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PAGE 1 OF 7

FDA Committee Advocates Tysabri's Return To Market

By Aaron Lorenzo
Washington Editor

GAITHERSBURG, Md. – Members of an FDA advisory committee voted unanimously in favor of bringing Tysabri (natalizumab) back to the multiple sclerosis market, but with restrictions.

Calling the decision “a great day for patients,” Burt Adelman, the executive vice president of development at Biogen Idec Inc., said the verdict also served as “an endorsement of our view and the regulatory agency’s view,” on Tysabri’s efficacy and manageable risk profile. “Physicians and patients are going to have to sit down and make individual decisions.”

Notably, the dozen voting members of the Peripheral and Central Nervous System Drugs Advisory Committee said no new trials are necessary, as close monitoring of any

See Tysabri, Page 3

Neurocrine Dropping APL-MS Work After Missed Endpoint

By Karen Pihl-Carey
Staff Writer

On a day when an FDA advisory committee was voting on whether to bring the fallen multiple sclerosis drug Tysabri back on the market, another potential therapy for the disease failed to hit its endpoint and was dropped by developer Neurocrine Biosciences Inc.

The San Diego-based company discontinued its MS program for its altered peptide ligand (APL) technology.

The failure highlights the difficulties researchers face when trying to find better treatments for MS, which afflicts 250,000 to 350,000 people in the U.S. Neurocrine’s APL compound, NBI-5788, demonstrated an excellent safety profile in the Phase IIb study of 157 patients who were tested over a nine-month treatment period, but the study did not achieve statistical significance in efficacy.

See Neurocrine, Page 4

The Good, The Bad Or The Indifferent?

In Huntington's, Are Inclusion Bodies Answer, Not Problem?

By Anette Breindl
Science Editor

Inclusion bodies – sequestered clumps of misfolded proteins – might be the misunderstood heroes, rather than the villains, of neurodegenerative disease. Or, they might just be irrelevant altogether.

That’s the logical conclusion from data published this week in the early online edition of the *Proceedings of the National Academy of Sciences* by researchers from the Massachusetts Institute of Technology and Massachusetts General Hospital, located in Cambridge and Charlestown, Mass, respectively. The authors found that in models of both Huntington’s and Parkinson’s disease, a compound they studied increased the number of inclusion bodies, while reducing the cellular havoc those dis-

See Inclusion Bodies, Page 6

Financings Roundup

Neuromed's \$25M To Fuel Calcium Channel Research

By Jennifer Boggs
Staff Writer

In its fourth round of venture financing, Neuromed Pharmaceuticals brought in \$25 million, a portion of which will support ongoing development of its lead drug, NMED-160, in Phase II studies to treat chronic pain.

The Series D round included new investor James Richardson & Sons Ltd. (JRSL), of Winnipeg, Manitoba, and existing investors such as Boston-based MPM Capital; Vancouver, British Columbia-based firms Neuro Discovery LP and GrowthWorks Capital; Ontario-based CMDF; Houston-based Cogene Biotech Ventures; the Royal Bank of Canada; and BDC Venture Capital, an investment arm of the Business Development Bank of Canada. Along with the financing, Hartley Richardson, of JRSL, will join the company’s board.

See Financings Roundup, Page 5

INSIDE: ALEXZA PRICES IPO AT \$44M	2
CLINIC ROUNDUP.....	2, 6



Alexza Prices IPO At \$44M To Finance Clinical Work

By Jennifer Boggs
Staff Writer

Alexza Pharmaceuticals Inc. pushed through its initial public offering of 5.5 million shares at \$8 per share, for gross proceeds of \$44 million to support ongoing clinical development of drugs for acute indications.

The share price is lower than the \$10 to \$12 range set last month, which would have pulled in \$60.5 million at the mid-point, and is just more than half of the \$86.25 million anticipated when Alexza filed for the IPO in December. (See *BioWorld Today*, Dec. 27, 2005.)

But the company's shares, listed on Nasdaq under the symbol "ALXA," did well the first day of trading, gaining \$51 cents Wednesday to close at \$8.51.

