



Tuesday August 11, 2009

## **ANGIOTECH'S LICENSEE, COOK MEDICAL, ANNOUNCES CE MARK APPROVAL AND EUROPEAN LAUNCH OF THE ZILVER® PTX® STENT**

### **The World's First Peripheral Drug-Eluting Stent Now Available in Europe**

**Vancouver, BC, August 11, 2009** – Angiotech Pharmaceuticals, Inc. (NASDAQ: ANPI, TSX: ANP) today announced Cook Medical, a license holder of Angiotech's paclitaxel technology, reported CE Mark approval and limited commercial launch of the Zilver® PTX® Drug-Eluting Peripheral Stent in Europe. This approval represents a global landmark in bringing drug-eluting stent (DES) technology to people suffering from peripheral artery disease (PAD), a chronic disease affecting tens of millions of patients worldwide that is a leading cause of leg amputation and shortened lifespan.

"The awarding of the CE Mark is set to herald a revolution in the treatment of peripheral arterial disease," said Dr. Michael Dake, Professor in the Department of Cardiothoracic Surgery at Stanford University Medical School and Medical Director of the Cath/Angio Laboratories at Stanford University Medical Center, Palo Alto, California. "This global study demonstrates that the Zilver PTX has the integrity, safety and durability needed to successfully address many of the well-known limitations of current treatments for the management of PAD."

"Cook is to be congratulated for succeeding where many others have failed in making drug-eluting stent technology a reality for patients with peripheral vascular disease," said Dr. Bill Hunter, President and CEO of Angiotech. "The Zilver PTX stent platform has shown tremendous mechanical performance in clinical trials, and when combined with the proven benefits of paclitaxel in the prevention of restenosis, the Zilver PTX is poised to become the first choice for interventionalists in the management of this common medical condition."

For the first time, patients in Europe today had access to a highly effective medical treatment for PAD when physicians in several countries completed placements of a CE Mark approved DES designed specifically to treat severe blockages in one of the largest arteries in the leg. Following the evaluation of more than 1,200 patients worldwide during its development, the Zilver PTX stent received CE Mark approval on July 24, 2009 and the first commercial implantations of the device were conducted today in a coordinated effort by physicians in the United Kingdom, Germany, France, Holland, Belgium, Sweden and Spain.

The Zilver PTX is specifically designed and CE Mark approved to treat PAD affecting the main blood vessel in the thigh, the superficial femoral artery (SFA). It is a self-expanding stent made of nitinol, a space-age 'shape memory' metal that offers unique mechanical advantages for a stent implanted in the SFA, such as the ability to resist kinking or fracturing as a result of normal movement of the leg. In addition, the Zilver PTX provides targeted delivery of paclitaxel, a drug proven to reduce restenosis, the re-narrowing of the artery with scar tissue resulting from the trauma of opening the vessel by balloon angioplasty. Originally discovered by Angiotech and licensed to Cook Medical for peripheral artery disease (and other indications) and to Boston Scientific Corporation (BSC) for coronary artery disease (and other indications), Angiotech's paclitaxel technology has been successfully and safely used in millions of patients suffering from coronary artery disease as part of BSC's TAXUS paclitaxel-eluting coronary stent program. As a result of these combined attributes, the clinical trial results suggest that the Zilver PTX stent is a durable and clinically effective peripheral stent that also has an excellent patient safety profile.

The granting of the CE Mark follows the largest clinical evaluation ever conducted for a peripheral vascular DES, led by Dr. Dake. As reported by Cook, the Zilver PTX registry involved 791 patients from Europe, Russia, Canada and Korea and demonstrated highly positive results. Failure rates for the device were very low, with only 8 percent of patients with de novo (new) lesions requiring a re-intervention to reopen the artery within

the first 12 months – a rate significantly surpassing existing treatments for PAD in the SFA, such as balloon angioplasty and bare metal (non-drug-eluting) stents. Also, specific patient groups that are often difficult to treat, such as diabetics and patients with in-stent restenosis (i.e. patients whose previously placed bare metal stent had become blocked by scar tissue), were shown in the trial to benefit from the Zilver PTX. Importantly, the trial data indicates that the positive results achieved in the first year after treatment are largely maintained through the second year (24 months), an important clinical milestone.

### **About Peripheral Arterial Disease (PAD)**

PAD is one of the fastest-growing and most pervasive diseases of our time, and it is estimated to affect 27 million individuals in Europe and North America.<sup>1,2,3</sup> Physical symptoms are only present in approximately one third of these individuals.<sup>1,4,5</sup> The ‘silent’ nature of this condition results in a significant number of patients being diagnosed only after their disease has progressed to a severe stage. Symptomatic PAD initially results in intermittent claudication (IC).<sup>6</sup> IC is characterized by muscle pain or fatigue in the legs that occurs during exercise and is relieved by a short period of rest. Further disease progression can result in critical limb ischemia (CLI)<sup>6,7</sup>, a severe condition associated with chronic pain, ulcers or gangrene due to severe arterial occlusion. In many countries, untreated PAD is the leading cause of leg amputation. Approximately 120,000 to 400,000 leg amputations occur annually due to PAD.<sup>6,7</sup> Even when treated, current therapies such as bypass surgery and balloon angioplasty<sup>8</sup> are either much more invasive or have shown only limited long-term success rates. PAD, either directly or indirectly, results in a high mortality rate; only 30% of patients are still alive 15 years after initial diagnosis with the disease<sup>4</sup>.

