Angiotech Receives FDA Approval for its Proprietary Bio-SealT Lung Biopsy Device

The Associated Press

/FROM PR NEWSWIRE DALLAS 888-776-3971/ [STK] [IN] [SU] TO BUSINESS EDITORS: Angiotech Receives FDA Approval for its Proprietary Bio-SealT Lung Biopsy Device VANCOUVER, Dec. 20, 2012 /PRNewswire/ - Angiotech Pharmaceuticals, Inc. ("Angiotech") announced today that it received approval on December 19, 2012 from the U.S. Food and Drug Administration ("FDA") to market and sell its proprietary Bio-Seal Lung Biopsy Tract Plug System in the United States. The device is the first of its kind approved by the FDA, and represents a significant advance in the safety of this important diagnostic procedure.

"Bio-Seal represents a significant and proprietary addition to our broad portfolio of products for the diagnosis of cancer," said Thomas Bailey, President and CEO of Angiotech. "This device has been shown in clinical studies to significantly reduce complication rates in patients receiving a lung biopsy procedure, which we expect will enable physicians to more aggressively pursue diagnostic options for this patient population." Angiotech's Bio-Seal product is a novel biopsy device system that contains a proprietary hydrogel plug designed to prevent air leaks that can lead to a collapsed lung, or pneumothorax, in patients having lung biopsies. On contact with moist tissue, the hydrogel plug absorbs fluids and expands to fill the void created by the biopsy needle puncture. The plug is absorbed into the body after healing of the puncture site has occurred. Pneumothorax is the most common potential complication in patients undergoing lung biopsy procedures. In cases where a chest tube is inserted to treat pneumothorax, an extended hospital stay for such patients may be required until the condition has stabilized. Industry estimates indicate that over 250,000 lung biopsy procedures are performed annually in the United States.

Bio-Seal has undergone a human clinical trial in the United States which was designed to assess the safety and efficacy of Bio-Seal, with the primary endpoint being reduction in rates of pneumothorax in patients undergoing lung biopsy procedures. The clinical trial was a prospective, randomized, multi-centered safety and efficacy evaluation. The complete data for the Bio-Seal study was presented at the 2009 Society of Interventional Radiology. The trial achieved its primary end point, with clinical success in 85% of patients treated with Bio-Seal, as compared to 69% for the control patients (p=0.002), representing a 50% reduction in the risk of pneumothorax in the Bio-Seal patient group.

Angiotech expects that this product will be made commercially available in the U.S. during the first quarter of 2013. Angiotech expects market this product globally under the brand name "BioSentryT".

Forward Looking Statements Statements contained in this press release that are not

based on historical fact, including without limitation statements containing the words "believes," "may," "plans," "will," "estimates," "continues," "anticipates," "intends," "expects" and similar expressions, constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and constitute "forward-looking information" within the meaning of applicable Canadian securities laws. All such statements are made pursuant to the "safe harbor" provisions of applicable securities legislation. Forward-looking statements may involve, but are not limited to, comments with respect to our objectives and priorities in 2012 and beyond, our strategies or future actions, our targets, expectations for our financial condition and the results of, or outlook for, our operations, research and development and product development. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, events or developments to be materially different from any future results, events or developments expressed or implied by such forward-looking statements. Many such known risks, uncertainties and other factors are taken into account as part of our assumptions underlying these forward-looking statements and include, among others, the following: general economic and business conditions in the United States, Canada and the other regions in which we operate; market demand; competition; technological changes that could impact our existing products or our ability to develop and commercialize future products; governmental legislation and regulations and changes in, or the failure to comply with, governmental legislation and regulations; availability of financial reimbursement coverage from governmental and third-party payers for products and related treatments; adverse results or unexpected delays in pre-clinical and clinical product development processes; adverse findings related to the safety and/or efficacy of our products or products sold by our partners; decisions, and the timing of decisions, made by health regulatory agencies regarding approval of our technology and products; the requirement for funding to conduct research and development, to expand manufacturing and commercialization activities; and any other factors that may affect our performance. In addition, our business is subject to certain operating risks that may cause any results expressed or implied by the forward-looking statements in this press release to differ materially from our actual results. These operating risks include: our ability to successfully manufacture, market and sell our products; changes in our business strategy or development plans; our ability to attract and retain qualified personnel; our ability to successfully complete pre-clinical and clinical development of our products; our failure to obtain patent protection for discoveries; loss of patent protection resulting from third-party challenges to our patents; commercialization limitations imposed by patents owned or controlled by third parties; our ability to obtain rights to technology from licensors; liability for patent claims and other claims asserted against us; our ability to obtain and enforce timely patent and other intellectual property protection for our technology and products; the ability to enter into, and to maintain, corporate alliances relating to the development and commercialization of our technology and products; market acceptance of our technology and products; the availability of capital to finance our activities; our ability to service our debt obligations; and any other factors referenced in our other filings with the SEC. For a more thorough discussion of the risks associated with our business, see the "Risk Factors" section in our quarterly report for the three and nine months ended September 30, 2012 filed with the SEC on November 14, 2012 on Form 10Q.

Given these uncertainties, assumptions and risk factors, investors are cautioned not to place undue reliance on such forward-looking statements. Except as required by law, we disclaim any obligation to update any such factors or to publicly announce the result of any revisions to any of the forward-looking statements contained in this press release to reflect future results, events or developments.

About Angiotech Angiotech develops, manufactures and markets medical device products and technologies, primarily within the areas of interventional oncology, wound closure and ophthalmology.Our strategy is to utilize our precision manufacturing capabilities and our highly targeted sales and marketing capabilities to offer novel or differentiated medical device products to patients, physicians and other medical device manufacturers or distributors. For additional information about Angiotech, please visit our website at www.angiotech.com.

SOURCE Angiotech Pharmaceuticals, Inc.

-0- 12/20/2012 /CONTACT: Investor Relations and Corporate Communications
 Angiotech Pharmaceuticals, Inc.
 (604) 221-6933
 ir@angio.com CO: Angiotech Pharmaceuticals, Inc.

ST: British Columbia PRN -- TO855 -- 0000 12/20/2012 19:28:00 EDT
http://www.prnewswire.c

Source URL (retrieved on *03/28/2015 - 12:06am*):
http://www.mdtmag.com/news/2012/12/angiotech-receives-fda-approval-its-proprietary-bio-sealt-lung-biopsy-device