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Page 1 of 7

Ventrus Hits Trifecta in Pivotal VEN 307 Trial

By Marie Powers
Staff Writer

Shares of Ventrus Biosciences Inc. (NASDAQ:VTUS) gained 14.8 percent Monday, closing at $12.58, after the company reported improvement in three measures of efficacy in a pivotal Phase III study of VEN 307 (diltiazem hydrochloride cream) in anal fissures.

Because anal fissures have largely been ignored by drug developers, gastroenterologists often prescribe specially compounded diltiazem or nitroglycerin, which has numerous side effects. VEN 307 would become the first FDA-approved treatment for pain associated with the condition.

A calcium channel blocker, diltiazem hydrochloride has been marketed in oral formulations for more than two decades to treat angina and high blood pressure. Applied perianally, the drug has been shown to normalize internal anal sphincter pressure and to reduce anal maximal resting pressure. Its

See Ventrus, Page 3

Mologen Shares Rise on Cancer Immunotherapy Phase II Data

By Cormac Sheridan
Staff Writer

Shares in Mologen AG jumped 17 percent to a 52-week high Monday on news that the company's DNA-based cancer immunotherapy, MGN1703, hit the primary endpoint, a prolongation of progression-free survival (PFS), in a Phase II trial in patients with metastatic colorectal cancer (CRC).

The outcome was a pleasant, though not wholly unexpected, surprise for the Berlin-based company, which had earlier struggled with recruitment difficulties. The study was originally slated to recruit 129 patients, but Mologen was unable to meet the target in a timely manner.

Nevertheless, clinical investigators reported that many of the patients participating in the study were experiencing stable disease, to a degree that would not be expected without some beneficial treatment

See Mologen, Page 4

Hyperactive Hippocampus: Response or Root Cause?

Quieting Memory-Related Brain Structure Can Improve Memory

Anette Breindl
Science Editor

Scientists have reported they were able to improve memory in patients with amnestic mild cognitive impairment – a neurological condition somewhere between normal age-related memory loss and outright dementia that often progresses to Alzheimer's disease – by treating them with low doses of the anti-epileptic drug Keppra (levetiracetam, from Brussels, Belgium-based UCB SA).

The drug appears to work by reducing activity in the hippocampus, a brain structure that is important for memory formation. Hippocampal activity is increased during amnestic mild cognitive impairment, as well as in individuals from families with familial Alzheimer's disease, even before those individuals have developed outright Alzheimer's disease themselves.

See Memory, Page 5

Financings Roundup

Regentis Raises $10M for Knee Cartilage Regeneration Product

By Catherine Shaffer
Staff Writer

A Series C financing round of $10 million will support clinical studies and commercial launch of Regentis Biomaterials Ltd.'s knee cartilage regeneration product, GelrinC, in Europe, including a sales force and a postmarket study.

GelrinC is a cartilage implant made of polyethylene glycol diacrylate and denatured fibrinogen originally developed at the Technion Israel Institute of Technology that has performed well in initial human trials, according to Regentis.

"We are very pleased with the results to date," Regentis CEO Alastair Clemow told *BioWorld Today*.

Founded in 2004, Or-Akiva, Israel-based Regentis plans to develop GelrinC for a range of indications, with

See Financings Roundup, Page 6

Other News To Note

• **Allon Therapeutics Inc.**, of Vancouver, British Columbia, said data recently published in the *International Journal of Alzheimer's Disease* showed that its lead product, davunetide, prevented neuronal cell death at different cellular pathways associated with neurodegenerative diseases such as Alzheimer's and progressive supranuclear palsy. Data also were presented at the International Stockholm/Springfield Symposium on Advances in Alzheimer Therapy meeting in Stockholm, Sweden.

• **Biogen Idec Inc.**, of Weston, Mass., said two dosing innovations designed to help patients receiving once-a-week Avonex (interferon beta-1a) for relapsing forms of multiple sclerosis are now available. Those innovations are: an intramuscular autoinjector for chronic use and a new dose-titration regimen facilitated by the AVOSTARTGRIP titration devices.

