

Acusphere's AI-700 Pilot Study Exceeds Expectations

WATERTOWN, Mass., Jan 6, 2005 (BUSINESS WIRE) -- Acusphere, Inc. (NASDAQ:ACUS) today announced that all six of its independent blinded readers were able to read a subset of ultrasound images from the pilot phase of the Phase 3 clinical program at sensitivity and specificity levels that exceeded the pre-specified clinical endpoint criteria for success in the pivotal trials for its lead product candidate.

Acusphere believes it has now met all of the objectives of the pilot study for AI-700, a cardiovascular drug in development for the assessment of coronary heart disease, the leading cause of death in the United States. The AI-700 Phase 3 clinical program includes a pilot phase and a pivotal phase. The objectives of the pilot study included: i) training and qualifying new clinical sites, and ii) training and qualifying independent blinded readers. These six blinded readers have now been qualified and have begun the blind reads for the Phase 3 pivotal trials. Blinded readers for nuclear imaging and angiography, the reference standards for evaluating the accuracy of AI-700 pivotal studies, have also completed training and pivotal Phase 3 study reads are ongoing. Acusphere previously announced that more than 20 clinical sites have been successfully trained and qualified in the pilot study and are now actively enrolling in the pivotal studies. Through the pilot study, Acusphere has also learned more about the enrollment rates of all the clinical sites in the pivotal study, which the Company continues to believe will be completed on schedule during the second half of 2005.

"We are very pleased with the high levels of sensitivity and specificity, especially since these pilot study images were generated by the same clinical investigators and were evaluated by the same blinded readers as we are using in our pivotal trials," said Sherri C. Oberg, President and Chief Executive Officer of Acusphere. "This is a significant step forward that increases our confidence level in the prospects for AI-700, and we are very pleased with our progress." As part of the AI-700 Phase 3 pivotal trial design, ultrasound images taken with AI-700 are to be independently read by panels of echocardiologists who have no patient information other than the images. These physicians are referred to as "blinded" readers. To qualify for the pivotal trials, the proficiency of the blinded readers was tested by having them evaluate myocardial perfusion in a sample of AI-700 enhanced echo images generated during the training, or pilot, studies. In an effort to ensure that this analysis would be relevant to the blinded readers' proficiency in the pivotal trials, Acusphere selected a sample of 20 images from the pilot study that it believed would be most representative of the range of images that would be generated in the pivotal studies. As will be required in the pivotal study, the blinded readers looked only at the images. They were required to assess whether or not patients had abnormal myocardial enhancement, and identify the location of the defects. Sensitivity and specificity relative to nuclear imaging or angiography were calculated to quantify the proficiency of the readers in the same set of patients. All six blinded readers read at a proficiency level that exceeded the pre-specified clinical endpoint criteria for success in the pivotal trials and have moved forward into the pivotal phase. In the pivotal phase, the blind reads will be conducted on an ongoing basis during the trial enrollment period, thereby minimizing the number of images that need to be read once enrollment is completed.

Since one of the purposes of the pilot study was to train the investigators how to do the protocol, the images in the pilot study were expected to be poorer in quality than those that would be generated in the pivotal study after training has been completed. The image quality in the pilot study and the sensitivity and specificity of the blind reads are higher than Company expectations. The Company noted that the images evaluated by the blinded readers, while exceeding expectations, represent a small subset of the patients from the pilot study, and that it must complete two pivotal studies, totaling about 600 patients, before submitting a New Drug Application to the Food and Drug Administration. The Company noted that there can be no assurance that the results of the larger pivotal studies will be consistent with findings from this blinded reader training.

About Acusphere, Inc.

Acusphere (NASDAQ:ACUS) is a specialty pharmaceutical company that develops new drugs and improved formulations of existing drugs using its proprietary microparticle technology. Acusphere's three initial product candidates are designed to address large unmet clinical needs within cardiology, oncology and asthma. These product candidates were created using proprietary technology that enables Acusphere to control the porosity and size of nanoparticles and microparticles in a versatile manner that allows particles to be customized to address the delivery needs of a variety of drugs. Acusphere's lead product candidate, AI-700, is a cardiovascular drug in Phase 3 clinical development. AI-700 is designed to enable ultrasound to compete more effectively with nuclear stress testing, the leading procedure for detecting coronary heart disease. An estimated 9.5 million procedures are done each year in the U.S. to detect coronary heart disease, the leading cause of death in the United States. For more information about Acusphere visit the Company's web site at www.acusphere.com.

This Release contains forward-looking statements, including statements regarding confidence levels in AI-700 generally, and the results for and the timing of completion of the Phase 3 clinical trials. The Company's actual results may differ materially from those anticipated in these forward-looking statements based upon a number of factors, uncertainties associated with research, development, testing and related regulatory approvals, including uncertainties regarding the ultimate outcome of Acusphere's Phase 3 clinical trials for AI-700, unproven markets, future capital needs and uncertainty of additional financing, competition, uncertainties associated with intellectual property, complex manufacturing, high quality requirements, dependence on third-party manufacturers, suppliers and collaborators, loss of key personnel, uncertainties associated with market acceptance and adequacy of reimbursement, technological change and government regulation, and other risks and challenges detailed in the Company's filings with the U.S.

Securities and Exchange Commission, including the Company's most recent Quarterly Report on Form 10-Q for the quarter ended September 30, 2004. Readers are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this Release. The Company undertakes no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this Release or to reflect the occurrence of unanticipated events.

SOURCE: Acusphere, Inc.

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