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PAGE 1 OF 7

Lawmaker Questions FDA Over Outsourcing Antibiotic Reviews

By Donna Young
Washington Editor

WASHINGTON – The head of a House subcommittee that oversees the FDA has demanded answers from Commissioner Margaret Hamburg about why the agency is considering “outsourcing” the efficacy analyses of older marketed antibiotics to a nonprofit standards-setting group, whose 2,000 members include numerous drugmakers.

The FDA is considering using Wayne, Pa.-based Clinical and Laboratory Standards Institute (CLSI), a nonprofit organization that promotes the development and use of voluntary consensus standards and guidelines, to provide postmarket information for updating the labeling of the older antibiotics.

The FDA said it is facing the enormous task of ensuring that drug labeling for older antibiotics, which are mostly
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Financings Roundup

PolyMedix Extends Cash Runway with Modest \$21M Public Offering

By Jennifer Boggs
Assistant Managing Editor

PolyMedix Inc., which, like many of its fellow biotechs, plans to scale back some of its R&D operations to concentrate resources on two lead programs, is hoping to push those programs into Phase II studies with a \$21 million public offering.

The Radnor, Pa.-based firm is offering up to 21 million units priced at \$1 per unit – each consisting of one share and a five-year warrant to purchase 0.30 shares at \$1.25 apiece – and proceeds will triple the company’s bank balance. The heavy dilution, though, didn’t sit well with investors, which dropped the firm’s shares (OTC BB:PVMX) 36 cents, or 28 percent, to close Wednesday at 93 cents.

PolyMedix had a little more than \$10 million as of June
See Financings Roundup, Page 4

Thinking Outside of the Pocket

Peptide Brings Transcription Factors Into Druggable Realm

By Anette Breindl
Science Editor

In the Nov. 12, 2009, edition of *Nature*, researchers reported that they were able to directly target the transcription factor Notch through the use of a hydrocarbon-stapled peptide. The peptide, SAHMI, was able to inhibit the growth of T-cell acute lymphoblastic leukemia or T-ALL cells both in culture and in animal models.

Notch is a transcription factor that controls cell division, differentiation and death; it was first discovered as a protein that is hyperactive in more than half of all patients with T-ALL. Notch, and transcription factors, in general, have to date been considered both highly desirable therapeutic targets and, by and large, highly undruggable ones.

Beyond its specific implications for T-ALL, the discov-
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NEW CO NEWS

Aduro Raises \$2M in Series A for a Revived *Listeria* Vaccine

By Catherine Hollingsworth
Staff Writer

Privately held Aduro BioTech has completed a Series A-1 financing that will provide the company with \$2 million to advance a vaccines program, which utilizes the bacteria *Listeria* to fight cancer and other infectious diseases.

The Berkeley, Calif.-based biotech is acquiring the intellectual property rights to the *Listeria*-based technology from Anza Therapeutics, a spinout of Cerus Corp., which previously conducted three Phase I trials of the *Listeria* vaccine in oncology and hepatitis C.

Aduro plans to pick up where Anza left off, focusing on those initial applications of the *Listeria* vaccine in oncol-
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OTHER NEWS TO NOTE

• **Amsterdam Molecular Therapeutics**, of Amsterdam, the Netherlands, has successfully treated Duchenne's muscular dystrophy in an animal model with its gene therapy. The proof-of-concept studies were performed in collaboration with a group at the University of Rome and demonstrated effectiveness in the heart as well as in skeletal muscles. AMT is developing a gene therapy product for DMD based on exon skipping technology, which results in bypassing the genetic defect so that the functional protein can be formed again.

• **Jubilant Organosys Ltd.**, of New Delhi, India, through its subsidiary, Jubilant Biosys Ltd., and Duke University in Durham, N.C., have signed a letter of intent to develop a multi-faceted drug discovery partnership. Under the proposed partnership, Duke and Jubilant will select and manage a portfolio of translational research projects over a period of five years with the objective of developing four to five technologies. In addition, Jubilant and Duke will collaborate on two innovative biomarker studies to be conducted in Kolkata, India.