According to the company's prospectus, Alexza expects net proceeds to total about \$38.7 million – or \$44.9 million if underwriters exercise in full the 825,000-share over-allotment. Money will fund ongoing research and clinical development activities for its four lead product candidates, all of which are based on the company's Staccato technology, designed to vaporize unformulated drug compounds into inhaled aerosol versions.

About \$14 million has been earmarked for preclinical and clinical testing of AZ-001 (Staccato prochlorperazine), expected to begin a Phase IIb trial in the first half of 2006 in patients suffering moderate to severe acute migraine headaches. The company hopes to finish that trial and start a Phase III study within the next 18 months.

Approximately \$11 million has been allocated for AZ-002 (Staccato alprazolam), set to begin a Phase IIa study in acute panic attacks associated with panic disorder. Behind that product is AZ-004 (Staccato loxapine), expected to start Phase IIa testing this year in schizophrenic patients suffering acute agitation, and AZ-003 (Staccato fentanyl), scheduled to enter the clinic during the first half of this

year in acute pain.

For 2005, Alexza reported an overall net loss of \$32.4 million. As of Dec. 31, 2005, the company had cash, cash equivalents and marketable securities totaling \$38.4 million.

New York-based Piper Jaffray & Co. and San Francisco-based Pacific Growth Equities LLC are acting as joint book-running managers, while RBC Capital Markets and JMP Securities, both of New York, are acting as co-managers.

After the offering, the company will have about 22.6 million shares outstanding. ■

CLINIC ROUNDUP

- **CoTherix Inc.**, of South San Francisco, started a Phase III trial of Ventavis (iloprost) Inhalation Solution in combination with sildenafil citrate. The trial will evaluate the safety and efficacy of the combination treatment in pulmonary arterial hypertension. It also will include an arm to explore the efficacy of less frequent Ventavis dosing. The trial, called VISION (Ventavis Inhalation with Sildenafil to Improve and Optimize Pulmonary Arterial Hypertension), involves 180 patients who will be randomized to one of three treatment groups for 16 weeks. The primary clinical endpoint is an increase in the distance walked in six minutes.

- **Generex Biotechnology Corp.**, of Toronto, reported positive preliminary results of a six-month clinical trial of Oral-lyn, the company's oral insulin spray product, in juvenile patients with Type I diabetes mellitus. The objective of the study is to document the effects of replacing the lunchtime dose of subcutaneously injected regular insulin with Oral-lyn. Investigators concluded that during the first two and a half months, replacement of regular insulin with Oral-lyn was associated with overall adequate glycemic control and similar fructosamine and glycosylated hemoglobin concentrations.

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Brady Huggett, **(404) 262-5408**

Aaron Lorenzo, **(202) 719-7816**

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

Karen Young, **(404) 262-5423**

Kay Torrance, **(404) 262-5454**

Fax: **(404) 814-0759**

Randall Osborne, **(415) 384-0872**

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

VP/Group Publisher

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

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Tysabri

Continued from Page 1

future treatment would essentially allow for further study to better define the immune system-modifying drug's safety and efficacy profile. But at this point, Chairman Karl Kiebertz said that "there are sufficient data to move forward."

The FDA typically follows the advice of its advisory committees, and a final decision on Tysabri's supplemental biologics application is due later this month. Adelman said Cambridge, Mass.-based Biogen Idec could re-launch the products weeks later and noted that up to 100,000 patients in the U.S. could be eligible for treatment with Tysabri. He declined to forecast any sales projections and also demurred on the company's pricing strategy.

The recommendations came during the second of a two-day public hearing on the MS drug, which was pulled off the shelves a year ago after three months of marketing because of its link to an often-fatal disorder called progressive multifocal leukoencephalopathy (PML), a risk currently estimated at 1-in-1,000.

Members of the committee acknowledged that PML would likely resurface, as did FDA officials, in future Tysabri therapy. "We assume we're going to see them," said Robert Temple, the director of the FDA's Center for Office of Drug Evaluation I, later adding that patients should assume dire consequences if PML is contracted.

Committee members all agreed that monotherapy would not eliminate Tysabri's PML probability, although they didn't endorse combination therapy with current front-line treatments as a good alternate option, either.