• **BioTime Inc.**, of Alameda, Calif., said data published in *Biomaterials* showed that the survival of human heart-derived cells is markedly improved when the cells are formulated in HyStem-C, a product being developed by BioTime under the trade name Renevia as a cell delivery device. Data showed that when cells were transplanted with HyStem-C there was a significant increase in the number of surviving transplanted cells compared to cells transplanted without matrix.

• **Biovest International Inc.**, a subsidiary of Accentia Biopharmaceuticals Inc., both of Tampa, Fla., said it plans to file a marketing authorization application with the European Medicines Agency (EMA) for BiovaxID, its personalized cancer vaccine in follicular non-Hodgkin's lymphoma, following pre-filing meetings with the EMA. If approved. BiovaxID would be the first cancer vaccine available in Europe for lymphoma patients. The company filed last month for the vaccine's marketing approval in Canada and expects to meet with the FDA to discuss a U.S. filing.

Stock Movers

5/14/12

Company	Stock Change	
Nasdaq Biotechnology	-$2.65	-0.20%
Anthera Pharmaceuticals Inc.	+$0.18	+9.28%
Keryx Biopharmaceuticals Inc.	+$0.27	+14.29%
Telik Inc.	+$0.42	+15.00%
Tranzyme Inc.	+$0.26	+9.03%
Ventrus Biosciences Inc.	+$1.62	+14.78%
Xenoport Inc.	+$0.72	+13.82%

(Biotechs showing significant stock changes Monday)

• **Cellerant Therapeutics Inc.**, of San Carlos, Calif., said preclinical data showed that cryopreserved, allogeneic mouse myeloid progenitor cells significantly improved survival in mice irradiated with lethal doses of radiation. The study, published in *Radiation Research*, demonstrated how the cells produced dose-dependent survival benefits in mice, even when administration of the product was delayed by up to seven days post-irradiation. Cellerant is developing CLT-008, human myeloid progenitor cells, for treating acute radiation syndrome, under a five-year, potential $170 million contract with the Biomedical Advanced Research and Development Authority.

• **Immuron Ltd.**, of Melbourne, Australia, said it entered an agreement with **Ziwell Medical Pte. Ltd.**, of Singapore, for the distribution of Travelan, a drug designed to prevent traveler's diarrhea, in Singapore, Malaysia and Brunei. Under the terms, Ziwell is required to attain regulatory approval for the sale of Travelan in those territories and to sell specified minimum volumes. There also is agreed timetable for the launch and sales in those countries. Financial terms were not disclosed.

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Lynn Yoffee, **(404) 262-5408**
Jennifer Boggs, **(404) 262-5427**
Anette Breindl, **(518) 595-4041**
Marie Powers, **(770) 487-8673**
Trista Morrison, **(858) 901-4785**
Mari Serebrov, **(703) 678-7376**
Catherine Shaffer, **(734) 883-7224**
Sharon Kingman, **44 20-8995-3336**
Nuala Moran, **44 127-0812775**
Cormac Sheridan, **353-87-6864323**
Senior Vice President/Group Publisher: Donald R. Johnston, **(404) 262-5439**

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Ventrus

Continued from page 1

vasodilator activity has the potential to improve blood supply, thus decreasing pain associated with anal fissures.

The condition – a tear in the lining of the anal canal characterized by severe pain during or following bowel movement – results in more than 1 million physician office visits annually. Poor vascular supply of the anal epithelium combined with increased activity of the internal anal sphincter smooth muscle often perpetuate ulceration, leading to surgery, explained Russell H. Ellison, chairman and CEO of New York-based Ventrus.

The placebo-controlled trial randomized 465 subjects to two doses of VEN 307 or placebo three times daily for eight weeks, followed by a four-week blinded observation period. Both the 4 percent and 2 percent diltiazem treatment arms demonstrated significant improvement compared to placebo in the primary endpoint of average of worst anal pain associated with or following defecation (pain score improvement 0.44, p = 0.0108 at 4 percent; 0.43, p = 0.0134 at 2 percent) and in the secondary endpoints of overall anal-fissure-related pain (pain score 0.36, p = 0.030 at 4 percent; 0.40, p = 0.0183 at 2 percent) and anal fissure healing (32.7 percent, p = 0.0181 at 4 percent; 31.2 percent, p = 0.0359 at 2 percent).

