

Vitruvias, Sinotherapeutics launch approved version of Propafenone ER in the U.S.

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Vitruvias Therapeutics Inc., an Auburn, Alabama-based finished-dose generic drug company, and Sinotherapeutics Inc., a Shanghai-based generic drug company, have launched a bioequivalent FDA-approved version of Rythmol SR.

Rythmol SR, known generically as propafenone hydrochloride, is an antiarrhythmic drug supplied in extended-release capsules of 225, 325 and 425 mg for oral administration.

Dr. Jason Wan, Founder and CEO of Sinotherapeutics said, “We are pleased that we found Vitruvias. Like us, they are a young company, but they are growing rapidly through hard work, dedication and persistence in what is a very difficult U.S. market. We are confident they will maximize the value of our asset and we look forward to their future participation with other products in our very robust pipeline.”

Carl Whatley, Chairman and CEO of Vitruvias, added, “We are pleased to have found a Chinese partner with the resources and technical skills to formulate these high-barrier generics. Dr. Wan has put together a tremendous team in Shanghai and they are in the process of filing their many high-barrier ANDAs in the pipeline. The education and experience that Dr. Wan and his core technical and managerial team possess has prepared them to tackle both the scientific and business challenges of such a large, yet untapped market. China’s rapid entry into the global pharmaceutical markets is testimony to the modernization of China’s regulatory system and the repatriation of many experts like Dr. Wan.

It is indicated for the treatment of sustained ventricular tachycardia that is deemed to be life-threatening. It is also indicated for the conversion to and/or maintenance of sinus rhythm in patients with supraventricular arrhythmias without structural heart disease and for the maintenance of sinus rhythm in patients with paroxysmal atrial fibrillation or atrial flutter associated with disabling symptoms.