• **Merck Eprova AG**, of Schaffhausen, Switzerland, a wholly owned subsidiary of Merck KGaA, has signed an exclusive license agreement with **Isofol Medical AB**, of Gothenburg, Sweden, to use Merck Eprova's folate compound Modufolin in oncology. Isofol will conduct Phase I and II studies using a combination of Modufolin and antifolates starting this year and expected to be finished by the end of 2010.

• **Nucryst Pharmaceuticals Corp.**, of Princeton, N.J., entered a definitive agreement to sell to subsidiaries of **Smith & Nephew plc.**, of London, substantially all of Nucryst's operations and assets including all rights to its nanocrystalline silver technology for \$21 million in cash plus the value of working capital. The closing of the sale is subject to the approval of Nucryst shareholders. Nucryst also entered into an amalgamation agreement with the **Westaim Corp.**, of Toronto, which currently owns approx-

News Aggregators' Glitches Still Misdating BioWorld Articles

BioWorld continues to receive puzzled calls and emails from subscribers asking why they are seeing *BioWorld Today* articles, some published years ago, showing up on assorted websites as having been published in early November 2009.

The problem has been traced to news aggregators, companies that pull articles from a wide array of publications for their customers. Unfortunately, BioWorld has no control over these services, and the misdating of the articles is caused by a flaw in their systems, not BioWorld's.

We are, however, working diligently to resolve the problem. In the meantime, the BioWorld archives continue to function correctly.

– Glen Harris, Managing Editor

imately 75 percent of Nucryst's outstanding shares, under which Nucryst will amalgamate with a newly formed Westaim subsidiary to form Amalco, and Nucryst shareholders other than Westaim will receive one redeemable preferred share in Amalco, with shares worth \$1.77. Following the transaction, Nucryst intends to delist from the Toronto and Nasdaq exchanges.

• **OPKO Health Inc.**, of Miami, said it has completed the acquisition of rolapitant, a neurokinin-1 (NK-1) receptor antagonist, and a related compound from **Schering Corp.**, of Kenilworth, N.J. Rolapitant recently completed Phase II testing for prevention of nausea and vomiting related to cancer chemotherapy and surgery, and other indications. Phase I testing also has been initiated for a second compound in the same class. OPKO said the compounds may have advantages over presently marketed products. OPKO obtained the compounds for an undisclosed amount from Schering, which divested the development programs in connection to its merger with **Merck & Co. Inc.**, of Whitehouse Station, N.J. (See *BioWorld Today*, March 10, 2009.)

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AHC Media LLC

FDA

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made by generic manufacturers, many of them foreign firms, are updated to ensure appropriate use against organisms. Many antibiotics have become resistant to certain bugs, but the product labeling does not reflect that information.

But in a letter this week to Hamburg, Rep. Rosa DeLauro (D-Conn.), chairwoman of the House Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies, raised concerns that CLSI lacks experience in reviewing human clinical trial data.

"FDA decisions about antibiotic resistance and efficacy of drugs already on the market should be based on data from outcomes of clinical studies in humans, not the kinds of test tube studies or animal studies that CLSI primarily relies upon to make its determinations," she told Hamburg. "Any proposal that would outsource this work is highly questionable and would reflect poorly on the FDA."

While DeLauro said CLSI was a "well-respected" organization with "highly regarded" work, developing standards is a "very different task" than interpreting the results of studies to evaluate disease outcomes for drugs taken by patients.

DeLauro expressed concern that "test-tube" evaluations of the older drugs may compare "unfavorably" to newer, more expensive drugs. "The older drugs still could provide treatment results that are equivalent, or even surpass the newer, more expensive drugs," she argued.

The congresswoman also raised concerns about CLSI's membership, which includes drugmakers and other industries regulated by the FDA.

While the FDA has "essential safeguards" in place to minimize potential conflicts of interest among those making decisions about the efficacy and safety of products, the consensus process used by CLSI includes drug companies, and "that approach is not appropriate for research interpretations used by a regulatory agency," DeLauro charged.