"To be honest, the outcome of this study exceeded our expectations," Ellison told *BioWorld Today*. "We got the two symptomatic endpoints in pain that matter the most to patients in addition to a very meaningful effect on healing. These three endpoints have never been shown in a single trial." The study was conducted in 31 centers in Europe by S.L.A. Pharma AG, a privately held pharmaceutical firm located outside Basel, Switzerland, with an operations arm in the UK, that licensed rights to the product from St. Mark's Hospital and Research Institute in London, which developed the drug's topical formulation and conducted proof-of-concept studies. In turn, Ventrus licensed rights to diltiazem hydrochloride cream in North America.

Ventrus is "pretty agnostic" about dose selection, Ellison said, and expects to receive guidance from the FDA when meeting to discuss the Phase III findings. Because diltiazem is approved in oral formulations for angina and high blood pressure, the compound is eligible for the FDA's 505(b)2 registration pathway.

In the meantime, Ventrus plans to initiate a second pivotal Phase III of VEN 307 in anal fissures, primarily in the U.S., in the second half of the year, with a new drug application (NDA) filing expected by the end of 2013.

"Given a standard PDUFA, we could commercialize in the second half of 2014," Ellison said.

Ventrus also is anticipating near-term data from lead compound VEN 309 (iferanserin ointment) in the larger indication of hemorrhoidal disease. The Phase III trial, under way at 74 U.S. sites, is fully enrolled, with data expected to report in late June or early July. Because the drug would be used in a chronic, recurrent, intermittent-use condition, positive findings would trigger additional carcinogenicity studies, a second pivotal trial and a double-blind recurrence trial similar to the Phase III TARGET 3 trial by Salix Pharmaceuticals Inc., of Raleigh, N.C., in patients with irritable bowel syndrome with diarrhea (IBS-D).

In the Salix study, subjects with IBS-D will be treated with Xifaxan (rifaximin), and those who respond to the initial course of treatment will be followed until symptoms recur. At that time, they will undergo double-blind randomization either to another course of Xifaxan or placebo. The primary endpoint is the proportion of subjects who responded to repeat treatment in both IBS-related abdominal pain and stool consistency compared to placebo during a four-week treatment-free follow-up period.

Salix plans to submit the analysis from TARGET 3 in response to the FDA's 2011 complete response letter on its supplemental new drug application for Xifaxan in IBS. (See *BioWorld Today*, Nov. 15, 2011, and Feb. 25, 2011.)

Ellison hopes for a smoother regulatory pathway for VEN 309, which has highly selective, antagonistic activity against peripheral 5-HT2A receptors involved in clotting and in the contraction of arteries and veins – events believed associated with hemorrhoid formation. By limiting 5-HT2A receptor activity, VEN 309 improves the flow of blood out

See Ventrus, Page 7

Mologen

Continued from page 1

effect in this population. On the recommendation of the study's independent monitoring committee, the company unblinded the trial and crunched the numbers on the 58 patients who were enrolled.

Patients recruited into the study were randomized to receive either MGI703, as maintenance therapy, or placebo, after initially completing first-line therapy, comprising chemotherapy plus Avastin (bevacizumab). Three were discarded as screening failures.

The drug attained the PFS prolongation endpoint in the intent-to-treat population of 55 patients "with a small but," Mologen CEO Matthias Schroff told *BioWorld Today*. Statistical significance was borderline in the group. A much stronger efficacy signal was see in what the company called "a pre-defined target population" of 46 patients, who matched certain biomarker and treatment profiles and who, Schroff said, offered a good representation of the wider patient population.

In this group, PFS was more than doubled as compared with placebo, with a high level of statistical significance ($p < 0.02$), and the risk of tumor progression was more than halved in those on MGN1703.

