquarters in Silver Spring, Md., which began in 2003, has progressed smoothly, said von Eschenbach.

He left the FDA in January, and his new position for Greenleaf Health does not involve lobbying. Rather, he is advising organizations about long-term strategies involving product discovery, development and delivery.

The medical product industry, too, is facing its own challenges, he noted. As with the computer industry, where the success of a laptop or hard drive is dependent on the microprocessor and other components and vice versa, health care has become an industry in which the success of a therapeutic intervention is increasingly becoming reliant on the use of diagnostic tests, von Eschenbach said.

What used to define market share is no longer the case, he said, noting that drugs and devices in the future will not always be made for large populations, given the progress of personalized medicine and the knowledge of mechanisms of diseases.

"Industry has to rethink market share based on what are commonalities as it relates to fundamental mechanisms for which you are developing an intervention," von Eschenbach said.

Firms should be developing their interventions against a mechanism rather than against the outcome of the disease, he said.

For instance, von Eschenbach said, when angiogenesis inhibitors were being developed as cancer treatments, no one had considered at that time that they also could be successful treatments for macular degeneration of the eye, as is now the case, with many doctors substituting Genentech Inc.'s cancer drug Avastin (bevacizumab) for its much more expensive, but basically similar, drug Lucentis (ranibizumab).

From a mechanistic perspective, he explained, both cancer and macular degeneration "are diseases with abnormalities of angiogenesis operative."

Novartis AG's Gleevec (imatinib mesylate), which is

approved to treat chronic myeloid leukemia and gastrointestinal stromal tumors, is another example, von Eschenbach noted.

"Who in oncology would have ever said those diseases are the same?" he asked. "But from a mechanistic point of view, they can be thought of as the same."

While the medical products industry and the FDA currently are transforming their models for developing and regulating therapies, Congress also must transform its mindset, said von Eschenbach.

Lawmakers, he said, must understand that the FDA needs the ability to engage with drugmakers. "You can't do this in a vacuum," von Eschenbach contended. "There is going to have to be consultation, corroboration and cooperation," he said.

However, von Eschenbach added, "that doesn't mean the FDA is going to stop being a strong regulatory agency, and it doesn't mean the industry doesn't have to remain economically viable. The FDA should be and ought to be the strongest, most effective regulatory agency on the planet protecting and promoting public health of the people it serves. But that doesn't mean it doesn't do it in collaboration and cooperation with industry."

If the FDA and industry are forced to work in separate silos, new therapies will be delayed, von Eschenbach said.

"The more you isolate the FDA from the industry and isolate the industry from the FDA, the greater problems you are going to have," he said.

If personalized medicine is going to move forward, von Eschenbach contended, "why would we not want to do that in dialogue with each other so that we are aligning discovery and development with the regulatory pathway that is going to bring those things rapidly and efficiently to patients? Why are we going to create barriers or partitions between those rather than create this in a way that is much more seamless?"

The FDA, he said, must make a better case to Congress and reassure lawmakers about the necessity of communication between the agency and industry if regulation is going to be able to keep up with the scientific advances that lie ahead. ■

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Meritage

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ment by various biotechs. OPKO Health Inc. is working on an ophthalmic formulation, while Salix Pharmaceuticals Ltd. has rectal foam and gastro-resistant capsule formulations.

Yet some formulations of budesonide have run into trouble. Topigen Pharmaceuticals Inc. and NicOx SA recently discontinued development of TPI 1020, an inhaled nitric oxide formulation of the drug, after a Phase IIa miss in chronic obstructive pulmonary disease. While TPI 1020 failed to significantly improve on conventional budesonide in the trial, the companies plan to investigate other indications.

And just last week, shares of MAP Pharmaceuticals Inc. fell 76 percent after a Phase III trial of its unit dose budesonide (UDB) failed to outperform placebo in pediatric asthma. The company cited a placebo effect which may have skewed symptom improvement data, and MAP is working with partner AstraZeneca to evaluate the data and determine next steps for the program. (See *BioWorld Today*, Feb. 25, 2009.)