"I can't believe anyone would want to recommend that at this point," said Justin McArthur, a neurologist from Johns Hopkins in Baltimore, although others said combination use could be explored down the road after the PML risk of monotherapy is better determined.

In trying to define patients appropriate for Tysabri therapy, which would be dosed monthly at certified infusion sites if it returns to the market, they agreed that a definitive MS diagnosis is imperative. They also favored its use in patients with relapsing features of the disease and said the drug should not be limited by the severity of a patient's disability. Surprisingly, committee members were more torn on the issue of primary use, with seven saying it could be used as first-line therapy.

"We didn't hear any recommendations for a very restricted approach to which patients should be treated," Adelman said, although the director of the FDA's Division of Neurology Drug Products, Russell Katz, later said issues around first- and second-line therapy indications are "an unanswered question at the moment."

Committee members pointed to concerns around neutralizing antibodies and recommended regular screening as part of a mandatory risk-management plan that has been proposed by Biogen Idec. Such screening

would exclude drug use in patients with high numbers of positive antibodies, which could lead to hypersensitivity reactions.

Committee members recommended that a proposed mandatory patient registry, which the company would update twice annually by contacting physicians, should include reports of deaths, PML, serious adverse events and other infections, as well as the use of intravenous steroids. Kiebertz, a neurology professor at the University of Rochester, said final registry details would "have to be negotiated" between the FDA and Biogen Idec. There was also committee opposition to assigning single vials to particular patients.

Several members suggested that a proposed observational study should have a control group. Biogen Idec has said it would evaluate the drug in 5,000 patients over five years to glean more adverse event information, absent a control, and would seek serious adverse event information in the study rather than through the registry. There was no firm consensus on the study, though, and again Kiebertz said the committee would leave final details up to the FDA and Biogen Idec.

Proposed checklists to watch for PML or other immunosuppressive symptoms received committee support, although FDA officials acknowledged that there would be difficulties in distinguishing between PML symptoms and exacerbations of MS. Also, Kiebertz noted that underreporting or misreporting is "likely to occur," to some extent, given that patients have the burden of answering the questions. The checklists would be done monthly, in advance of each infusion, and failure to comply would preclude a patient from receiving Tysabri.

In support of the checklist's self-reporting system, several committee members recommended regular MRIs at intervals as frequent as every six months, though no clear consensus was reached.

Should patients discontinue Tysabri treatment, committee members suggested that physicians use their own clinical judgment on the duration of a washout period before beginning another therapy. Alfred Sandrock, Biogen Idec's vice president of neurology, recommended an eight- to 10-week period, and for the reverse, he advised a two-week washout period before putting patients on Tysabri.

Throughout the two-day meeting, numerous patients voiced their support for Tysabri, and after the final vote, John Richert of the MS Society said "we are very pleased" that the committee managed to "determine a reasonable balance" between the product's efficacy and safety considerations. It remains under regulatory review in Europe, where an initial decision has yet to be reached.

The drug is partnered with Elan Corp. plc, of Dublin, Ireland. On Wednesday, shares in Biogen Idec (NASDAQ:BIIB) gained \$3.50 to close at \$49, and it continued to climb in after-market trading. Elan's stock (NYSE:ELN) gained \$3.11, or 24.5 percent, to close at \$15.81. ■

Neurocrine

Continued from Page 1

"It is a very difficult disease, and this endpoint was a surrogate endpoint for efficacy," said Gary Lyons, president and CEO of Neurocrine. "Phase III trials would have required two-year dosing, and before we made that type of investment, we wanted to have more confidence that we had an active drug."

Despite the disappointing results in the MS trial, the company intends to continue its Phase II trial of the technology, which uses a different APL epitope, in Type I diabetes. Those results are expected in the third quarter.

Lyons said "there's no way of telling" whether the diabetes trial will have a better outcome, but he stressed that it is a controlled trial with more doses and a longer treatment regimen than the MS trial had.

Wall Street was indifferent. Neurocrine's stock (NASDAQ:NBIX) rose 60 cents Wednesday to close at \$69.30.

The company "didn't expect there would be much fallout," Lyons said. "I think investors are eager for us to redirect our resources."