The company also is following overall survival, although those data are not yet available. "We're still collecting data, which means a lot of patients are still alive. We just have to wait and see," Schroff said. "We have some patients who are over 400 days on treatment already." In Europe, first-line therapy is typically administered over 4.5 to six months, Schroff said, and results in a median survival benefit of two years (including the treatment period).

MGN1703, a DNA-based agonist of Toll-like Receptor 9 (TLR-9) is based on the company's dSLIM (double Stem Loop Immunomodulator) format. It comprises two closed-loop, single strands of DNA, attached to either end of a double-stranded stem. The complete molecule, which is non-coding, resembles a dumbbell shape.

It is entirely closed and does not require chemical modification, such as the formation of relatively toxic species, such as phosphorothioates, to protect against exonuclease degradation. That allows for a greater dosing flexibility.

It could explain Mologen's apparent success where others have failed, most notably Coley Pharmaceutical Group (now part of New York-based Pfizer Inc.), which suffered a Phase III reversal in lung cancer with another DNA-based TLR-9 agonist, PF-3512676. (See *BioWorld Today*, June 21, 2007.)

A different trial design could be another factor. Mologen studied the Coley data very carefully, Schroff said, and opted to administer MGN1703 after, as opposed to in combination with, first-line therapy.

The combination approach, which Coley pursued, could have resulted in the benefits of immune system activation being wiped out by subsequent rounds of chemotherapy, Schroff said.

Mologen also is gearing up for a Phase II study of MGN1703 in lung cancer, although it will not wait for an outcome from that trial before seeking a deal.

"The main strategy now is to go out with the data and find a partner," Schroff said. In parallel, the company will continue with plans to progress the CRC clinical program. "The data are so convincing that we don't want to wait."

Mologen is funded into 2013, having raised €2.7 million in a capital increase this year, in addition to the €7.5 million it held on its balance sheet at the end of 2011.

Its stock (FRANKFURT:MGN) closed at €11.40 Monday, up €1.65, implying a market capitalization of around €145 million. ■

Other News To Note

• **Maxygen Inc.**, of San Mateo, Calif., said it will receive a $30 million payment from **Bayer HealthCare LLC**, of Deerfield, Ill., part of Bayer AG, following Bayer's continued development of a recombinant factor VIIa candidate (previously designated by Maxygen as MAXY-VII) in hemophilia. Maxygen sold the compound to Bayer, along with its other hematology assets, in July 2008 for $90 million in cash. The additional, final payment was contingent on Bayer's additional clinical development of the product. (See *BioWorld Today*, July 3, 2008.)

• **Neurotune AG**, of Zurich, Switzerland, inked a deal with the ALS Therapy Development Institute (ALS TDI) in Cambridge, Mass., to investigate a potential treatment for amyotrophic lateral sclerosis (ALS). Under the terms, ALS TDI will use one of the compounds developed by Neurotune, aimed at maintaining neuromuscular junction strength and stability, in a preclinical model of ALS to determine if the treatment has an effect on disease course.

• **S1 Biopharma Inc.**, of Jersey City, N.J., said it is expanding into male sexual health with SIP-205, a drug in development for hypoactive sexual desire disorder and related dysfunctions. ■

Clinic Roundup

• **AesRx LLC**, of Newton, Mass., said it started a Phase I/IIa trial of its Aes-103 anti-sickling agent in patients with sickle cell disease. The trial, conducted as part of an ongoing collaboration with the National Institutes of Health, will examine the safety and tolerability of the oral small molecule in patients with stable disease, and also evaluate Aes-103's pharmacokinetic and pharmacodynamics properties.

Memory

Continued from page 1

When it was first discovered, such increased activity was "initially thought to be more of a compensatory change," Sharon Rosenzweig-Lipson told *BioWorld Today*. Rosenzweig-Lipson is vice president of research at AgeneBio, a start-up that is in clinical trials with Keppra.

In response to failing memory, the hippocampus was thought to go into a kind of overdrive. But the new study adds to the evidence that rather than being a response to the problem of worsening memory, excess hippocampal activity may be responsible for it, at least in part.