The Connecticut Democrat also noted that some members of the FDA's Anti-Infective Drugs Advisory Committee, which met on Oct. 26 to discuss CLSI's role in updating antibiotic drug labeling, also were members of the standards group.

"But that information was not made public and no waivers were required for these very obvious conflicts of interest," DeLauro said.

She noted that three of the panelists stepped aside after it was brought to regulators' attention before last month's meeting that they were CLSI members. But, she said, "others with CLSI connections continued to serve."

DeLauro also accused the FDA of stacking the deck in favor of CLSI at the meeting, which included supportive presentations from the Pharmaceutical Research and Manufacturers of America and other groups.

But Glen Fine, CLSI's executive vice president, said DeLauro had been misinformed about the role his group

may be asked to play in updating antibiotic labeling and the way the organization functions.

CLSI's membership includes representatives from government, industry and health professionals, he explained, noting that the FDA also is a member.

"In everything we do, we seek balance, openness, transparency and have very sophisticated administrative procedures of how we conduct the proceedings to develop the best practice standards and guidelines," Fine told *BioWorld Today*. "We follow very rigidly the requirements of the American National Standards Institute, which accredits us as a valid, highly credible standards development organization."

While none of CLSI's 210 standards and guidelines are required to be followed by U.S. law, they carry "the weight of the law" because "everybody involved with them are the best thought leaders in the world," he said.

Fine noted that all members of CLSI must fully disclose their conflicts of interest and "check their guns at the door."

The role the FDA is considering for CLSI is "not outsourcing," he insisted.

"I personally take offense with the term 'outsource,'" Fine said. "The FDA has not given up its legal or authoritative responsibility to a private entity. It is merely using the advice from an organization like CLSI to help assist it in looking at revising drug labels."

The FDA is facing a choice of requiring generic drugmakers to conduct clinical trials to establish the current efficacy of the older antibiotics in combating pathogens – which regulators have expressed is an unfeasible option, given the expense to do so – or force the drugs off the market, which also would not be feasible given the need for the drugs.

The other option is to use the data already collected and analyzed by CLSI or another standards group, Fine said.

"In our process, people make those decisions on the best available data out there, and whether it is clinical data that exists or test-tube studies or other mechanisms these scientists use, they use the best available data to make the best available decisions on what the most effective use of these antibiotics is," he said. "We have a very sophisticated model to make those decisions," which he said is the same one the FDA uses when it is studying initial breakpoint – the point at which the bug is susceptible to a drug.

But Diana Zuckerman, president of the National Research Center for Women & Families, who testified at the October advisory meeting, argued that the FDA should evaluate antibiotic resistance using "the gold standard" of clinical trials.

The FDA, she said, should not rely on analyses from CLSI, whose membership includes companies with a financial stake in the game.

Drugmaker members of CLSI, Zuckerman said, should play no role in a process where they could tip the balance in their own favor. ■

Financings Roundup

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30, which, along with another \$10 million available through a May equity line facility deal with Dutchess Equity Fund LP, was expected to carry the firm through the fourth quarter of 2010 and get through Phase I testing with lead compounds, antibiotic PMX-30063 and heparin antagonist PMX-60056. But funds would not be sufficient for Phase II.

PMX-30063, an intravenously administered defensin mimetic antibiotic, started a Canadian Phase IIb trial in June to evaluate safety and identify dose-limiting toxicities. The company plans to file an investigational new drug application in the U.S. prior to starting Phase II studies next year, initially in complicated skin and skin structure infections caused by Gram-positive bacteria, a crowded field that has proved tough for companies so far.

South San Francisco-based Theravance Inc. and partner AstraZeneca plc, of London, finally won approval for antibiotic Vibativ (telavancin) in cSSSI in September – nearly three years after first submitting a new drug application – but other firms have yet to see success. Last year, New York-based Pfizer Inc. withdrew its NDA for dalbavancin after the FDA asked for an additional trial. Cambridge, Mass.-based Targanta Therapeutics Corp. (later acquired by The Medicines Co.) received a complete response letter for oritavancin, as did ceftobiprole, an antibiotic from Basel, Switzerland-based Basilea Pharmaceutica AG. And the FDA told Arpida A/S, of Reinach, Switzerland, in January that another trial would be needed for approval of its antibiotic, iclaprim, in cSSSI. (See *BioWorld Today*, Sept. 15, 2008, and Jan. 21, 2009.)