The company's APL technology evolved from work by Larry Steinman, a Neurocrine co-founder and a professor at Stanford University, who identified with his colleagues one of the dominant immune cells that attacks the insulating sheath, myelin basic protein. In MS, the body's own immune system targets healthy central nervous system cells and destroys the insulating sheath around nerves.

The discovery of myelin basic protein led to the APL therapeutic approach, which directly targets the autoreactive immune cells. The scientists modified a portion of the myelin basic protein so the antigen was no longer capable of activating the immune cells but could induce an immune response that would regulate the pathogenic cells.

In preclinical studies, it seemed to work. The APL reduced disease severity and progression for extended periods. Then, a Phase II study started in 2001 in 144 patients showed a hyperimmune response in the high doses of NBI-5788, but a shrinkage of lesions in patients taking the low dose (5 mg) on a weekly basis.

"In an effort to avoid any hyperimmune responses we went with the lower dose" in the most recent Phase II trial, Lyons said, but the company decreased the frequency of administration to monthly instead of weekly.

Not only did the 5-mg dose display no evidence of activity, but the placebo group improved by 50 percent. That led Neurocrine's researchers to conclude that "either the drug is inactive or we under-dosed," Lyons said. "Maybe if we had done weekly [dosing] we may have seen something, but once monthly wasn't enough in this trial."

The dropped program is another blow to the MS community, which is anxiously awaiting new therapies to battle the disease. Current treatments for MS include Avonex (Biogen Idec Inc.), Betaseron (Berlex Laboratories Inc.) and Rebif (Serono SA), as well a synthetic form of myelin basic

protein, Copaxone (Teva Pharmaceuticals Inc.), for the relapsing-remitting form. Novantrone (Serono SA) is approved to treat the advanced or chronic form of MS.

But the therapies have their limitations. They do not eliminate the disease, only reducing its severity and progression, and beta interferons often are associated with flu-like side effects. All of the compounds are linked to injection-site irritation.

The most efficacious treatment to date, Tysabri (Biogen Idec Inc. and Elan Corp. plc), spent a short time on the market last year but was yanked when it appeared to be linked to a serious side effect, progressive multifocal encephalopathy. The FDA will decide later this month to determine whether it can return.

With the MS program now discontinued, Neurocrine intends to focus its attention on its other pipeline products, which include an oral, small-molecule GnRH antagonist to treat endometriosis and benign prostate hyperplasia; urocortin 2 for congestive heart failure; and a CRF antagonist for anxiety/depression and irritable bowel syndrome. Neurocrine also is advancing a back-up compound for GnRH and a back-up CRF antagonist, and it has started a Phase I trial of its HI antagonist, NBI-75043, to treat insomnia.

The company is waiting to hear from the FDA in May in regards to its new drug applications for the capsule and tablet formulations of Indiplon for insomnia.

Lyons said the terminated MS program will have "no financial impact on the company," except that Neurocrine will not be spending any more money on it. "Cash flow-wise, it actually is positive," he said.

As of the end of 2005, Neurocrine had about \$275 million in cash, cash equivalents and short-term investments. It expects to reach profitability this year, if Indiplon is approved and launched. ■

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Financings Roundup

Continued from Page 1

"We're happy, not just with the money, but also bringing abroad JRSL – a group that has a history of really supporting and building quality enterprises," said Christopher Gallen, Neuromed's president and CEO. "We already had a great group of venture capital investors, and this really capped it off nicely."

To date, the company has raised \$74 million. Its last financing brought in \$32 million in November 2003. (See *BioWorld Today*, Nov. 5, 2003.)

At the close of its Series D, the firm, previously known as Neuromed Technologies, changed its name to reflect its shift from research and discovery to a clinical development-stage company looking toward commercial opportunities.

Neuromed, which was founded as a spin-off from the University of British Columbia in 1998, is building a pipeline based on its two target-specific calcium channel platforms: N-type calcium channel blockers designed to treat chronic pain, and T-type calcium channel blockers aimed at treating anxiety, epilepsy and hypertension.

Funds from the recent financing are expected to sustain the company for about two years and will be used to push the lead N-type candidate, NMED-160, through Phase II studies "over the course of 2006 and 2007, with the goal of starting Phase III in 2008," Gallen told *BioWorld Today*.

