



Armetheon and Lee's Pharma Enter into Agreement to Develop and Commercialize Tecarfarin in Greater China and Thailand

MILPITAS, Calif. and HONG KONG, Sept. 22, 2015 /PRNewswire/ -- Armetheon, Inc., a specialty pharmaceutical company developing novel small molecule drugs for cardiovascular diseases, today announced that Armetheon and China Cardiovascular Focus Limited, a subsidiary of Lee's Pharmaceutical Holdings Limited (Lee's Pharma), a public biopharmaceutical company listed on the main board of Hong Kong Stock Exchange (stock code: 950) with an operating history of over 20 years in the Chinese pharmaceutical industry, have entered into an agreement to initiate advanced-stage clinical testing, manufacturing and commercialization of Armetheon's investigational oral anticoagulant, tecarfarin, in the greater China market including Mainland China, Hong Kong, Macau, and Taiwan as well as Thailand.

Under the terms of the agreement, Lee's Pharma gains exclusive rights to develop and commercialize tecarfarin in the greater China market and Thailand. Tecarfarin is poised to enter into a final registration study (Tecarfarin for AntiCoagulation Trial, or "TACT") in the U.S. under a Special Protocol Assessment (SPA) agreed upon with the FDA. Armetheon will receive an upfront cash payment in the form of a licensing fee along with an equity investment and development and sales milestone payments. In addition, Armetheon will receive royalties on future net sales. Lee's Pharma will pay for the development, approval and commercialization of tecarfarin in the greater China market and Thailand.

"We are pleased to enter this agreement with Lee's Pharma, a leading Chinese pharmaceutical company, to develop and approve tecarfarin in the greater China market and Thailand," stated Sanjay Kakkar, MD, Armetheon's Chief Executive Officer. "This relationship is an important part of our global strategy seeking to bring tecarfarin to market in order to meet the needs of patients who require an alternative to warfarin. Furthermore, Lee's Pharma has a proven track record in the development of new compounds and in navigating the complex regulatory landscape in China. We believe this collaboration will become an important contribution to achieving the goal of seeking to establish tecarfarin as an oral anticoagulant available worldwide."

"With a substantial patient population at elevated risk of thrombosis, China has the potential to become an important market for alternative anticoagulant agents," said Dr. Xiaoyi (Benjamin) Li, Chief Executive Officer and Executive Director of Lee's Pharma. "We believe that tecarfarin can address the compelling needs in those patients requiring chronic anticoagulant therapy, and we look forward to collaborating closely with Armetheon to initiate the development of tecarfarin in greater China and Thailand."

Locust Walk served as an advisor to Armetheon in concluding this transaction.

About Tecarfarin

Tecarfarin is being investigated for use as an oral, once-daily anticoagulant that inhibits Vitamin K epoxide reductase (VKOR), an important enzyme in the coagulation system, and avoids CYP450 metabolism and renal elimination. In Phase 2 and Phase 2/3 (EMBRACE-AC) clinical testing, tecarfarin improved time in therapeutic range (TTR) in chronically anticoagulated patients. The effect of tecarfarin on TTR will be further investigated in the Company's pivotal clinical trial, TACT (Tecarfarin for AntiCoagulation Trial), which will be conducted under a Special Protocol Assessment agreed upon with the FDA. TACT is an open-label trial of 3,000 patients with any indication for anticoagulation, including prosthetic heart valve (PHV) patients. TTR was chosen as the endpoint for these trials on the basis of evidence suggesting that better anticoagulation control (as measured by higher TTR) can protect patients from severe or even fatal adverse events. Tecarfarin is monitored using INR (International Normalized Ratio) and is being investigated for use without the need for CYP2C9 genotyping since tecarfarin is not metabolized via the CYP450 system. In preclinical and early clinical studies, the anticoagulant effect of tecarfarin was reversed by existing and readily available antidotes for Vitamin K Antagonists.



About Lee's Pharma

Lee's Pharma is a research-based biopharmaceutical company listed in Hong Kong with over 20 years operation in China's pharmaceutical industry. It is fully integrated with strong infrastructures in drug development, manufacturing, sales and marketing. It has established extensive partnership with over 20 international companies and currently has 14 products in the market place. Lee's Pharma focuses on several key disease areas such as cardiovascular, oncology, gynecology, dermatology and ophthalmology. Lee's Pharma development program is lauded with 30 products stemming from both internal R&D efforts and collaborations with US, European and Japanese companies and aspiring to combat diseases such as liver cancer and pulmonary hypertension. The mission of Lee's Pharma is to become a successful biopharmaceutical group in Asia providing innovative products to fight diseases and improve health and quality of life. Additional information about Lee's Pharma is available at <http://www.leespharm.com>.

About Armetheon

Armetheon, Inc., is a privately held, specialty pharmaceutical company developing and commercializing innovative medicines addressing major unmet needs in cardiovascular disease, initially in thrombosis. Armetheon focuses on improved therapies with the goal of increased efficacy, safety, and utility, targeting specialty markets with clearly defined regulatory pathways. Armetheon's lead candidate, tecarfarin, is being investigated for use as a Vitamin K Antagonist and is currently in Phase 3 development for the prevention and management of thrombosis. For more information: www.armetheon.com.

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