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PAGE 1 OF 9

Ablynx, PTC In \$100M-Plus Deals

Seattle Genetics, Genentech Sign \$860M Deal For Cancer Antibody

By Jennifer Boggs
Staff Writer

Topping the spate of high-dollar collaborations announced Monday, Seattle Genetics Inc. signed Genentech Inc. to a potential \$860M partnership to develop SGN-40, a monoclonal antibody in early clinical testing in hematologic cancers.

That news sent shares of Seattle Genetics (NASDAQ:SGEN) shooting up 24 percent, or \$1.27, to close at \$6.56.

Other deals making headlines in the biotech space included a potential \$265 million licensing agreement between Ablynx NV and Boehringer Ingelheim, PTC Therapeutics Inc.'s deal with Pfizer Inc., which could reach more than \$141 million, and South San Francisco-based Catalyst

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JPMorgan Healthcare Conference

Catalyst, Wyeth Deal: Up To \$100M For Protease Targets

By Randall Osborne
West Coast Editor

SAN FRANCISCO – Their shoulders slung with phosphorescent green canvas bags issued by the meeting's sponsor, attendees of the JPMorgan Healthcare Conference swarmed like fireflies in the streets around the Westin St. Francis hotel on opening day, and clustered noisily inside the building for handshakes, back-claps and business card exchanges.

There was news to talk about. Capturing some of the buzz was the potential \$860 million-plus licensing deal for the monoclonal antibody SGN-40 between South San Francisco-based Genentech Inc. and Seattle Genetics Inc. (See story in this issue.) Genentech presented Monday at the conference.

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Financings Roundup

CRADA To Support Xytis Drug For Cocaine Addicts

By Aaron Lorenzo
Washington Editor

Xytis Inc. is planning to use \$40 million in government funds to further evaluate Neboglamine (XY2401) as a treatment for cocaine addiction.

Specifically, the Irvine, Calif.-based company signed a Cooperative Research and Development Agreement (CRADA) with the National Institute on Drug Abuse (NIDA) to test whether the antipsychotic compound can help addicts abstain from the narcotic or prevent them from relapsing into addiction.

Xytis CEO Vincent Simmon told *BioWorld Today* that the money would be used to support upcoming clinical trials of two types: a Phase I safety study to test Neboglamine's interaction with cocaine, followed by Phase II evaluations of

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Dynavax Falls On Phase III Tolamba Trial For Ragweed

By Karen Pihl-Carey
Senior Staff Writer

Dynavax Inc. lost a quarter of its value on Monday after reporting that the efficacy of its ragweed allergy drug could not be evaluated in a Phase III trial.

The stock (NASDAQ:DVAX) plunged 30.2 percent, or \$2.58, to end the day at \$5.96.

Interim one-year data from the two-year study called DARTT (Dynavax Allergic Rhinitis Tolamba Trial) showed no meaningful ragweed-specific allergic disease in any of the treatment or placebo groups, making it impossible for Dynavax to measure Tolamba's treatment effect.

"This does not at all say that the drug failed," said Deborah Smeltzer, Dynavax's vice president of operations and chief financial officer. But the future of Tolamba is unclear at this point. Dynavax is working with consultants and

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OTHER NEWS TO NOTE

• **Accera Inc.**, of Broomfield, Colo., granted **Nestle Purina PetCare Global Resources Inc.** the right to develop its AC-1203 compound for use in healthy aging and wellness in dogs and other companion animals. Under the terms, Purina will handle future development, manufacturing and commercialization costs for those indications, and will pay Accera an up-front fee and additional milestone payments. Specific financial terms were not disclosed.

• **Advanced Viral Research Corp.**, of Yonkers, N.Y., entered a financing agreement in which Cornell Capital Partners agreed to purchase \$1.5 million in three-year 9 percent secured convertible debentures, and five-year warrants to acquire 48 million shares of Advanced Viral common stock priced at 3 cents per share. Proceeds will be used to support the company's clinical programs in cancer and dermatology, and also to supplement its product pipeline with additional products and technologies. Advanced Viral's lead product, AVR118, is a cytoprotective agent aimed at treating cachexia-related disorders.

• **BioVeris Corp.**, of Gaithersburg, Md., said it has received a \$2.8 million payment from Roche Diagnostics, a division of **F. Hoffman La Roche Ltd.**, of Basel, Switzerland. However, BioVeris believes it is owed more under a nonexclusive license to its ECL technology. The payment represents Roche's preliminary calculation of amounts owed for 2004 sales that were outside Roche's licensed field, and BioVeris has notified Roche that this amount does not fully satisfy its obligations. BioVeris, which does not believe that the payment is indicative of amounts that will be owed for subsequent years, has appointed an independent auditor to examine the sales and accounting records and accounts of all uses of BioVeris' ECL technology by Roche and its affiliates.