Even barring similar regulatory hurdles, the space is filled with potential competitors, such as San Diego-based Trius Therapeutics Inc.'s oxazolidinone antibiotic, tore-zolid, which recently demonstrated a 98 percent cure rate in cSSSI. PTK 0796, a compound from Boston-based Paratek Pharmaceuticals Inc., also has shown a 98 percent clinical success rate in cSSSI.

Among other companies working in cSSSI is Cempra Pharmaceuticals Inc., of Chapel Hill, N.C., which recently started a pivotal Phase II/III trial of CEM-102 in acute bacterial structure infections, with the goal of establishing non-inferiority compared to Pfizer's Zyvox (linezolid).

PolyMedix is hoping PMX-30063 will prove particularly useful against drug-resistant bacterial strains by directly lysing bacterial cell membranes. The first indication will go after cSSSIs caused by strains of *Staphylococcus aureus*, but the firm has said use could expand to include other infections and other bacterial strains.

Meanwhile, the potential market for its second candidate, PMX-60056, is a little more clear cut. Part of the company's heptagonist program, PMX-60056 is designed to bind to and reverse the anticoagulant effects of unfractionated heparin and low-molecular-weight heparin, both clot prevention drugs that carry a high risk of bleeding and for

which there are few reversal agents available.

PolyMedix recently completed a Phase Ib trial showing that PMX-60056 completely reversed the anticoagulant effects of heparin and normalized blood clotting time in patients in less than 10 minutes, with no serious adverse events reported.

In addition to funding Phase II activities, money from the recent public offering will be used for general working capital needs.

Merriman Curhan Ford acted as lead placement agent, with Boenning & Scattergood Inc. and Noble Financial Capital Markets serving as co-placement agents and Fordham Financial Management Inc. acting as a selected dealer in the offering.

In other financings news:

- **Altair Therapeutics Inc.**, of San Diego, secured \$17 million in a financing round led by Domain Associates LLC, with participation from AgeChem Venture Fund LP and existing investors Thomas, McNerney & Partners LLC, Forward Ventures and Carlsbad, Calif.-based Isis Pharmaceuticals Inc. Funds will be used to complete Phase IIa trials of lead product, inhaled AIR645, a dual IL-4 and IL-13 inhibitor for asthma, and to advance research and development in new target programs. Altair was founded in 2007 to develop a respiratory drug portfolio licensed by Isis. (See *BioWorld Today*, Oct. 17, 2007.)

- **CBio Ltd.**, of Brisbane, Australia, filed for a proposed initial public offering on the Australian stock exchange, with plans to gain a listing Dec. 14. The firm is seeking to raise up to A\$30 million (US\$27.9 million), with oversubscriptions of up to A45 million, though an offer of new shares of \$1 apiece. The IPO includes a A\$3 million priority offer allocation for existing shareholders. Funds will be used to continue developing XToll, a therapy aimed at autoimmune diseases such as rheumatoid arthritis. CBio said the minimum subscription is A\$13 million, which is needed to complete the ongoing Phase II trial.

- **Cellerix SA**, of Madrid, Spain, closed a €27 million (US\$40.5 million) financing round, led by YSIOS Capital Partners, LSP (Life Science Partners) and Ventech, and including participation from Grupo Genetrix and existing investors Roche Venture Fund and Novartis Venture Fund. New shareholders include Bankinter SA, Capital Riesgo Madrid and JV Risk Technologies SL. Proceeds will be used to complete clinical development of lead product Ontaril in perianal fistulas and preparation for a market launch in the second half of 2012. Funds also will support additional pipeline work on allogenic programs in autoimmune diseases. Florent Gros, representing Novartis, and a second representative from Genetrix will join Cellerix's board.