Most approaches to Alzheimer's disease focus on amyloid-beta accumulation and, to a lesser extent tau protein. Those two proteins are responsible for the plaques and tangles that are the most striking anatomical features of brains with Alzheimer's disease, and multiple trials have attempted to make a dent in Alzheimer's by targeting them directly, or the enzymes that produce them.

The idea that altered neural activity is important in Alzheimer's does not necessarily contradict the importance of those proteins. Recent research by other groups, in fact, has shown that beta-amyloid proteins may be regulated in part by neuronal activity.

But, Rosenzweig-Lipson said, they approach the problem "from a different perspective, [namely], what's happening with the circuitry, and how do we address the circuitry?"

Other researchers are also looking for ways to focus on neural activity instead of amyloid beta. (See *BioWorld Today*, May 2, 2012.)

And certainly, drug discovery for Alzheimer's disease can use some fresh ideas. The last 14 Phase III trials of Alzheimer's drug hopefuls have failed, most recently the CONCERT trial of Medivation Inc.'s Dimebon (laterpirdine). (See *BioWorld Today*, Jan. 18, 2012.)

In their work, which was published in the May 10, 2012, issue of *Neuron*, senior author Michela Gallagher, who is a professor of psychology and neuroscience at Johns Hopkins University and a founder of AgeneBio, and her team first used magnetic resonance imaging to compare the levels of brain activity in either normal subjects or those with amnestic mild cognitive impairment.

They found that the latter group had higher levels of activity in their left hippocampus. Rosenzweig-Lipson said that it was not necessarily surprising that only one side of the hippocampus showed greater activity for the particular task used in their experiments, since hippocampal activation depends on the specifics of the task.

The researchers then treated the patients with amnestic mild cognitive impairment with either low doses of Keppra, taken twice daily for two weeks, or placebo. Healthy controls received placebo throughout the study.

The team repeatedly both measured the brain activity of their subjects, and tested them on a memory task where they were shown pictures and had to identify each picture as new, old or new but similar to one they had seen before.

They found that the treatment regimen reduced the level of hippocampal activity in the amnestic subjects so that it was no longer different from those of controls. Patients also improved in their ability to tell whether a picture was similar to one they had seen before, or new.

Notably, in the experiments reported in *Neuron*, treatment did not improve the patients' performance on more general memory tests. But Rosenzweig-Lipson is not worried about those results, ascribing them to the short duration of the study.

Two weeks, she said, "is likely insufficient for seeing improvment on those memory measures. Longer trials are typical for treatments that evaluate effects on memory symptoms and will be needed to determine the effectiveness of these types of therapies."

AgeneBio has intellectual property related to Keppra's use in memory loss, and also has earlier programs based on its own compounds. A dose-finding Phase II trial investigating Keppra's effects on memory is currently under way at Johns Hopkins, and Rosenzweig-Lipson said the company is "looking to initiate Phase IIb trials" once it is complete, likely within 12 to 18 months. ■

Clinic Roundup

• **BioAlliance Pharma SA**, of Paris, said it started its Phase III ReLive trial testing Livatag (doxorubicin Transdrug) in nearly 400 patients with hepatocellular carcinoma, who are resistant or intolerant to Nexavar (sorafenib, Onyx Pharmaceuticals Inc. and Bayer AG). Overall survival is the primary endpoint.

• **Cyclacel Pharmaceuticals Inc.**, of Berkeley Heights, N.J., said it completed enrollment of the Phase II portion of the investigator-initiated Phase II/III trial comparing sapacitabine, an oral nucleoside analogue, to low-dose cytarabine in patients, 60 or older, with previously untreated acute myeloid leukemia or high-risk myelodysplastic syndromes who are unfit for intensive chemotherapy. The study has reached the accrual goal of about 100 patients. The company said more than 40 percent of patients are still alive and longer follow-up is needed to assess overall survival.

• **Fibrocell Science Inc.**, of Exton, Pa., said it submitted to the FDA its Phase II protocol for testing lead therapy azficel-T in improving the range of motion, function and flexibility in patients with existing restrictive burn scars. Azficel-T, an autologous cell therapy, previously gained approval as LaViv for reducing the appearance of moderate to severe nasolabial fold wrinkles. (See *BioWorld Today*, June 23, 2011.)