• **Caliper Life Sciences Inc.**, of Hopkinton, Mass.,

launched its Caliper Discovery Alliances & Services business, a service organization created from the integration of NovaScreen Biosciences, a provider of in vitro discovery services, and Xenogen Biosciences, a provider of in vivo discovery services. Caliper Discovery Alliances & Services offers more than 700 in vitro assay types, including receptor, enzyme, and ion channel screening and profiling assays, side-effect and ADME-tox panels, as well as cellular models for immunology, oncology and other fields. In vivo offerings include more than 85 pharmacological assays that measure more than 400 different parameters for applications such as in vivo compound profiling and phenotyping, and target validation studies. Other in vivo services include creation of genetically modified animal models and biophotonic imaging-based animal models for oncology and other therapeutic areas. Caliper acquired NovaScreen in October 2005 and Xenogen last August.

• **Cambridge Antibody Technology (CAT)**, of Palo Alto, Calif., granted **iCo Therapeutics Inc.** an exclusive worldwide license to develop CAT-213, a human monoclonal antibody. The compound, initially developed by CAT as a potential treatment for allergy disorders, will be advanced by iCo for treatment of ocular allergies. Under terms of the agreement, Vancouver-based iCo will pay CAT an up-front fee, clinical and regulatory milestone payments, and royalties on future sales.

• **Cytochroma Inc.**, of Markham, Ontario, entered a license and supply agreement with **aOvaTechnologies Inc.**, of Madison, Wis., to co-develop and commercialize products directed at treating and preventing hyperphosphatemia in patients with chronic kidney disease. Cytochroma is gaining exclusive worldwide rights to aOvaTech's technology for use in human health care, and in exchange, aOvaTech will receive an undisclosed up-front license fee and royalties on the sale of products covered by the license. aOvaTech also will supply Cytochroma with material. Specific financial terms were not disclosed.

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Genentech

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Biosciences Inc.'s \$100 million research and license agreement with Madison, N.J.-based Wyeth. (See story in this issue.)

For Seattle Genetics, the partnership with Genentech marks its largest deal to date, and involves an exclusive, worldwide license for SGN-40, a product that has generated much interest since early data were presented at scientific meetings last year. The compound is designed to target the CD40 antigen, which is expressed on most B-cell malignancies, as well as on solid tumor types such as bladder, renal and ovarian cancers.

For a drug with that kind of "big market potential, it makes sense to partner it," said Clay Siegall, president and CEO of Bothell, Wash.-based Seattle Genetics. "We went for the number one company in the world that develops antibody drugs for cancer."

Genentech develops and sells the blockbusters Avastin (bevacizumab) for colorectal cancer, and Herceptin (trastuzumab) for breast cancer. Its deal with Seattle Genetics marks the second so far this year. Last week, the South San Francisco-based company agreed to partner on Exelixis Inc.'s MEK inhibitor LX518, in development for cancer. (See *BioWorld Today*, Jan. 4, 2007.)

Shares of Genentech (NYSE:DNA) closed at \$83.80 Monday, up 12 cents.

The companies will work together to develop SGN-40, which is Phase I and Phase II testing in multiple myeloma, chronic lymphocytic leukemia and non-Hodgkin's lymphoma, with Genentech picking up the costs associated with all further development.

Under the licensing terms, Seattle Genetics expects to receive \$60 million in up-front cash, and be eligible to receive more than \$800 million in milestones, most of which "are focused on regulatory events and product approvals," Siegall told *BioWorld Today*. Genentech agreed to pay \$20 million in committed milestones during the first two years of the collaboration.

Upon commercialization, Seattle Genetics would be looking at a double-digit royalty, "starting from the mid-teens and escalating based on increasing sales figures," Siegall said.

In the U.S., the company holds a co-promotion option, which would be "a great way to begin efforts" to create its own sales force, he added.

In separate news, Seattle Genetics entered a collaboration with Santa Monica, Calif.-based Agensys to co-develop and commercialize cancer drugs using Seattle Genetics' antibody-drug conjugate (ADC) technology.

"That deal's important to us because it's helping to expand our cancer pipeline," Siegall said. "We're getting up to two products we'll be able to co-develop."

The companies agreed to jointly screen and select ADC products to a selected undisclosed target, and will equally share preclinical and clinical development costs as well as

any profits. Up to three additional targets could be identified, and Seattle Genetics has the right to exercise a co-development option on one of those at the time an investigational new drug application is filed.

For the remaining two products, the company would be eligible for fees, milestones and royalties.

Work with Agensys likely would focus on solid tumors, "which would be a nice complement to our pipeline, which has more of a hematological focus," Siegall said.

That pipeline includes CD33-targeting antibody SGN-33, in Phase I testing in acute myeloid leukemia and myelodysplastic syndromes, and SGN-70, an anti-CD70 antibody that is in manufacturing for clinical trials. The company also is developing SGN-30, which is in multiple Phase II trials in combination with chemotherapy. Those studies are being conducted in collaboration with the National Cancer Institute.

Ablynx, BI Partner On AD Program

Belgian firm Ablynx could receive nearly \$265 million in a worldwide collaboration with Boehringer Ingelheim to discover and develop Alzheimer's disease drugs using Ablynx's Nanobodies platform.

That deal calls for an up-front fee, and development and commercial milestones, and Ablynx also could receive undisclosed royalties on any commercialized product. Ingelheim, Germany-based Boehringer will be responsible for funding work in the collaboration.