The peripheral vascular stent market is estimated to be \$200 million in Europe and \$1 billion worldwide, with approximately 1/3 of these procedures occurring in the lower limbs. There were approximately 140,000 bypass surgeries performed to treat blockages of the Superficial Femoral Artery in the European Union in 2008 and 200,000 of these surgeries in the United States.

The Zilver PTX drug-eluting stent is an investigational device not available in the United States.

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<sup>1</sup> Belch JJ, Topol EJ, Agnelli G, et al. Critical issues in peripheral arterial disease detection and management: a call to action. *Arch Intern Med.* 2003;163(8):884–892.

<sup>2</sup> Golomb BA, Dang TT, Criqui MH, et al. Peripheral arterial disease: morbidity and mortality implications. *Circulation.* 2006;114(7):688–699.

<sup>3</sup> Hirsch AT, Haskal ZJ, Hertzner NR, et al. ACC/AHA 2005 guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic). *J Am Coll Cardiol.* 2006;47(6):1239–1312.

<sup>4</sup> Fowkes FG, et al. Edinburgh Artery Study: prevalence of asymptomatic and symptomatic peripheral arterial disease in the general population. *Int J Epidemiol* 1991; 20(2): 384–392.

<sup>5</sup> Selvin E, Erlinger TP. Prevalence of and risk factors for peripheral arterial disease in the United States: results from the National Health and Nutrition Examination Survey, 1999-2000. *Circulation* 2004; 110(6): 738–743.

<sup>6</sup> Norgren L, Hiatt WR, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). Available at: [www.tasc-2-pad.org](http://www.tasc-2-pad.org). Accessed October 2007.\*

<sup>7</sup> Jaccard Y, et al. Influence of secondary infection on amputation in chronic critical limb ischemia. *Eur J Vasc Endovasc Surg* 2007; 33(5): 605–609.

<sup>8</sup> <http://www.americanheart.org/presenter.jhtml?identifier=3020257>

## **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 for the remainder of 2009 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 and drug 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; technological changes that could impact our existing products or our ability to develop and commercialize future products; competition; existing governmental regulations and changes in, or the failure to comply with, governmental 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 substantial 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 Quarterly Report on Form 10-Q to differ materially from our actual results. These operating risks include: our ability to attract and retain qualified personnel; our ability to successfully complete pre-clinical and clinical development of our products; changes in our business strategy or development plans; 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; our ability to successfully manufacture, market and sell our products; the availability of capital to finance our activities; our ability to restructure and to service our debt obligations; and any other factors referenced in our other filings with the applicable Canadian securities regulatory authorities or the Securities and Exchange Commission (“SEC”). For a more thorough discussion of the risks associated with our business, see the “Risk Factors” section in our annual report for the year ended December 31, 2008 filed with the SEC on Form 10-K, and our quarterly report for the three months ended June 30, 2009 filed with the SEC on Form 10-Q.

**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.**

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### **About Angiotech Pharmaceuticals**

Angiotech Pharmaceuticals, Inc. is a global specialty pharmaceutical and medical device company with over 1,500 dedicated employees. Angiotech discovers, develops and markets innovative treatment solutions for diseases or complications associated with medical device implants, surgical interventions and acute injury. To find out more about Angiotech (NASDAQ: ANPI, TSX: ANP), please visit our website at [www.angiotech.com](http://www.angiotech.com).

### **About Cook Medical:**

Cook Medical was one of the first companies to help popularise interventional medicine, pioneering many of the devices now commonly used worldwide to perform minimally invasive medical procedures. Today, the company integrates device design, biopharma, gene and cell therapy, and biotech to enhance patient safety and improve clinical outcomes in the fields of aortic intervention; interventional cardiology; critical care medicine; gastroenterology; radiology, peripheral vascular, bone access and oncology; surgery and soft-tissue repair; urology; and assisted reproductive technology, gynaecology and high-risk obstetrics. Cook is a past winner of

the prestigious Medical Device Manufacturer of the Year Award from Medical Device & Diagnostic Industry magazine. For more information, visit [www.cookmedical.com](http://www.cookmedical.com).

**FOR ADDITIONAL INFORMATION:**

DeDe Sheel  
Investor Relations and Corporate Communications  
Angiotech Pharmaceuticals, Inc.  
(415) 293-4412  
dede.sheel@fd.com

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