At the same time, Neuromed will work to advance a second-generation N-type calcium channel blocker, while heading to the clinic with its T-type compounds, which could enter human trials in 2007.

"I believe we're the only company in the world with a sole focus on developing calcium channel drugs," Gallen said, and successful approval could open the door to "a huge global market."

If approved, NMED-160 wouldn't be the first N-type calcium channel blocker to hit the market. The target previously was validated by Dublin, Ireland-based Elan Corp. plc, which gained approval for its pain drug, Prialt (ziconotide) in December 2004. While Prialt "showed to be very powerful in blocking" the calcium channel, the drug is limited by its intrathecal administration, Gallen said.

U.S. sales of Prialt totaled \$2 million for the fourth quarter of 2005, and \$6.3 million for the full year. Shortly after gaining European approval for the drug last month, Elan sold Prialt's European rights to Tokyo-based Eisai Co. Ltd., in a deal worth up to \$100 million. (See *BioWorld Today*, Feb. 10, 2006.)

Neuromed's NMED-160 and second generation N-type channel blockers are designed as oral and intravenously active drugs that "we believe will produce pain relief for chronic pain that's as powerful as morphine, yet have very little or nothing of the major morphine side effects," he said.

And, with an estimated 50 million people in the U.S. suffering from chronic pain, "we think these are potential blockbuster compounds," he added.

Neuromed actively is seeking a global partner for NMED-160, and in that partner hope to find a co-developer

for its second-generation N-type blockers.

"We're looking for a transformative, Phase II-quality deal," Gallen said.

For now, the company plans to hold onto its T-type platform, hoping to ultimately build its own sales force to market the drug in smaller indications, while considering partnership opportunities for the larger markets, including hypertension.

Over the next couple of years, the company's focus will be to work on its pipeline, preparing for the possibility of introducing Neuromed to the public markets.

"In the long run, it's clearly a goal" to go public, Gallen said. "We have a great pipeline, and right now is a good time for us to really build value in the company."

Neuromed has offices in Vancouver and Conshohocken, Pa.

In other financing news:

- **BioTrove Inc.**, of Woburn, Mass., closed an additional \$7 million in an oversubscribed round of venture capital funding, bringing the total amount raised by the company since July 2005 to \$15 million. Proceeds are expected to accelerate the commercialization of BioTrove's OpenArray genomics and its RapidFire pharmaceutical screening product. Participating investors include Catalyst Health and Technology Partners, of Newton, Mass.; Echelon Ventures, of Burlington, Mass.; Fletcher Spaght, of Boston; and CB Health Ventures, of Boston.

- **Cepheid**, of Sunnyvale, Calif., priced a public offering of 10 million shares of common stock at \$8.60 per share, which would pull in gross proceeds of \$86 million. In addition, the company agreed to grant underwriters a 30-day option to purchase an additional 1.5 million shares to cover overallotments. Cepheid, a molecular diagnostics company, expects to use the proceeds to fund future acquisitions of molecular markers and complementary products, technologies or companies in fields such as oncology and infectious diseases. New York-based UBS Investment Bank is acting as sole book-running manager, with William Blair & Co. and Robert W. Baird & Co., both of Chicago, acting as co-managers. The offering is expected to close March 13. Shares of Cepheid (NASDAQ:CPHD) closed at \$8.56 Wednesday, down 59 cents.

- **The Immune Response Corp.**, of Carlsbad, Calif., completed a private placement of \$8 million of secured notes that are convertible into 400 million shares of stock at 2 cents per share. Investors also received warrants to purchase an aggregate of 1.2 billion shares of stock priced at 2 cents each, which could generate up to an additional \$24 million in gross proceeds. Funds will be used to support the company's ongoing and planned clinical activities and for general corporate purposes. Its lead products candidates are multiple sclerosis drug NeuroVax and HIV drug IRI03, both of which are in Phase II. The company's stock (OTC BB:IMNR) lost 10 cents Wednesday to close at 14 cents.

See Financings Roundup, Page 7

Inclusion Bodies

Continued from Page 1

eases cause.