Ablynx, of Ghent, Belgium, focuses its discovery efforts on Nanobodies, compounds that are designed to cross the blood-brain barrier with greater ease than conventional antibodies. The company's technology has led to a number of other collaborations, including a November 2005 deal with Wyeth, in which Ablynx could receive up to \$212 million for the development and commercialization of Nanobodies directed at the tumor necrosis factor-alpha protein and its receptors. (See *BioWorld Today*, Nov. 7, 2006.)

PTC, Pfizer Sign \$141M-Plus Deal

PTC Therapeutics Inc.'s GEMS technology landed it a partnership with big pharma firm Pfizer Inc. to focus on as many as 10 targets.

In exchange for access to its Gene Expression Modulation by Small-Molecules (GEMS) platform, PTC expects to receive an up-front payment of \$10 million, plus a \$10 million equity stake and research funding. Beyond that, PTC would earn up to \$121 million in milestones per target, and New York-based Pfizer, which would retain exclusive worldwide rights to any product developed, agreed to pay PTC royalties on any product resulting from the collaboration.

The GEMS technology platform is designed to identify small molecules that modulate post-transcriptional control mechanisms, and PTC uses the platform to help build its own internal pipeline. The company's most advanced

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JPM Conference

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Another pact, this one platform-based, pairs Catalyst Biosciences Inc., also of South San Francisco, with Wyeth Pharmaceuticals Inc., the Madison, N.J.-based division of pharma giant Wyeth. Joseph Camardo, vice president of medical affairs for Wyeth Pharmaceuticals, is slated to speak during a JPMorgan session this morning.

Valued as high as \$100 million (excluding royalty payments), the Catalyst deal involves collaboration and license agreements for discovery research, as well as preclinical work using the firm's engineered human proteases technology called Alterase.

Wyeth is paying for development of drug candidates against two targets – one each in metabolic disease and oncology – along with manufacturing and marketing costs. Nassim Usman, Catalyst's CEO, said Wyeth rendered a satisfying up-front payment, but he declined to be more specific. "It's not like this is a deal where it's \$100 million based on launch of the product," said Usman. His background includes 12 years at another platform company that recently charmed big pharma: Sirna Therapeutics Inc., of San Francisco (formerly Ribozyme Pharmaceuticals Inc.), which Merck & Co. Inc. is buying for \$1.1 billion. (See *BioWorld Today*, Nov. 1, 2006.)

The Merck buyout, Usman said, was "great news for the rest of us. Big pharma needs other approaches in the future, and we can provide them."

Catalyst's deal with Wyeth brings enough cash to operate through the end of 2008, by which time Catalyst expects to enter the clinic with the first of its own drug candidates. They include an anti-inflammatory agent for acute cardiovascular disorders and a disease target "that will probably be disclosed in a week or two," Usman said.

Wyeth has proven its interest in inflammatory disease, too, by way of the recent potential \$189 million deal with Princeton, N.J.-based Pharmacopeia Drug Discovery Inc., focused on compounds inhibiting JAK3. Another big-pharma player, Pfizer Inc., of New York, gained strong Phase II data with its JAK3 rheumatoid arthritis drug CP-690,550. (See *BioWorld Today*, Jan. 5, 2007.)

The metabolic-disease target in the Catalyst/Wyeth deal had an undisclosed major pharma firm sniffing around for a possible Alterase-based deal, too. "It's actually a public domain target, but the two companies both came up with that target as being interesting and amenable to our approach," Usman said.

That approach – tweaking proteases to alter their substrate specificity so that they can inactivate any protein target – offers benefits over monoclonal antibodies, he noted.

Alterase "is particularly good in a case where there are very high concentrations of the target," Usman said. "Monoclonal antibodies don't do well, [because] you get dose limited."

Another setting ideal for Alterase is the complement cascade in cardiovascular disorders. "You really need to knock out the target completely, because if you don't, it will

get amplified in the next step," he said, and pointed to a third advantage of Alterase over monoclonal antibodies: intellectual property.

"There's a lot of IP in the antibody space, which makes it hard to get at the target," Usman said, whereas the Alterase method has a clearer shot.

Protease drugs already on the market include Activase (alteplase) tissue-plasminogen activator, also known as T-PA, from Genentech, and Indianapolis-based Eli Lilly and Co.'s Xigris (activated drotrecogin alfa) for sepsis. The wrinkle remedy Botox (botulinum toxin) from Allergan Inc., of Irvine, Calif., also is a protease.

The JPMorgan conference runs through Thursday. ■

Genentech

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GEMS-based product, PTC299, an oral, small molecule aimed at inhibiting vascular endothelial growth factor (VEGF) is in Phase I development in healthy volunteers. That product is being developed for cancer.

Elsewhere in its pipeline, the South Plainfield, N.J.-based firm is advancing PTC124, its drug candidate aimed at patients with Duchenne's muscular dystrophy or cystic fibrosis due to a nonsense mutation. Promising Phase II results reported last year showed that PTC124 can restore function of the cystic fibrosis transmembrane conductance regulator protein in airway cells and significantly reduce blood neutrophil counts.

PTC has a preclinical hepatitis C program partnered with Kenilworth, N.J.-based Schering-Plough Corp., and several discovery programs.