- **Envoy Therapeutics Inc.**, of Jupiter, Fla., secured a loan from Takeda Research Investment, the venture arm of Osaka, Japan-based **Takeda Pharmaceutical Co. Ltd.**, which it may elect to convert to Envoy preferred stock should

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T-ALL

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ery likely opens the door to broader targeting of transcription factors. First author Raymond Moellering said in a press release that "A variety of key transcription factors assemble in a manner similar to Notch. . . . Our approach could offer a template for targeting many other master regulators in cancer." And co-senior author Greg Verdine said the findings amounted to "open season on transcription factors and other intractable drug targets."

The reason for the finding's broad significance is that the concept of undruggable has as much to do with technologies used to make drugs as with the targets. Currently, small molecules are generally able to target proteins that have hydrophobic pockets both inside and outside of cells. Protein drugs can target flatter surfaces, but are limited to the outside of cells because they are too large to penetrate.

Most of the bulk of a protein drug, however, does not come from the part that interacts with its target. Instead, it is devoted to stabilizing the interacting part. Without such stabilization, the business end of a protein is likely to change its three-dimensional shape rapidly, which means that it rarely enters cells in the first place and does not bind the target efficiently if it does. The basic concept of stapled drugs is to take the active part of a protein and force it to keep its shape by tethering two of its amino acids together in a way that prevents it from flipping wildly between conformations.

Notch is inhibited by the mastermind-like or MAML protein. In the studies now published in *Nature*, the authors tested a series of MAML fragments, some of which had been stapled, for their ability to keep their shape and bind to Notch. While the unmodified peptide is in an alpha-helical shape for less than a quarter of the time, one of the stapled fragments spent more than 90 percent of its time as an alpha-helix.

The authors further tested the stable fragment, named SAHMI, in a panel of human T-ALL cell lines, and found that such treatment decreased the expression of genes that normally are activated by Notch, and inhibited cell proliferation. SAHMI treatment prevented animals from developing T-ALL when they received a bone marrow transplant containing cells with activated notch; when treatment was begun after T-ALL had developed, SAHM inhibited cancer progression, and in some instances, led to regression of tumor cells.

The technology is licensed to Aileron Therapeutics, a Cambridge, Mass.-based biotech firm co-founded by Verdine, who also is co-chairman of the company's scientific advisory board. Co-senior author James Bradner serves as a consultant to the company. Aileron closed a \$40 million Series D funding last summer and is in preclinical development with stapled peptides targeting. (See *BioWorld Today*, June 9, 2009.)

Aileron CEO Joseph Yanchik told *BioWorld Today* that "There's certainly interest in bringing [SAHMI] to the clinic," and that Aileron is doing preclinical work on the peptide to see whether it could make a viable clinical candidate, though "it's a little early to tell."

More generally, he said, the study adds evidence about the potential breadth of problems that the stapled peptide technology could be applied to. "Right now we have not found an obvious limitation to this technology," he said. "The premise of the company was to make undruggable targets druggable . . . we think we've got the best technology to shift that line." ■

Financings Roundup

Continued from page 4

the company complete a second private equity financing. TRI will receive certain rights from Envoy related to a specific therapeutic field, while scientists at the two companies craft a research alliance. Envoy will use the loan, along with proceeds from a recent \$8 million financing, to work on treatments for neurological and psychiatric diseases.

- **Metabolix Inc.**, of Cambridge, Mass., priced a public offering of 3 million shares of common stock at \$9 each for gross proceeds of \$27 million. Underwriters Jefferies & Co. and Thomas Weisel Partners LLC have a 30-day option to purchase up to 450,000 additional shares to cover over-allotments, which could bring the total financing to \$31 million. Net proceeds are expected to fund working capital and other general corporate purposes. Metabolix is developing industrial biotech products such as bioplastics.

- **NexMed Inc.**, of East Windsor, N.J., raised \$750,000 in gross proceeds from the issuance of new convertible notes due Dec. 31, 2011, purchased by investors, including The Tail Wind Fund Ltd. NexMed is working on a late-stage terbinafine treatment for onychomycosis and a late-stage alprostadil treatment for erectile dysfunction and has earlier programs in development for female sexual arousal disorder and psoriasis.