Financings Roundup

Continued from page 1

knee cartilage repair as a first step.

The product is formulated as a liquid that is injected into the area of damage. It becomes solid when exposed to UV light for 90 seconds. Because it is initially liquid, the material conforms perfectly the cavity it is injected into.

That perfect fit is important because, as Clemow said, "Nature abhors a vacuum." Gaps and cavities within a joint will fill in with an undesirable fibrous tissue that is unlike normal cartilage and can cause pain.

Regentis plans to initially market GelrinC for regeneration of cartilage of the knee. The articular cartilage can be damaged by injury to the joint, osteoarthritis, rheumatoid arthritis or other diseases of the joints.

Cartilage is unable to heal itself, so once it is destroyed, it will not regrow on its own. That results in pain and limited range of motion of the joint.

Standard treatments include debridement or microfracture at the bone surface, to promote growth of fibrocartilage (scar tissue), transplantation of cartilage from healthy joint, and transplantation of cultured cartilage cells.

None of those treatments have proven entirely satisfactory, and none match the tight-fitting seal of the GelrinC material.

In addition to fluidity, another property of the material that contributes to its success is its biodegradation process. The material is slowly degraded over time through an enzymatic mechanism. That degradation allows cartilage tissue to slowly backfill around the eroded surface of the implant, until, after six to 12 months, the GelrinC material is completely gone.

The importance of the fibrinogen in the implant is that it allows degradation through enzymatic means rather than hydrolysis, which would otherwise be the case with a PEG material.

Regentis is currently conducting a human study in Europe, and will be seeking marketing approval for the product as a device. "We have filed for our CE mark," said Clemow. "We have not yet been reviewed. We expect to receive CE mark approval in the next two to three months."

Regentis has not had any interactions yet with the FDA. In the future, it will seek approval for GelrinC as a device, through the FDA's Center for Devices and Radiological Health (CDRH).

The company will be developing its regulatory strategy for the U.S. over the next 12 months, Clemow said.

Existing investors Medica Venture Partners, SCPVitalife, and the Technion Investment Opportunities Fund returned for the C round, and were joined by new investors Royal DSM and Crossroad Fund.

Clemow said that Regentis will use the funding to conduct a postmarket study in Europe, so that it can develop an expanded database supporting its sales efforts, and for publication.

"We're taking a measured approach in Europe," Clemow said. "We've begun to invest in infrastructure in Europe . . . with the expectation that we'll be launching next year."

Regentis believes its material has potential for other indications beyond cartilage of the knee. Those opportunities would include other types of cartilage, but also possibly bone and other soft tissues.

In other financing news:

• **Intercell AG**, of Vienna, Austria, said it completed its financing transaction consisting of €20 million (US$25.7 million) secured loan provided by BB Biotech and an equity private placement of about €15.2 million. The Intercell shares were placed at an adjusted price of €2.30. The financing is expected to secure the company's funding needs until it reaches financial self-sustainability and will be used for R&D work. (See *BioWorld Today*, May 9, 2012.)

• **Marshall Edwards Inc.**, of San Diego, completed a previously announced rights offering for gross proceeds of $5.2 million, before fees and expenses. Stockholders exercised subscription rights for the purchase of 11.7 million units. The company will issue 5.8 million shares of common stock and warrants to purchase 2.9 million shares of common stock. Proceeds will be used to advance ME-143 and ME-344, the company's two lead oncology candidates.