The company has a pending initial public offering, which it filed in April, with hopes of raising \$86 million to fund ongoing clinical activities. ■

OTHER NEWS TO NOTE

• **Endo Pharmaceuticals Holdings Inc.**, of Chadds Ford, Pa., and **Penwest Pharmaceuticals Co.**, of Danbury, Conn., amended several components of their collaboration for Opana ER (oxycodone HCl) extended-release tablets CII. With respect to the product's U.S. sales, Endo's royalty payments to Penwest will be calculated starting at 22 percent of annual net sales, and based on agreed-upon levels of net sales achieved, the royalty rate can increase to a maximum of 30 percent. No royalty payments will be due to Penwest for the first \$41 million of royalties that would otherwise have been payable beginning from the time of the product launch last July. Penwest is entitled to receive milestone payments of up to \$90 million based upon the achievement of certain agreed-upon annual sales thresholds. The amendment also resolves the parties' ongoing disagreement with regard to sharing of marketing expenses during the period prior to when the product reaches profitability.

Financings Roundup

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its ability to reduce the desire or craving for cocaine.

He called the funding "a pass-through," meaning that the money is tabbed solely for those future trials. Xytis, which will supply the drug for testing, will manage the studies in tandem with NIDA, and a third party is likely to conduct them under their watch. At the earliest, Simmon said, this testing will get under way late this year.

Neboglamine is a positive allosteric glycine site-specific modulator of the glutamate N-methyl-D-aspartic acid (NMDA) receptor complex, a mechanism designed to stop cocaine stimulation. A similar effect on norepinephrine is thought to produce the same result.

To date, animal models have demonstrated Neboglamine's ability to improve cognitive performance, as well as its anxiolytic and antidepressive activity. Recently completed Phase I studies testing single-dose escalations of the drug and its food interaction profile indicate that it's safe and well tolerated within the dose range expected for efficacy.

The CRADA arrangement remains subject to the completion of a number of studies, including Xytis-run safety and tolerability trials of a dose-escalating design, which are expected to be completed next quarter. The privately held company, which has raised \$24.5 million in venture capital funding to date, also is using those tests to evaluate patients' 24-hour quantitative electroencephalogram (EEG) changes and their 24-hour Holter electrocardiogram (ECG), to examine their sleep architecture in polysomnography recordings and also to investigate a series of psychometric tests. Exploring the drug's pharmacodynamic effect on those physiological variables is expected to help in selecting the most responsive target patient population with schizophrenia, Neboglamine's primary indication, and possibly cognitive dysfunction and depression comorbidity, for future Phase II studies.

In addition, NIDA will conduct safety trials evaluating the interaction of cocaine and Neboglamine in animals and humans before the CRADA-supported studies begin. NIDA is a component of the National Institutes of Health in Bethesda, Md.

Going forward for Xytis, its focus will turn to beginning a Phase II trial of XY2405 for traumatic brain injury. The 400-patient study is expected to last about a year.

Specialty Firm Proprius Raises \$11M

Proprius Pharmaceuticals Inc. brought in \$11 million in a Series A financing that could grow to \$17 million down the road.

The initial tranche will provide the San Diego company enough funding to progress current programs, including Indaflex, a topical nonsteroidal anti-inflammatory drug in clinical development for osteoarthritis of the knee. Specifically, the money is tabbed for completing a Phase II trial of Indaflex and advance it toward pivotal Phase III trials later this year.

The round was led by Atlas Venture, of Waltham, Mass.,

together with San Diego-based Forward Ventures and CDIB BioScience Venture Management in Taiwan. Returning investors included Fog City Fund, of San Francisco, and Windamere Venture Partners, of La Jolla, Calif.

In conjunction with the financing, Atlas' Jean-Francois Formela, Forward's Stuart Collinson and Fog City's Nancy Olson have joined Proprius' board.

IsoTis Eyeing \$30M-\$40M Raise

IsoTis Inc. plans to raise between \$30 million and \$40 million by offering newly issued Nasdaq-listed common shares to the public in an underwritten offering, further to its exchange offer for the outstanding shares of IsoTis SA.

IsoTis Inc., of Irvine, Calif., intends to offer the shares after securing its Nasdaq listing and consummating the exchange offer. If the conditions to the exchange offer are met, IsoTis Inc. expects to become Nasdaq-listed Jan. 26 and close the exchange offer next month.

The company plans to use net proceeds to support sales, marketing and general administrative activities, clinical research and product development activities and fund working capital and other general corporate purposes.

IsoTis Inc. expects to file a registration statement with the SEC to register the proposed public offering of the shares within the next 45 days.

Austrian Company Gets Seed Funding

The newly formed biopharmaceutical firm f-star raised €1.5 million (US\$2 million) in additional seed financing, this time from Atlas Venture.