- **Stemina Biomarker Discovery Inc.**, of Madison, Wis., closed on the first \$1 million of a \$3 million round of Series A funding. It also recently received a \$150,000 grant from the National Science Foundation. Funds will go toward its devTOX development toxicity product, designed to be an all-human-based screen for assessing toxicity of existing and development-stage drugs, on the developing human embryo. ■

OTHER NEWS TO NOTE

- **Sol-Gel Technologies**, of Ness Ziona, Israel, said the FDA accepted its investigational new drug application for a Phase II study of DER45-EV Gel for the topical treatment of rosacea.

Aduro

Continued from page 1

ogy and hepatitis C virus (HCV). While Anza's trials administered the *Listeria* vaccine intravenously, Aduro plans to deliver it through intramuscular (IM) administration.

Aduro anticipates entering human trials in 2011 and providing human proof-of-concept results by mid-2011.

The Series A funds will allow Aduro to conduct an IM toxicology study and an immunogenicity study next year in primates to measure response. In addition, the company expects that the funds will enable it to file an investigational new drug application in late 2010 in patients chronically infected with the hepatitis C virus.

The company would need to raise additional funds to take the program into actual clinical trials. Aduro CEO Stephen Isaacs said that the company likely could enter the clinic for its HCV vaccine in 2011, possibly in treatment failure patients. And he said an efficacy trial in HCV could hopefully begin in 2012.

Aduro also has secured \$2.7 million from the Department of Defense for development of a therapeutic vaccine for hepatitis C, and from the National Institute of Allergy and Infectious Diseases for a prophylactic vaccine against the bio-terror agent that causes tularemia.

Isaacs called *Listeria* "a magic bug" because of its ability to stimulate the immune system. Aduro has re-engineered the "bug" to make it safe for use in a vaccine to attack cancer cells and viruses that cause serious infection, he said.

The company's immediate focus is to develop the *Listeria* vaccine for patients who already have diseases. Though, Isaacs said the *Listeria* bacteria could potentially be developed to build up immunity in disease-free people.

Listeria is found throughout the environment and can exist in humans without causing infection. Although outbreaks of listeria infections have been linked to ready-to-eat foods, listeriosis is rare in humans with an occurrence rate in the U.S. of about five cases per million people per year, according to the U.S. Agriculture Department. Except in immune-compromised individuals or pregnant women, *Listeria* is not a very dangerous bug, Isaacs said.

Aduro completed a Series A-1 round once before, in 2008, when it was focused on heat technology for killing cancer. The company has since sold that technology to Marlborough, Mass.-based Aspen MediSys Inc., and turned its focus to the vaccine.

Isaacs, who founded Cerus in 1991, was in retirement and busy with an educational nonprofit group he founded based in Kenya when the *Listeria* project lured him back to the biotech field. "I love this kind of thing, and this start-up stage is the most fun," said Isaacs, who grew Cerus from two people to 150 and took the company public in 2007.

Cerus, which marketed the Intercept Blood System for decontaminating donated blood, started the *Listeria* program in 2002. It was spun out in 2007 when Anza was

formed. Earlier this year, an investor syndicate that included Sofinnova Ventures decided it would take too long to realize a return from the program and made the technology available.

Isaacs, who had retired from Cerus in 2004, raised the money to take over the *Listeria* program that Cerus had started. Mike Powell, general partner of Sofinnova Ventures and a former board member and chairman of Anza, said in a statement that the *Listeria* vaccine technology "may indeed have blockbuster potential."

According to Aduro, the *Listeria* approach overcomes many of the current limitations of other therapeutic vaccine platforms by potentially providing superior potency, the ability for repeat administration and low manufacturing costs. Another advantage the company cites is the ability to use the same proprietary *Listeria* strain to construct multiple vaccines.

"There are obvious advantages to Aduro's technology, in that *Listeria* vaccines stimulate both the innate and adaptive arms of the immune system, which make them extremely potent agents," Drew Pardoll, co-director of the Sidney Kimmel Cancer at The Johns Hopkins University, said in a statement.