Elaine Phillips, president and CEO of Meritage, said there's "no question" that budesonide works in pediatric asthma. However, she noted that using a subjective endpoint like symptom improvement can "bake in a lot of ambiguity" to a clinical trial. That's why Meritage's ongoing Phase IIb trial of its oral viscous budesonide (OVB) will look at symptom improvement alongside eosinophil effect, a more objective endpoint evaluated via esophageal biopsies.

Meritage's randomized, double-blind, placebo-controlled study started last month and is expected to enroll 80 pediatric patients with eosinophilic esophagitis (EE). Three doses of the drug will be evaluated, and data are expected in the second half of the year.

There are no FDA approved treatments for EE, which affects an estimated 320,000 people in the U.S., about 90,000 of whom are children. Phillips called the disease "asthma of the esophagus" – attacks can be caused by various food or environmental allergens, triggering eosinophils to infiltrate the esophagus. The resultant swelling can lead to nausea, vomiting, problems swallowing, failure to thrive and other complications.

Phillips said awareness of EE has risen in the past decade as its incidence has increased alongside that of other allergic conditions. Yet with no approved treatment options, doctors often recommend changes in diet or may try to have patients point a steroid inhaler at their throat and swallow.

One group of physicians from Children's Hospital in San Diego and the University of California in San Diego published data in the *American Journal of Gastroenterology* showing that a "home brew" of oral budesonide lowered eosinophil counts and reduced symptoms of EE. The data contributed to Meritage's decision to develop OVB, Phillips said. She added that OVB's convenience, stability

483s and Warning Letters: Now What?

The agency issued 5,100 483s, 471 warning letters in 2007, and 5,585 recalls were issued. If you're in the industry long enough, chances are you'll have to deal with a 483, a warning letter, or a recall. But just because they are common, that doesn't mean they should be taken lightly.

In Part 1 of 3 sessions on FDA Enforcement, this 90-minute *BioWorld Today* audio conference introduces attorney and educator Roseann Termini. She will, through case studies and interactive exercises, help attendees understand these enforcement actions, and show how to respond to minimize liability risk.

"483s, Warning Letters, Recalls, and other Common FDA Enforcement Actions" is just \$325 per listening site. Scheduled for March 4, from 1-2:30 p.m., E.T., it includes presentation handouts and a Q&A session with the speaker. A conference CD (MP3 format) also is available. Please call 800-688-2421 or 404-262-5474 and mention conference code **T09544**.

and optimized formulation should provide incentives for physicians to use it rather than trying to create their own home brew.

Meritage isn't the only one who sees a market for EE. Last month, Cephalon Inc. paid a hefty \$100 million up front for the option to acquire Ception Inc. and its pediatric EE product reslizumab for another \$250 million. The drug is a humanized monoclonal antibody against interleukin-5 and is in a Phase IIb/III trial. (See *BioWorld Today*, Jan. 15, 2009.)

Phillips said Meritage would be interested in what any potential partners might have to offer for OVB, but the company also could see "taking this product all the way," all by itself. Phillips and other members of her management team hail from Verus, where they launched the Twinject epinephrine auto-injector for severe allergic reactions and anaphylaxis. The product was later sold to Sciele Pharma Inc.

Even before Verus, the core Meritage management team, along with Chairman Cam Garner, worked together at Dura Pharmaceuticals Inc., a specialty pharmaceutical company with 500 sales reps. Dura was acquired by Elan Corp. plc for \$1.8 billion. (See *BioWorld Today*, Sept. 13, 2000.)

For the near term, Meritage is staying focused on its Phase IIb trial of OVB, although Phillips said the company may do some pipeline-building due diligence this year.

San Diego-based Meritage raised \$22.5 million in Series A financing in March 2008, concurrent with its spin-out from Verus. Investors included Domain Associates, Latereil Venture Partners and the Vertical Group. The money should last beyond the end of the Phase IIb trial, Phillips said. ■

CLINIC ROUNDUP

• **Hana Biosciences**, of South San Francisco, said an independent data monitoring committee has completed a planned, pre-specified safety review of interim data from the ongoing pivotal rALLY trial of Marqibo (vincristine sulfate liposomes injection) for the treatment of adult acute lymphoblastic leukemia (ALL) in second relapse. The review continued to support the acceptable safety profile observed with Marqibo in earlier studies, and no new safety concerns were identified. The committee recommended that the trial continue to completion per protocol.