"What is unique here is that there has been a real focus on finding aggregation inhibitors and breaking up these inclusions, at the same time that the field is moving in the direction that maybe inclusions aren't so bad," Ruth Bodner told *BioWorld Today*, adding that "it's certainly still a controversial notion" that inclusion bodies might be harmless, or even protective. Bodner is a postdoctoral fellow at MIT's Center for Cancer Research and the paper's first author.

Based on recent research showing that inclusion bodies might be a helpful part of the response to mutant proteins, the researchers first investigated a series of small molecules for their effect on the signal of mutant huntingtin. Five compounds raised the level of mutant huntingtin; two of those, termed B2 and B5, were chosen for further study. Both compounds were derivatives of the same chemical scaffold, and in cell culture, both increased the level of mutant huntingtin and the number and size of inclusion bodies.

Working in cell culture, the scientists found that B2 was able to prevent one cellular hallmark of Huntington's disease: the toxicity caused by the fact that the proteasome, which has been described variously as the cell's trash disposal or inventory control system, is unable to digest mutant huntingtin protein. The finding that chemicals that increased mutant huntingtin also had beneficial effects "was initially a surprise," Bodner said. "But it could be consistent with the idea that what matters is the level of oligomers rather than inclusions."

Bodner and her colleagues tested the effect of changing B2's chemical structure on its effectiveness and found that when they made minor changes to its chemical structure, its activity was greatly reduced in both assays. The structural specificity suggested that B2 had a specific molecular target, but that target could be either mutant huntingtin or another protein.

The scientists next tested whether B2's effects were specific to huntingtin, which they were not. When the researchers tested it in a model of Parkinson's rather than Huntington's disease, they found that there, too, inclusion body formation was increased while cellular toxicity was reduced. Huntingtin and alpha-synuclein have different structures, though Bodner said "it is still possible that B2 is binding to related conformations of disease proteins, such as oligomers."

B2 did not affect the level of several chaperone proteins, which are something like the stylists of the neurodegeneration world, helping the major players fold correctly. But the combination of high structural specificity and effectiveness across different diseases makes it the more likely scenario that it is binding "to some quality control protein

in the cell," Bodner said.

The researchers currently are working on developing more potent analogues of B2. Asked about commercial prospects for extension of this work, Bodner said: "It is gratifying that there is significant interest on the part of both pharmaceutical and biotechnology companies in treatments for Huntington's disease. Although this segment of the neurodegenerative market is small, relative to a disease like Alzheimer's, our interactions with industry reflect an increased appreciation of the potential for a truly efficacious product in this market. I believe that the work we have carried out to date brings us a step closer to such a product." ■

CLINIC ROUNDUP

- **Genmab A/S**, of Copenhagen, Denmark, said 77 percent of patients who received two doses of HuMax-CD20 in a Phase I/II dose-escalation study to treat active rheumatoid arthritis obtained ACR20. Even on an intent-to-treat basis, which included six patients who did not receive both doses, 63 percent obtained ACR20. None of the seven placebo patients achieved ACR20. The study included 39 patients who had previously failed at least one disease modifying anti-rheumatic drug. In August, the study was expanded into a Phase II trial, which will include 200 additional patients.

- **MGI Pharma Inc.**, of Minneapolis, said the March edition of *The European Journal of Neurosurgery*, *Acta Neurochirurgica*, published 56-month follow-up data showing that Gliadel Wafer provided a durable long-term survival benefit for patients with high-grade malignant glioma. The product is approved by the FDA to treat patients with newly diagnosed high-grade malignant glioma as an adjunct to surgery and radiation. It also is indicated to treat recurrent glioblastoma multiforme in addition to surgery. The data showed that patients treated with Gliadel Wafer in combination with radiation therapy had a significant survival advantage at three years compared with placebo (9.2 percent vs. 1.7 percent; $p=0.01$).

- **Santarus Inc.**, of San Diego, said clinical results indicated Zegerid (omeprazole/sodium bicarbonate) powder for oral suspension provided physicians with an option for treating patients in need of nighttime gastric acid control. The study evaluated Zegerid, Nexium (esomeprazole magnesium) and Prevacid (lansoprazole) in reducing the occurrence of nocturnal acid breakthrough (NAB) when given to patients with nocturnal symptoms of gastroesophageal reflux disease on an empty stomach at bedtime. Of the 49 patients who completed the study, 61 percent experienced NAB while treated with Zegerid, compared to 92 percent who experienced it while being treated with either Nexium or Prevacid.