Founded last year to develop and exploit technology to generate improved antibodies and antibody fragments, Vienna, Austria-based f-star previously received more than €1.1 million in loans and grants from Austrian government agencies for research, technology and innovation. Its modular antibody technology allows the engineering of new binding sites into constant and variable domains of antibodies, so additional functionality can be built into antibody formats of any size. The company said this has the potential to improve antibody-based therapeutics' specificity, efficacy and pharmacokinetics. ■

OTHER NEWS TO NOTE

- **illumina Inc.**, of San Diego, and the Children's Hospital of Eastern Ontario entered a research collaboration to develop molecular diagnostic tests to screen newborn babies for spinal muscular atrophy and hemoglobinopathies. Under the terms, illumina and CHEO initially will develop assays to screen newborns for those two indications using illumina's VeraCode technology and BeadXpress reader. illumina will gain global commercialization rights to assays developed in the collaboration.

Dynavax

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investigators to determine the next steps.

The drug is made up of immunostimulatory sequences linked to Amb a 1, the purified major allergen of ragweed. It is designed to suppress the Th2 cells responsible for inflammation associated with the allergy.

In all three study arms of the Phase III trial there was a minimal change from baseline in the total nasal symptom score (TNSS), the primary efficacy endpoint.

"We don't know yet what happened in this case," Smeltzer told *BioWorld Today*. "We were expecting to see similar results to what we had published in the Phase II/III trials."

Dynavax reported Phase IIb data in March 2006 at the annual meeting of the American Academy of Allergy, Asthma and Immunology in Miami that demonstrated Tolamba produced a statistically significant 21 percent reduction in the change from baseline of TNSS vs. placebo in the first year. The reduction was 28.5 percent in the second year.

Smeltzer said that while the TNSS in the placebo group was about 2.5 in the Phase II/III program, it was "much lower, down in the 1 range" in DARTT.

"Normally, you would expect the placebo group to have much higher allergy symptoms than the treatment group," she said. But such challenges "are not unprecedented in allergy trials."

The DARTT study is being conducted at 30 centers and in 738 ragweed allergic subjects who are 18 to 55 years old. They were randomized to receive either the same dosing regimen used in the Phase IIb trial, a higher dose or a placebo. Those in the treatment groups received six doses of Tolamba over six weeks before the start of the 2006 ragweed season.

Patients with severe cases of ragweed allergy currently are treated with a traditional immunotherapy of crude allergen extracts administered at low doses monthly over three to five years. Dynavax believes Tolamba can offer a benefit by its less frequent dosing regimen (once a week for six weeks), which has demonstrated relief in patients for up to two years. Patients with milder forms of allergy take antihistamines or corticosteroids to relieve symptoms, but the medicines "don't treat the underlying disease," Smeltzer said.

As it works to determine Tolamba's future, Dynavax also is developing TLR9 agonists such as Heparisav, a hepatitis B vaccine in Phase III; a therapy for non-Hodgkin's lymphoma in Phase II; and a therapy for metastatic colorectal cancer in Phase I. The company's stock surged on positive Phase III data of Heparisav in November. (See *BioWorld Today*, Nov. 30, 2006.)

In October, Dynavax raised \$29.5 million in net proceeds in a public offering.

"We have over \$100 million in committed cash available to us, which is over two years of burn," Smeltzer said, "so

we're in a very strong financial position."

MedImmune's Second-Generation FluMist Approved

Despite an FDA complete response letter requesting more information last summer, MedImmune Inc. gained final approval of its second-generation FluMist vaccine and intends to make it available as planned for the 2007-2008 influenza season. The new refrigerated formulation – known as CAIV-T (cold adapted influenza vaccine-trivalent) – should offer physicians and schools a more convenient method for storing the vaccine. A frozen formulation of FluMist was approved in 2003.

The FDA granted approval of CAIV-T to prevent influenza in healthy children and adults from 5 to 49 years old. It issued a complete response letter last July asking for more information on data already submitted by Gaithersburg, Md.-based MedImmune. (See *BioWorld Today*, July 19, 2006.)

MedImmune intends to expand the label for CAIV-T to include children younger than 5. To date, the vaccine has been tested in about 60,000 people, including those as young as 6 weeks of age and adults up to 98 years old. In a pivotal Phase III trial involving 8,500 children between 6 months and 59 months, FluMist demonstrated a statistically significant 55 percent relative reduction in the incidence of influenza caused by any strain, including both matched and mismatched strains, when compared with the injectable influenza vaccine. The company filed last July with the FDA to expand the age indication for FluMist to include children as young as 1 who do not have a history of wheezing or asthma.

MedImmune's stock (NASDAQ:MEDI) rose 7 cents on Monday, to close at \$34.25.

Privately Held Horizon Agrees To SPA For HZT-501

Pain therapeutic company Horizon Therapeutics Inc. reached an agreement with the FDA on a special protocol assessment for a Phase III program of HZT-501.

The product is a formulation of the nonsteroidal anti-inflammatory drug (NSAID) ibuprofen, combined with the H2 receptor antagonist famotidine. It is designed to offer pain relief while reducing stomach acidity. While NSAIDs are effective as pain relievers, they often come with serious gastrointestinal side effects such as ulcers.

Data from a pilot study published in a 1996 issue of *The New England Journal of Medicine* showed famotidine administered with NSAIDs significantly reduced the incidence of gastric and duodenal ulcers vs. placebo.