"And significantly, the *Listeria* vaccines have demonstrated the key ability to break tolerance in rigorous pre-clinical disease models," said Drew Pardoll, who will chair Aduro's scientific advisory board and who has been associated with the *Listeria* program since 2002. ■

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CLINIC ROUNDUP

• **Geron Corp.**, of Menlo Park, Calif., said published data showed that oligodendrocyte progenitor cells (OPCs) derived from human embryonic stem cells (hESCs), when transplanted into a rodent model of cervical spinal cord injury, reduced tissue damage within the lesion and improved recovery of locomotor function. Those data provide preclinical proof of concept for the use of GRNOPCI, Geron's hESC-derived oligodendrocyte progenitor product, in patients with cervical spinal cord injuries, the company said. Data were published online in advance of print in the journal *Stem Cells*. GRNOPCI is in Phase I studies to treat patients with spinal cord injury.

• **Roche AG**, of Basel, Switzerland, said published data showed that women at intermediate to high risk of early breast cancer recurrence taking Xeloda (capecitabine) as part of their chemotherapy regimen had a 34 percent reduction in the risk of the cancer returning or death. Patients receiving the Xeloda-containing regimen were sig-

nificantly less likely to have their cancer spread to another part of the body. Although the results are not yet mature, there was a trend toward superior overall survival in patients taking the Xeloda-containing regimen compared to those women receiving only standard agents. Data from the Landmark Study were published in the November 2009 issue of *The Lancet Oncology*.

• **Theratechnologies Inc.**, of Montreal, said results from a pooled analysis from both its Phase III trials of tesamorelin in HIV-infected patients with lipodystrophy showed that treatment with 2 mg daily for 26 weeks resulted in significant visceral adipose tissue (VAT) decrease (-13.1 more or less 21.1 percent vs. placebo) and showed no clinically significant changes in limb fat or in abdominal subcutaneous adipose tissue. At week 52, improvements in VAT and triglycerides observed at week 26 were sustained in tesamorelin-treated patients. Theratechnologies filed a new drug application for tesamorelin earlier this year. The drug is partnered with EMD Serono Inc., an affiliate of Darmstadt, Germany-based **Merck KGaA**. (See *BioWorld Today*, June 2, 2009.)

APPOINTMENTS AND ADVANCEMENTS

Advanced BioHealing Inc., of Westport, Conn., promoted Therésa Dixon to vice president of government affairs & health economics, promoted Kathy McGee to vice president and general manager, promoted Keith O'Briant to senior vice president of North American sales and promoted Dean Tozer to senior vice president.

NeuroTherapeutics Pharma Inc., of Chicago, appointed Corey S. Goodman to its board.

Oncothyreon Inc., of Seattle, appointed Douglas E. Williams to its board.

Pro-Cure Therapeutics Ltd., of York, UK, appointed Alastair J. Riddell nonexecutive chairman.

Resverlogix Corp., of Calgary, Alberta, named A. Brad Cann chief financial officer.

RetroVirox Inc., of San Diego, appointed Ronald C. Griffith vice president of research and development.

Rockwell Medical Technologies Inc., of Wixom, Mich., added Jur Strobos to its scientific advisory board.

Seaside Therapeutics LLC, of Cambridge, Mass., appointed Daniel E. Geffken chief operating officer, John C. Amedio vice president of manufacturing and process development and W. Roger Rush vice president of preclinical development.

Seattle Genetics Inc., of Bothell, Wash., appointed Bruce J. Seeley executive vice president, commercial.

Soligenix Inc., of Princeton, N.J., appointed Robert J. Rubin to its board.

Synergy Pharmaceuticals Inc., of New York, named Alan F. Joslyn to its board.

Transdel Pharmaceuticals Inc., of La Jolla, Calif., appointed Joachim P. H. Schupp chief medical officer.

Trinity Biosystems, of Menlo Park, Calif., named Gail J. Maderis to its board.

XOMA Ltd., of Berkeley, Calif., appointed Susan Kramer vice president, project and alliance management.

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Lane-Changing Trends and Fork-in-the-Road Dynamics

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