OTHER NEWS TO NOTE

• **ACE BioSciences A/S**, of Odense, Denmark, and Nordic Vaccine A/S, of Copenhagen, Denmark, agreed to develop fast-acting vaccines, which could provide better protection to patients and can be delivered in parenteral, patch, or oral formulations. Initial work in the collaboration will focus on ACE BioSciences' vaccines for travelers' diarrhea caused by *Campylobacter*, using Nordic Vaccine's non-alum adjuvants to enhance the protection afforded by the developmental vaccine. Financial terms were not disclosed.

• **Affymetrix Inc.**, of Santa Clara, Calif., said the Korean National Institute of Health and Center for Disease Control and Prevention will use the Affymetrix GeneChip Human Mapping 500K Array Set for a series of genome-wide association studies in critical disease areas, such as diabetes, hypertension, asthma and metabolic syndrome. The Korean NIH will work with its academic and industry collaborators to generate more than 10 billion individual genotypes from 20,000 human DNA samples.

• **Emisphere Technologies Inc.**, of Tarrytown, N.Y., said **Novartis AG**, of Basel, Switzerland, exercised its license option for the development and commercialization of an oral parathyroid hormone (PTH) using Emisphere's eligen delivery technology. Under the terms, Emisphere is eligible for milestone payments totaling up to \$30 million, plus royalties on any product sales. The agreement followed the January court decision favoring Emisphere in its litigation with Indianapolis-based **Eli Lilly & Co.**, which effectively terminated the PTH agreement between those companies. (See *BioWorld Today*, Jan. 13, 2006.)

• **Gilead Sciences Inc.**, of Foster City, Calif., said the FDA granted traditional approval status to its once-daily antiretroviral Viread (tenofovir disoproxil fumarate) and its fixed-dose product, Truvada (emtricitabine and tenofovir disoproxil fumarate), which combines the company's Emtriva and Viread in a single daily tablet. Traditional approval was granted following review of 48-week data from a second confirmatory pivotal trial. The FDA previously granted accelerated approval for Viread and Truvada in October 2001 and August 2004, respectively. (See *BioWorld Today*, Oct. 30, 2001, and Aug. 4, 2004.)

• **Open Biosystems Inc.**, of Huntsville, Ala., said Northwestern University joined its Open Access RNAi Program, gaining access to Open Biosystems' whole-genome lentiviral shRNAmir libraries, including libraries that target the entire human and mouse genomes with multiple constructs per gene. The Open Access RNAi Program is designed to offer RNAi technologies without big financial burdens to individual investigators, while providing continual updates and technical support.

Financings Roundup

Continued from Page 5

• **Novelos Therapeutics Inc.**, of Newton, Mass., closed its previously announced private placement of 11.2 million shares priced at \$1.35 each for gross proceeds of about \$15.1 million. Investors also received warrants to purchase an aggregate of about 8.4 million shares of common stock at an exercise price of \$2.50 per share. Novelos expects to use the funds to support Phase III development of NOV-002 in lung cancer. In separate news, the company said it filed a special protocol assessment for a single pivotal Phase III study of NOV-002 in advanced non-small-cell lung cancer, in combination with first-line chemotherapy, with a primary endpoint of overall survival. The company expects to finalize the SPA by the end of the second quarter and to initiate patient enrollment during the third quarter. Shares of Novelos (OTC BB:NVLT) gained 4 cents Wednesday to close at \$1.91.

• **Theratechnologies Inc.**, of Montreal, filed a preliminary prospectus in Canada in connection with an agreement to issue and sell 10.5 million shares at \$1.95 each to a syndicate of underwriters led by BMO Nesbitt Burns, of Vancouver, British Columbia, and including Canaccord Capital, also of Vancouver, and Jennings Capital, of Calgary, Alberta. Gross proceeds are expected to total \$20.5 million, plus overallotment funds if underwriters purchase an additional 1.6 million shares, and will be used to finance the company's research and development work and working capital requirements. ■

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