The Phase III program will include two trials involving 1,200 mild-to-moderate pain patients, including those with osteoarthritis. The primary endpoint will be the reduction in the risk of development of ibuprofen-associated upper gastrointestinal ulcers. The trials will be blinded for up to 24 weeks and will be followed by a four-week safety evaluation period.

HZT-501 targets the NSAID pain market, which grew more than 20 percent to 73 million prescriptions in 2005. More than 26 million ibuprofen prescriptions are written in the U.S. each year. ■

OTHER NEWS TO NOTE

• **Juvaris BioTherapeutics Inc.**, of Pleasanton, Calif., closed the first two rounds of a Series A financing, with a \$6 million investment from Kleiner Perkins Caufield & Byers Pandemic & Biodefense Fund. The second closing, expected to occur within 120 days, would bring the total round to \$12 million. Funds will be used to advance the company's lead vaccine products for influenza and pneumonia into the clinic, and to pursue immunotherapy products for hepatitis B and biodefense applications.

• **Merck Serono SA**, of Geneva, was launched after **Merck KGaA**, of Darmstadt, Germany, successfully closed its share purchase agreement of **Serono SA**, of Geneva. The new company will have 28 projects in clinical development and a combined research and development budget totaling about €1 billion (US\$1.3 billion). The \$13.3 billion deal was announced last year. (See *BioWorld Today*, Sept. 22, 2006.)

• **Movetis NV**, of Belgium, closed a €49 million (US\$63.8 million) Series A round, led by Sofinnova Partners (France) and Life Science Partners, with participation from Sofinnova Ventures (US), KBC Private Equity, KBC Private Equity Fund Biotech, GIMV, Quest for Growth and BIP Investment Partners. Movetis, which specializes in gastroenterology, licensed products and technologies from **Janssen Pharmaceutica NV**, of Belgium, and U.S.-based **Ortho-McNeil Pharmaceutical Inc.**, both of which are affiliates of Johnson & Johnson. The company's late-stage development compound has completed three pivotal trials in chronic constipation, targeting patients who are treated with laxatives without satisfactory results. Other products in development are aimed at treating ascites, pediatric regurgitation, diabetic gastroparesis and severe forms of dyspepsia. Movetis' board includes CEO Dirk Reyn; Staf Van Reet; Antoine Papiernik, of Sofinnova Partners; Martijn Kleijwegt, of Life Science Partners; and Jim Healy, of Sofinnova Ventures. Ruth Devenyns, of KBC, will be an observer.

• **Protherics plc** has filed a New Drug Submission to Health Canada for DigiFab, a digoxin antidote already approved in the U.S. for treatment of life-threatening digoxin toxicity or overdose. The London-based company hopes to receive Canadian approval in 2008. It already has filed for approval in the U.K. and in Europe and hopes to have approvals in six to 12 months. Protherics recently announced an agreement with **F. Hoffmann-La Roche Ltd.**, of Basel, Switzerland, to replace its digoxin antidote, which is being withdrawn from the market.

• **Provid Pharmaceuticals Inc.** has signed a definitive agreement to acquire **Tripes Discovery Research**, the Bude, U.K.-based drug discovery division of Tripes Inc., for \$2 million. The Tripes board of directors has approved

the sale. North Brunswick, N.J.-based Provid said it will continue to offer the TDR LeadQuest libraries and LeadDiscovery platform to customers. The sale is expected to close in the first quarter.

• **Sequenom Inc.**, of San Diego, and Qiagen GmbH, a wholly owned subsidiary of **Qiagen NV**, of Venlo, the Netherlands, entered a strategic collaboration to jointly develop a preanalytical solution for small-molecule (fetal) DNA enrichment for prenatal diagnostics. The arrangement will combine Qiagen's preanalytical sample preparation technologies in life sciences and molecular diagnostics with Sequenom's capabilities in genetic analysis technology. The primary goal is to develop a set of reagents that optimize the enrichment of small nucleic acid fragments, such as circulating free fetal nucleic acids in maternal plasma or serum, as well as short nucleic acids in blood, plasma or serum, for the analysis of cancer and other key disorders. Sequenom will retain exclusive distribution rights to the specific technology for enriching short nucleic acids developed under this collaboration.

• **Targeted Genetics Corp.**, of Seattle, is raising \$8.72 million in a private placement of 2.18 million shares, along with warrants to purchase up to an aggregate of 763,000 shares, priced at \$4 each. Warrants will be exercisable at \$5.41 per share. The company anticipates net proceeds of about \$8.1 million, which will be used for working capital and other general corporate purposes. Special Situations Fund, through its Special Situations Life Sciences Fund, is the lead investor in the financing. Greenway Capital also participated in the investment. Pacific Growth Equities LLC acted as the exclusive placement agent.

• **The North Carolina Biotechnology Center**, of Research Triangle Park, N.C., approved \$350,000 in loans to four young research-based companies. Addrenex Pharmaceuticals, of Morrisville, N.C., is developing Clonicef, an oral, extended-release formulation for symptoms associated with excessive adrenaline secretion, and Teotten Diagnostics, also of Research Triangle Park, is developing tests for hospital-acquired infections. Both received one-year Small Business Research loans of \$150,000. Two other companies each received \$25,000 Business Development Loans: Axitare, which is developing technology to screen libraries of natural compounds that could enhance the flavor and aroma of foods, and BioMedomics, which focuses on diagnostics targeting point-of-care personalized genetic testing for specific disease biomarkers.