• **Regenerative Sciences Inc.**, of Denver, said it secured a $2 million investment from philanthropist and businessman John C. Malone, chairman of Liberty Media Corp. In addition to advancing the firm's clinical and lab-based stem cell research, the investment will help support the national expansion of its Regenexx Physician Network. Regenerative Sciences' procedures use a patient's own stem cells to help repair a broad range of common injuries and degenerative conditions, including cartilage lesions, torn ligaments and tendons, osteoarthritis and bulging spinal discs. ■

Clinic Roundup

• **Histogenics Corp.**, of Waltham, Mass., said intermediate term data showed significant improvement ($p < 0.0001$) in the mean measures of all patient-reported outcomes across all time points for up to four years and at final follow-up for each patient with osteoarthritis of the knee treated with NeoCart for up to five years. NeoCart is an autologous bioengineered neocartilage grown outside the body using a patient's own cells for the regeneration of cartilage lesions. Data were presented at the International Cartilage Repair Society meeting in Montreal.

Clinic Roundup

• **Isconova AB**, of Uppsala, Sweden, reported Phase I results showing that its vaccine adjuvant, Matrix M, met both the primary and secondary endpoints when tested in a group of elderly subjects, ages 65 to 75, who were administered Vaxigrip (seasonal influenza split vaccine) adjuvanted with Matrix M or Vaxigrip alone. The adjuvanted vaccine was well tolerated, with an excellent safety profile, and higher antibody responses were seen in the adjuvant group.

• **Pearl Therapeutics Inc.**, of Redwood City, Calif., said previously undisclosed Phase IIb data showed that PT003, a fixed-dose combination with long-acting muscarinic antagonist glycopyrrolate and long-acting beta-2 agonist formoterol fumarate, was associated with a significant improvement in home peak expiratory flow rate (PEFR), a measure of lung function, when compared to placebo, individual components of PT003 and open-label active controls ($p < 0.03$ for all comparisons). That improvement was observed for both morning and evening PEFR assessments, which might suggest a morning and evening bronchodilator effect with twice-daily administration of PT003.

• **Promethera Biosciences SA**, of Mont-Saint-Guibert, Belgium, said it treated the first two patients in a Phase I/II trial testing Promethera HepaStem, a cell-based therapy, in urea cycle disorders and Crigler-Najjar syndrome patients. The HepaStem technology involves the use of allogeneic adult liver stem cells.

• **S.L.A. Pharma AG**, of Basel, Switzerland, reported top-line data from its Phase II study testing four doses of Nalcol, an oral formulation of naloxone (2.5 mg, 5 mg, 10 mg and 20 mg) in treating opioid-induced constipation in patients with persistent noncancer pain, showing statistical significant for increasing spontaneous bowel movements (SBM) against placebo and baseline. Increases in SBMs were dose-related with clinically significant effects (greater than three SBMs per week) observed in the 5-mg, 10-mg and 20-mg doses. Patients receiving 20 mg of Nalcol displayed the greatest benefit, with an average of one SBM per week increasing to more than six per week.

Ventrus

Continued from page 3

of the dilated veins that comprise the hemorrhoid, thereby reducing bleeding, itchiness and pain

"There's never been an NDA for hemorrhoids," Ellison said. "There haven't even been well-designed, managed, controlled clinical trials. We've spent a lot of time working with FDA trying to figure out how to do the trial. We've been building it from the ground up, and you almost never get that chance these days."

The company expects to commercialize VEN 309 – to which it holds global rights – in the U.S., Europe and Japan and partner out the rest of the world after the pivotal data report. With $31.1 million in cash on hand as of March 31, that strategy should provide sufficient assets to complete the development and commercialization of VEN 307 and VEN 309, especially since Ventrus will target the small cadre of gastroenterologists and colorectal surgeons who specialize in anal fissures about one year before the hemorrhoid product likely would be launched.

Ventrus, which went public in 2010 through an initial public offering, has one additional product, VEN 308, a topical phenylephrine gel for fecal incontinence associated with ileal pouch anal anastomosis. (See *BioWorld Today*, Dec. 20, 2010.)

That candidate has FDA orphan drug designation, so "we're not burning exclusivity by waiting to develop it," Ellison said. ■

Pharma: Other News To Note

• **Stiefel**, of Research Triangle Park, N.C., part of GlaxoSmithKline plc, said the FDA approved a new drug application for Fabior (tazarotene) foam 0.1 percent, a topical formulation of a retinoid to treat acne vulgaris in patients 12 years and older. The approval was based on data from two pivotal Phase III studies.