• **ImmunoGen Inc.**, of Waltham, Mass., said patient dosing started in a Phase III trial of T-DMI in second-line treatment for HER2-positive metastatic breast cancer, triggering a \$6.5 million milestone payment from South San Francisco-based **Genentech Inc.** and Basel, Switzerland-based **F. Hoffman-La Roche Ltd.** The 580-patient study is designed to compare T-DMI, as a single agent, to capecitabine plus lapatinib. Partner Genentech also reported that patient enrollment is moving ahead of schedule in a Phase II study of T-DMI in third-line HER2-positive metastatic breast cancer, with enrollment expected to be completed this quarter and final data available in the first quarter of 2010. If those data are positive, Genentech has said it will discuss the possibility of an earlier approval path with the FDA.

• **Morphotek Inc.**, of Exton, Pa., a subsidiary of Eisai Corp. of North America, has commenced a multicenter Phase II study of its MORAb-009 monoclonal antibody in mesothelioma. The study will evaluate MORAb-009, plus the chemotherapy drugs pemetrexed and cisplatin, as a first-line treatment for patients with mesothelioma. The primary objective is to assess the efficacy of MORAb-009 as combination therapy with the current standard of care as determined by progression-free survival in patients with locally advanced malignant pleural mesothelioma. Secondary objectives include safety and antitumor activity of MORAb-009 as determined by objective response rate. Patients will have locally advanced malignant pleural mesothelioma who have not received any prior treatment for their disease.

• **Nektar Therapeutics Inc.**, of San Carlos, Calif., reported positive topline results Monday from a Phase II study of NKTR-118 in patients with opioid-induced constipation. The study is terminating early on the basis of overwhelming evidence of efficacy at two different dose levels of 25 mg once daily and 50 mg once daily. The study achieved a clinically meaningful and highly statistically significant, dose-dependent increase in spontaneous bowel movements from baseline after the first week of NKTR-118 treatment with the 25-mg dose and the 50-mg dose vs. placebo.

• **Pluristem Therapeutics Inc.**, of New York, said the FDA cleared the company's investigational new drug application to initiate a Phase I trial for the treatment of critical limb

ischemia using Pluristem's PLX-PAD. That will be the first trial using PLX-PAD, placenta-derived stem cells that are expanded using the company's 3D PluriX technology. PLX-PAD is an off-the-shelf, one-size-fits-all product. In the dose-ranging trial, the product will be administered to patients considered late stage and defined as patients afflicted with CLI who have not responded to traditional medical or surgical interventions.

• **Romark Laboratories LC**, of Tampa, Fla., said its study evaluating nitazoxanide in combination with peginterferon alfa-2a and ribavirin in patients with chronic hepatitis C virus infection with genotype 4 was published in the March 4, 2009, issue of *Gastroenterology*, the official journal of the American Gastroenterological Assoc. Institute. The study showed that the addition of nitazoxanide to standard-of-care therapy increased the rate of sustained virologic response when compared with patients given peginterferon plus ribavirin alone. An accompanying editorial commenting on the study also was published in the journal.

• **TissueGene Inc.**, of Rockville, Md., said that its South Korean licensing partner Kolon Life Science Inc. has received regulatory allowance from the Korea Food and Drug Administration to initiate a Phase IIa trial of TissueGene-C (TG-C) in patients with severe osteoarthritis of the knee. TG-C has been developed for the localized delivery of allogeneic human cells expressing TGF-beta1 to induce the regeneration of cartilage.

FINANCINGS ROUNDUP

• **FlexGen BV**, of Leiden, the Netherlands, said it completed an undisclosed equity financing round by BioGeneration Ventures and Credit Agricole Private Equity, which is expected allow the company to accelerate development and commercialization of FlexArrayer, an instrument designed to assist in the production of custom microarrays. The company is collaborating with partners in the areas of next-generation sequencing, biomarker validation and other applications.