• **Zyentia Ltd.**, of Cambridge, UK, entered a research collaboration to allow Louisville, Ky.-based **Potentia Pharmaceuticals Inc.** access to its AggreSolve platform for characterizing compounds. No financial terms were disclosed. Zyentia plans to seek additional research collaborations to support its internal pipeline. The company anticipates moving into preclinical testing with its lead candidates this year.

CLINIC ROUNDUP

• **AEterna Zentaris Inc.**, of Quebec, started the first of three Phase III studies with its luteinizing hormone-releasing hormone antagonist compound, cetrorelix, in benign prostatic hyperplasia. The study will assess an intermittent dosage regimen of cetrorelix as a potential safe and tolerable treatment providing prolonged improvement in signs and symptoms. The first study will involve about 600 patients in a Phase III program enrolling 1,500 patients total. The primary efficacy endpoint is absolute change in International Prostate Symptom Score between baseline before beginning treatment and week 52. AEterna also started a Phase I trial with its small-molecule oral anti-cancer drug, ZEN-012, in patients with solid tumors and lymphoma. The open-label, dose-escalation, multicenter trial will include up to 50 patients who have either failed standard therapy or for whom no standard therapy exists. Patients will receive a once-a-week administration of ZEN-012 for three consecutive weeks, followed by a one-week period without treatment. Primary endpoints will focus on the safety and tolerability of ZEN-012 as well as establish the recommended Phase II dose and regimen.

• **Allos Therapeutics Inc.**, of Westminster, Colo., said an independent data monitoring committee completed an interim analysis of safety data from the Phase 2 PROPEL trial (Pralatrexate in Patients with Relapsed Or Refractory PEripheral T-cell Lymphoma) of its antifolate, PDX (pralatrexate), in patients with relapsed or refractory peripheral T-cell lymphoma (PTCL), and recommended that the trial continue. The assessment evaluated the first 10 participants who completed at least one cycle of treatment with PDX, and no major patient safety concerns were identified. PROPEL is an international, multicenter, open-label, single-arm study that will enroll 100 patients with relapsed or refractory PTCL who have progressed after at least one prior treatment. Participants receive 30 mg/m² of PDX once every week for six weeks followed by one week of rest per cycle of treatment. The primary endpoint is objective response rate (complete and partial response). Secondary endpoints include duration of response, progression-free survival and overall survival.

• **Anesiva Inc.**, of South San Francisco, outlined its Phase II/III trial program for the development of 4975, its long-acting, non-opioid candidate for the acute treatment of severe pain. The company will focus on developing the product for postsurgical pain and osteoarthritis. Anesiva expects to start a series of trials, including three 50-patient Phase II studies to begin in the first half of this year and a 450-patient Phase III trial, to begin in the second half, for the postsurgical indication. For osteoarthritis, it intends to start a 200-patient Phase II trial of 4975 in the first half of this year.

• **Cephalon Inc.**, of Frazer, Pa., said Phase III data of

Fentora (fentanyl buccal tablet) demonstrated statistically significant improvement in opioid-tolerant patients with neuropathic pain as measured by the Sum of Pain Intensity Differences at 60 minutes ($p < 0.0001$). Statistically significant differences in pain relief compared with placebo were observed as early as 10 minutes. The drug was well tolerated with typical adverse events seen with opioids. Another trial in 78 opioid-tolerant patients with cancer showed similar results. The company will present the data at a medical meeting this year. Fentora is FDA-approved for the management of breakthrough pain in cancer patients tolerant to opioid therapy, and Cephalon intends to seek an expanded label to use Fentora to treat other pain conditions.

• **Incyte Corp.**, of Wilmington, Del., said preliminary results from a Phase IIa trial of INCB9471, the company's lead CCR5 antagonist for once-daily oral treatment in HIV patients, showed that the compound was well tolerated in the first seven treated patients over a 14-day trial period, with a 1.7 log¹⁰ viral load drop at day 14. Viral replication continued to be suppressed after the last dose with a nadir in viral load reduction of 2.1 log¹⁰ at day 20. Those data were presented at the JPMorgan Healthcare Conference in San Francisco. The company also reported proof-of-principle results from an ongoing Phase IIa trial of INCB13739, an oral inhibitor of 11-beta hydroxysteroid dehydrogenase Type 1 for Type II diabetes, showed that six treated obese insulin-resistant individuals who completed the trial showed completely inhibited 11beta-HSDI activity in both adipose tissue and liver following a single dose of the drug.

• **Myriad Genetics Inc.**, of Salt Lake City, said a Phase II prostate cancer trial of MPC-7869 (R-flurbiprofen) missed its primary endpoints and the company does not intend to pursue further development in an oncology indication. Statistical significance was not achieved for either of the two primary endpoints: time to systemic disease progression and the change in velocity of prostate specific antigen levels. The trial showed the therapy was well tolerated over long-term administration in elderly prostate cancer patients and demonstrated no significant differences in adverse events from the placebo arm. It included 246 patients with advanced disease who were assigned to one of three arms (800 mg once daily, 800 mg twice daily or placebo). Myriad will continue to develop MPC-7869 for Alzheimer's disease.

