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Building the New Biotech Leadership

| INSIDE

Part II of II

Amgen: Biggest Biotech Grows Bigger (Fast)

R&D, Marketing, and HR Scale Up

| PLUS

Serono: Fighting False Advertising

Biotech in the Healthcare Setting

The Power of Post-Approval Research

Amgen Executives (left to right) HR Head Ted Bagley,Recruiter Michele Jurbala, R&D Head Roger Perlmutter, and NA Marketing Head James Daly

Released-News

All items in Released News consist of press-release material. BEI alters contents for length only; it offers no validation or endorsement of the information or claims provided.

Targanta Acquires Late-Stage Antibiotic from InterMune

Targanta Therapeutics, a privately held biopharmaceutical company developing and commercializing antibacterial drugs to treat serious infections in the hospital setting, has acquired from InterMune, Inc., the worldwide ownership interest in oritavancin, an antibiotic that has completed two Phase III clinical trials. Oritavancin is a semi-synthetic glycopeptide antibiotic with bactericidal activity against clinically relevant serious Gram-positive infections, including multi-resistant strains. Approximately seventy percent of hospital infections are resistant to at least one class of existing antibiotics and so, new antibiotics are critically needed. Two large multicenter Phase III studies, conducted by Eli Lilly and Company and InterMune, in over 1750 patients have suggested oritavancin to be an effective and safe therapy for complicated skin and skin structure infections. In both Phase III studies, oritavancin reached its primary endpoint and appeared to be as effective as a commonly used treatment regimen, vancomycin followed by cephalexin. Additional indications, including nosocomial pneumonia (infection of the lungs contracted during a hospital stay) and catheter-related bacteremia (presence of bacteria in the blood associated with in-dwelling catheters), will also be evaluated.

Contact Targanta Therapeutics, www.targanta.com

Avigen Sells Its AAV Gene Therapy to Genzyme

Avigen, Inc., a biopharmaceutical company focused on unique small molecule therapeutics and biologics to treat serious neurological disorders, including neuropathic pain, has sold its AAV gene therapy assets to Genzyme Corporation, a leading biotechnology company, under an agreement that allowed Genzyme to acquire all of Avigen's non-pain related AAV assets. The assets include all rights to an extensive patent estate and Avigen's Parkinson's disease clinical trial program, which is in a Phase I /II study currently underway at the University of California, San Francisco (UCSF). Genzyme will make an upfront cash payment of $12 million to Avigen, with additional milestone payments and royalty payments on all products developed under Avigen's comprehensive AAV intellectual property (IP) portfolio, including the current Parkinson's disease program. Among the Avigen assets being acquired by Genzyme is AV201, an experimental treatment for severe Parkinson's disease, which is in an FDA-approved Phase I/II clinical trial. Genzyme will continue the clinical development of the Parkinson's program at UCSF. In addition, Avigen and Genzyme have agreed to continue and extend the collaboration with a world leader in hemophilia gene therapy research, Dr. Katharine High, by providing existing vector and regulatory assistance for the continued clinical development scheduled to be initiated in early 2006. "This agreement marks a significant milestone in Avigen's strategic move from a gene therapy company to a pharmaceutical company focused on small molecule therapeutics to treat neurological disorders," said Kenneth G. Chahine, Ph.D., J.D., Avigen's President and CEO. Rich Gregory, Genzyme's head of research said, "In addition to building an impressive AAV IP estate, Avigen has made significant progress in advancing the clinical utility of gene therapy, thereby making the addition of its assets an important strategic acquisition for us."

Contact Avigen, Inc., www.avigen.com and Genzyme Corporation, www.genzyme.com

Common Cancer Gene Triggers Death of Breast Cancer Cell

The National Surgical Adjuvant Breast and Bowel Project (NSABP), a not-for-profit, clinical trials cooperative group, announced a laboratory study performed on human breast cancer specimens collected as part of a clinical trial evaluating the breast cancer drug, Herceptin, that suggests a cancer-causing gene, called cMYC, can be triggered to cause the death of breast cancer cells. The study, led by Soonmyung Paik, MD, Director of the NSABP Institute of Molecular Pathology, evaluated the breast cancers of more than 3,000 patients treated on two large adjuvant breast cancer clinical trials conducted by the NSABP. This finding is the end result of a three-year-long project that required screening more than 51,000 individual test samples. The research team began by searching for cancer chromosomal abnormalities called gene amplification which were thought to influence the behavior of breast cancer. After screening for gene amplifications in 1,900 cases of breast cancer treated with chemotherapy as part of the NSABP B-28 trial, amplification of three genes (HER2, cMYC, and HTPAP) was found to lead to a poorer prognosis even after the use of standard chemotherapy.

In May 2005, the NSABP and the North Central Cancer Treatment Group, another research group also funded by the National Cancer Institute (NCI), announced the results from a joint analysis of data from the two similar clinical trials (NSABP B-31 and NCCTG N9831) conducted by the groups. The analysis showed significant clinical benefit by adding Herceptin, a monoclonal antibody that targets the HER2 protein, to standard chemotherapy in patients diagnosed with breast cancer with increased copies (amplification) of the HER2 gene. Adding Herceptin resulted in a 53% reduction in the recurrence rate. Dr. Paik believes this finding has potential applicability in other cancers, including breast cancers without HER2 amplification. "The possibility that a cancer gene can be manipulated to trigger the death of cancer cells themselves is a fascinating one and may potentially lead to development of substantially more effective treatment strategies for many kinds of cancer with fewer side effects," Dr. Paik said. He and his colleagues are actively searching for other cancer genes that interact with cMYC.

Contact NSABP, www.nsabp.pitt.edu

Pivotal Trials of Zensana Begin for Cancer Patients

Hana Biosciences, a biopharmaceutical company focused on advancing cancer care, announced that the FDA has cleared its Investigational New Drug (IND) application for Zensana (ondansetron oral spray), which is the first multidose oral spray 5-HT3 antagonist. Hana is initiating a series of pivotal pharmacokinetic trials, including comparison of Zensana to the commercially available ondansetron tablet (Zofran(R); GlaxoSmithkline). Hana acquired the exclusive rights to market the novel oral spray formulation in the U.S. and Canada from NovaDel Pharma, Inc. Hana expects to complete these pivotal trials by early 2006 and plans to file the New Drug Application (NDA) shortly thereafter. Commercial launch of Zensana is targeted for 2007. Annual U.S. sales for ondansetron were approximately $1 billion, representing a 66% market share among the four approved 5-HT3 products in 2004.

Zensana delivers full doses of ondansetron to patients receiving emetogenic chemotherapy. Ondansetron is approved to prevent chemotherapy and radiation-induced, and post-operative nausea