• **Ikano Therapeutics Inc.** (formerly Intranasal Therapeutics Inc.) of Saddle Brook, N.J., closed the second and final \$9 million tranche in a Series B preferred stock financing with its current investor syndicate. The company also announced it changed its name to Ikano Therapeutics to better align with its new corporate strategy. The company also announced that Michael Ross, managing partner of SV Life Sciences, the company's largest investor, has been elected chairman of its board.

• **Response Genetics Inc.**, of Los Angeles, entered into a purchase agreement with affiliated funds of Special Situations Funds to raise \$2 million from the private placement of 2 million shares of common stock at price of \$1 per share. Response is developing molecular diagnostic tests for cancer.

OTHER NEWS TO NOTE

• **Actelion Ltd.**, of Allschwil, Switzerland, said the FDA issued a complete response letter for its supplemental new drug application seeking to expand Tracleer's use to include patients suffering from pulmonary arterial hypertension with less severe disease (WHO Class II through IV symptoms). Tracleer (bosentan) currently is marketed for PAH patients with WHO Class III through IV symptoms. In its letter, the FDA requested that the REMS (risk evaluation and mitigation strategy) submission be finalized before the review can be concluded.

• **Aileron Therapeutics Inc.**, of Cambridge, Mass., and **Astex Therapeutics Ltd.**, of Cambridge, UK, each received \$500,000 in grant funding through the Multiple Myeloma Research Foundation's 2008 biotech investment awards. Based on the companies' achievement of clearly defined milestones, the MMRF will commit an additional \$500,000 to each in 2010. Aileron develops compounds using its Stapled Peptide platform, while Astex creates small-molecule drugs using its fragment-based drug discovery platform Pyramid.

• **Amgen Inc.**, of Thousand Oaks, Calif., was named as a defendant in a whistle-blower lawsuit alleging that the company illegally marketed Enbrel (etanercept) and Aranesp (darbepoetin alfa), according to reports from *Reuters* and *Dow Jones Newswires*. The lawsuit was filed in the U.S. District Court in Boston on behalf of the U.S. and several states, and parts of the filing were recently unsealed, *Dow Jones* reported.

• **Endo Pharmaceuticals Holdings Inc.**, of Chadds Ford, Pa., said it extended the subsequent offering period for all the outstanding shares of Lexington, Mass.-based **Indevus Pharmaceuticals Inc.** until 5 p.m. EST, March 13. As of Feb. 27, about 64.3 million shares were validly tendered, representing about 80.9 percent of Indevus' issued and outstanding shares. Endo offered to buy Indevus earlier this year for \$4.50 per share, or about \$370 million. In separate news, Endo said it licensed exclusive rights to develop and

market investigational drug axomadol in the U.S. and Canada from Aachen, Germany-based **Grunenthal GmbH**. Axomadol is in Phase II development in moderate to moderately severe chronic pain and diabetic peripheral neuropathic pain. Terms call for Endo to make an up-front cash payment, as well as additional milestone payments. Grunenthal also will receive a transfer price, including cost of goods and royalties on net sales of the product in the U.S. and Canada. (See *BioWorld Today*, Jan. 7, 2009.)

• **Hi-Tech Pharmacal Co. Inc.**, of Amityville, N.Y., said it signed an agreement to acquire the assets of **ECR Pharmaceuticals**, of Richmond, Va., for \$5.1 million in an all-cash transaction to be paid over an eight-month period. Additionally, Hi-Tech could pay up to \$4 million in performance incentives tied to future ECR product sales and profits. The deal gives Hi-Tech rights to ECR's product line, including branded prescription products for treating allergy, headache and dermatitis/poison ivy.

• **NanoViricides Inc.**, of West Haven, Conn., said it signed a material transfer agreement with a major undisclosed pharmaceutical company for the evaluation of one of its nanoviricide drug candidates by an independent consultant. The drug candidate was designed to eradicate viral infections of the external eye, including those caused by adenovirus and herpes virus. If results are favorable, the companies are expected to begin good-faith negotiations for a potential long-term, exclusive, worldwide licensing deal.

