UAMS News Bureau

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UAMS Begins Clinical Trial of Breast Cancer Vaccine

LITTLE ROCK – The University of Arkansas for Medical Sciences (UAMS) announces the start of a Phase 1 clinical trial to study the safety of a novel vaccine to prevent the recurrence of breast cancer.

UAMS has three research subjects enrolled in the Phase 1 clinical trial and plans on completing the trial sometime in 2012 after studying the safety of the vaccine in up to 18 research subjects. After the safety testing phase is completed, UAMS expects to conduct another clinical trial using the vaccine on up to 50 research subjects.

The vaccine was developed by Thomas Kieber-Emmons, Ph.D., professor of pathology and holder of the Josetta Wilkins Chair of Breast Cancer Research at the Winthrop P. Rockefeller Cancer Institute at UAMS. His research has been federally funded since 1992.

Here's how the vaccine would work: The surface of a cancer cell is covered with carbohydrates. If the vaccine could trigger an immune response to carbohydrates, it would destroy the cancer cells. But it is difficult to get the immune system to recognize carbohydrates on cancer cells.

So Kieber-Emmons used a chemical compound called a peptide to mimic a carbohydrate in hopes that the body would create an immune response to the

peptide that then cross-reacts with the carbohydrate on the tumor cell and destroys the cell.

“It’s not quite a bait and switch, but you’re trying to elicit a set of responses you just don’t see with carbohydrates. The true test will come during the clinical trial, but we anticipate our little deception will work to the advantage of breast cancer patients,” Kieber-Emmons said.

The successful effort to initiate the clinical evaluation of this novel approach to vaccine development involved a collaborative effort between the university and three well-known service providers – AmbioPharm Inc., a GMP-compliant manufacturer of peptide active pharmaceutical ingredients, Advantar Laboratories, a GMP-compliant laboratory offering analytical and formulation development services, and NextPharma Technologies, a contract manufacturer for clinical trial materials.

“The process of developing and manufacturing the vaccine required a very high level of interaction between UAMS, AmbioPharm, and Advantar over a two-year period,” Kieber-Emmons said.

UAMS, AmbioPharm, Advantar and NextPharma conducted weekly production and development meetings throughout 2009 and 2010 to facilitate the development and manufacture of the material being used in the clinical trial.

Rich Kenley, Ph.D., chief executive officer of Advantar Labs, said the partnership was able to initiate the Phase 1 trial rapidly and cost effectively. “We believe that the collaboration represents the optimal approach for translating leading-edge, innovative research into promising new therapies for important diseases.”

Jim Hampton, AmbioPharm executive vice president of business development and cGMP sales, said he is thrilled to see the vaccine make a successful entry into clinical trials. “The FDA had only a single question regarding the manufacturing section of the FDA submission.”

UAMS is the state’s only comprehensive academic health center, with colleges of Medicine, Nursing, Pharmacy, Health Related Professions and Public Health; a graduate school; a hospital; a statewide network of regional centers; and seven institutes: the Winthrop P. Rockefeller Cancer Institute, the Jackson T. Stephens Spine & Neurosciences Institute, the Myeloma Institute for Research and Therapy, the Harvey & Bernice Jones Eye Institute, the Psychiatric Research Institute, the Donald W. Reynolds Institute on Aging and the Translational Research Institute. Named best Little Rock metropolitan area hospital by U.S. News & World Report, it is the only adult Level 1 trauma center in the state. UAMS has more than 2,800 students and 775 medical

residents. It is the state's largest public employer with more than 10,000 employees, including about 1,000 physicians who provide medical care to patients at UAMS, Arkansas Children's Hospital, the VA Medical Center and UAMS' Area Health Education Centers throughout the state. Visit www.uams.edu or www.uamshealth.com.

About AmbioPharm

AmbioPharm, Inc. (APi) is a full-service peptide manufacturing company headquartered at its cGMP peptide manufacturing facility in North Augusta, S.C. In addition to manufacturing peptides, AmbioPharm also performs organic conjugations of peptides to proteins, toxoids, antifungals, KLH, and PEG. For additional information, visit www.ambiopharm.com.

About Advantar Labs

Advantar, based in San Diego, is a contract testing laboratory and small-scale clinical packaging company specializing in methods development/validation, pre-formulation/formulation development, clinical trial supplies and kitting, routine/compendial analysis, and ICH stability studies for small and large molecule programs including generics, proprietary drugs, biocompatibles and medical devices ranging in phase from pre-clinical through to clinical I-IV and commercial. For additional information, visit www.advantarlabs.com.

About NextPharma

NextPharma Technologies is a leading contract manufacturer in Europe and the United States. Their San Diego facility provided manufacturing and packaging services for the product developed by UAMS for this clinical trial. For additional information, visit www.nextpharma.com.