• **Neurocrine Biosciences Inc.**, of San Diego, said a second Phase II trial of Gonadotropin-releasing hormone receptor antagonist showed positive results over a three-month treatment period in patients with endometriosis. The trial included 68 subjects who were randomized to one of three treatment groups, including a placebo group. For the primary endpoint of Composite Pelvic Sign and Symptoms Score, which has a maximum possible value of 15, mean values at baseline were 7.8, 7.2 and 8.3 for the placebo, 50 mg and 100 mg groups, respectively. After treatment, there were reductions of 4.3 (placebo), 4.7 (50 mg) and 5.3 (100 mg) points in the score at week 12. The drug was generally well tolerated.

CLINIC ROUNDUP

• **ProEthic Pharmaceuticals Inc.**, of Montgomery, Ala., plans to file a new drug application with the FDA based on positive Phase III data for PRO-513, its candidate to treat migraine headaches. An eight-month, randomized, double-blind, placebo-controlled trial that enrolled 690 adults showed PRO-513 reached all of its primary endpoints by achieving statistical superiority to placebo in pain relief and the associated symptoms of nausea, photophobia or sensitivity to light and phonophobia, sensitivity to sound at two hours for all conditions. PRO-513 was well tolerated with no safety issues reported. The drug uses ProEthic's Dynamic Buffering Technology, which enhances the absorption of its active ingredient, diclofenac potassium.

• **Provectus Pharmaceuticals Inc.**, of Knoxville, Tenn., said PV-10, an injectable formulation of Rose Bengal (Provecta), received orphan drug status from the FDA for metastatic melanoma. The company is close to completion of a 20-subject Phase I study in Australia and expects to start a pivotal Phase II/III trial shortly thereafter.

• **QuatRx Pharmaceuticals Inc.**, of Ann Arbor, Mich., said a Phase II study of fispemifene in men with low testosterone levels demonstrated a 60 percent (100 mg), 60 percent (200 mg) and 78 percent (300 mg) increase in testosterone levels compared to baseline, while those on placebo showed a 14 percent increase. All primary endpoints were met and no safety issues were observed. Fispemifene is a selective estrogen receptor antagonist that is being developed as an oral treatment for testosterone deficiency and associated disorders in men.

• **Rigel Pharmaceuticals Inc.**, of South San Francisco, began enrollment and dosing in a Phase II study to test R788, an oral syk kinase inhibitor, in patients with refractory immune thrombocytopenic purpura. The trial is expected to evaluate several doses of R788, and the primary endpoint is improved platelet counts. In a separate study, Rigel is testing R788 in Phase II development in rheumatoid arthritis.

• **TaiGen Biotechnology Inc.**, of Taipei, Taiwan,

started enrollment for its Phase II trial of Nemonoxacin (TG-873870) in adult community-acquired pneumonia. The study is designed to evaluate the drug's effect in comparison with levofloxacin. TaiGen plans to develop the oral drug in multiple indications, including an upcoming Phase II trial in diabetic foot infections. An intravenous formulation of Nemonoxacin is set to enter the clinic this spring.

• **Targacept Inc.**, of Winston-Salem, N.C., began a Phase I trial of TC-2216, a compound that targets neuronal nicotinic receptors (NNRs) for treating depression and anxiety disorders. The study will involve healthy male volunteers. TC-2216 is designed to work by inhibiting the alpha4beta2 NNR to modulate the release of neurotransmitters that are involved in mood regulation.

• **ThromboGenics NV**, of Leuven, Belgium, has initiated Phase IIb of Microplasmin in vitrectomy (MIVI III), a multicenter, randomized, placebo-controlled, double-masked, dose-ranging trial to evaluate the safety and efficacy of micropasmin intravitreal injection prior to vitrectomy in the U.S. and will involve 120 patients at more than 12 sites. Microplasmin is a truncated form of the natural human protein plasmin. The company also is in Phase II development in Europe to evaluate microplasmin injection for nonsurgical treatment of diabetic macular edema and other back-of-the-eye conditions; the MIVI II trial, for diabetic macular edema, has started patient enrollment.

• **Xanthus Pharmaceuticals Inc.**, of Cambridge, Mass., said the FDA granted orphan drug designation to Xanafide (amonafide malate) for acute myeloid leukemia, which would provide for regulatory assistance and seven years of marketing exclusivity upon approval. Xanafide, an ATP-independent topoisomerase 2 inhibitor, is in a Phase II trial in patients with secondary AML.

• **XenoPort Inc.**, of Santa Clara, Calif., said results from a Phase I trial of different sustained-release tablet formulations of XPI9986 showed that all provided good absorption and conversion to R-baclofen, and one formulation provided a pharmacokinetic profile that might allow once-a-day dosing. At the JPMorgan Healthcare Conference in San Francisco, XenoPort said it plans to conduct an additional Phase I trial in healthy subjects prior to initiating a Phase II trial in patients with gastroesophageal reflux disease in the second half of this year.

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