• **Neose Technologies Inc.**, of Horsham, Pa., said it filed a certificate of dissolution, effective March 2. The company also will close its stock transfer books and will not recognize any stock transfers occurring after March 2.

• **Optimer Pharmaceuticals Inc.**, of San Diego, is accelerating plans to file for marketing approval in Europe of fidaxomicin (formerly OPT-80) in *Clostridium difficile* infection (CDI) based on results from its first CDI trial. Those data, reported in November 2008, showed that fidaxomicin met its primary endpoint of clinical cure and demonstrated a significantly lower recurrence rate vs. Vancocin (vancomycin, ViroPharma Inc.) The company plans to continue its second Phase III study before submitting a new drug application in the U.S. (See *BioWorld Today*, Nov. 12, 2008.)

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OTHER NEWS TO NOTE

• **Orexo AB**, of Stockholm, Sweden, said Abstral, a sublingual tablet formulation of fentanyl, received marketing authorization from the French and Spanish regulatory authorities for breakthrough cancer pain. It is expected to be launched in those territories during the second half of this year. The approvals trigger milestone payments of €1.3 million (US\$1.6 million).

• **Pearl Therapeutics Inc.**, of Redwood City, Calif., said it appointed Perry Karsen CEO. He most recently served as regional vice president, Asia/Pacific, and head of worldwide business development at Summit, N.J.-based Celgene Corp. Pearl is developing a pipeline of drugs to treat respiratory diseases, such as chronic obstructive pulmonary disease and asthma.

• **Rexahn Pharmaceuticals Inc.**, of Rockville, Md., said the company was notified by NYSE Alternext that it was not in compliance with listing requirements, in that it has stockholder equity of less than \$6 million and losses from continued operations and net losses in its five most recent fiscal years. The company must submit a plan by March 24, and would have until Aug. 24, 2010, to implement that plan if it is accepted.

• **Sinovac Biotech Ltd.**, of Beijing, said it received the good manufacturing practice certification for its recently opened filling and packaging production facility, issued by the FDA following a site inspection. That certification ensures that the company can meet potential production increases for marketed products Healive, Bilive and Anflu, with capabilities to fill and package Panflu, a pandemic influenza vaccine.

• **StemCells Inc.**, of Palo Alto, Calif., and **Stem Cell Sciences plc**, of London, entered a deal under which StemCells will acquire the operating subsidiaries and certain related assets of Stem Cell Sciences for 2.65 million shares of StemCells common stock and about \$715,000 in cash. Stem Cell Sciences focuses on commercializing applications of stem cell technologies for drug discovery and regenerative medicine research, while StemCells discovers and develops tissue-derived cellular products for therapeutic uses. Shares of StemCells (NASDAQ:STEM) lost 15 cents, or 9.6 percent, to close Monday at \$1.41.

• **Targeted Genetics Corp.**, of Seattle, said it is continuing its product-focused realignment strategy with the transfer of its adeno-associated viral (AAV) vector manufacturing technology. To that end, the company entered new license and manufacturing agreements with **Celladon Corp.**, of La Jolla, Calif., to enable Celladon to manufacture Mydicar, a genetically targeted enzyme replacement therapy for heart failure, through commercial manufacturing organizations or a commercial product develop-

ment partner. Under the terms, Celladon agreed to increase the payments to Targeted Genetics in the first six months of this year to support Mydicar manufacturing for Phase III studies, and the two firms also reached new milestone and royalty arrangements. Based on the increased Celladon revenue expected this year, in combination with reduced costs in other areas, Targeted Genetics anticipates adequate cash and short-term investments to support operations through June. The company continues to seek additional financing.

• **Xencor Inc.**, of Monrovia, Calif., said it entered a technology license and evaluation deal with New York-based **Pfizer Inc.** to optimize the performance of therapeutic monoclonal antibodies. Pfizer will apply Xencor's Xtend antibody half-life prolongation technology and XmAb ADCC enhancing technology to its antibody candidates. Under the terms, Pfizer will make an undisclosed up-front payment to Xencor, which also is eligible to receive additional consideration based on successful commercialization of products incorporating the Xencor technology. Specific financial details were not disclosed.

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