Armetheon announces issuance of a new U.S. patent for its Phase 2 clinical stage novel oral antiarrhythmic budiodarone

Patent claims include use in patients who are refractory to at least one first line therapy and include combination with a novel oral anticoagulant (NOAC)

Menlo Park, CA, February 13, 2017 – Armetheon, Inc., a specialty pharmaceutical company developing novel small molecule drugs for cardiovascular diseases, today announced the issuance on January 24, 2017 by the U.S. Patent and Trademark Office (USPTO) of a new patent covering the company's novel oral antiarrhythmic, budiodarone, the only known novel anti-arrhythmic in clinical development.

The new U.S. Patent No. 9,549,912 B2 is entitled "Methods for treating atrial fibrillation" and includes claims directed to the treatment of refractory atrial fibrillation (AF) in patients who have failed at least one first line therapy with anti-arrhythmic drugs, cardioversion or catheter ablation. Currently there are no FDA approved options for second line therapy in atrial fibrillation. The refractory AF patient population in the US alone is large, with an annual incidence of approximately 300,000 patients. Moreover, 40-60% of the prevalent US atrial fibrillation patient population (estimated at 4-5 million patients) fail at least one antiarhythmic drug, cardioversion or catheter based intervention.

The claims also include use of budiodarone in combination with any of the approved novel oral anticoagulants (NOAC) in the refractory patient population. This is important since the oral antiarrhythmic amiodarone (the standard of care for more than 50 years), as per guidance from professional medical societies in US and Europe, is not recommended for combination with the currently available NOACs primarily due to drug-drug interaction issues. Combination therapy using an oral antiarrhythmic and an oral anticoagulant could potentially provide symptom relief as well as stroke prevention, in a single pill. Reducing the duration of atrial fibrillation episodes, could reduce stroke risk, because long episodes are associated with a significantly high risk of stroke. Confirmation of the observations seen in two Phase 2 trials, that budiodarone reduces the long episodes of AF, provides a rationale by which its use in combination with a NOAC would add medical benefit above and beyond the use of each alone.

“This new patent, along with previously issued patents covering composition of matter and manufacturing process and intermediates, further expands and protects Armetheon’s antiarrythmic intellectual property estate,” said M. (Ken) Kengatharan, PhD, Armetheon’s President & *interim*

CEO. "With this new patent protection, we now have a sufficient term of exclusivity to develop and seek approval for budiodarone on its own as well as, in the long term, budiodarone in combination with a NOAC, which we believe may lead to a new generation of OACs that provides maximum stroke prevention as well as symptom relief."

Budiodarone has been studied in close to 129 subjects in 6 different clinical trials including two Phase 2a studies in patients with paroxysymal atrial fibrillation, where budiodarone was observed to have dose-dependent reduction in atrial fibrillation burden, episode duration as well as symptom relief that were both clinically and statistically significant.

Armetheon plans to initiate two new phase 2 clinical studies with budiodarone in the second half of 2017.

About Budiodarone

Budiodarone is being investigated as an anti-arrhythmic agent for the treatment of refractory atrial fibrillation, as well as in the future, ventricular tachycardia (VT) in patients with an implantable cardioverter defibrillator (ICD). In preclinical and Phase 2 clinical studies, budiodarone has displayed rapid onset and offset of action, and its elimination is not CYP450-dependent, suggesting a lower potential for drug interactions. Further, Phase 2 clinical studies suggest that budiodarone is well-tolerated. Preclinical studies to date have not shown evidence of tissue accumulation and have demonstrated potent inhibitory effects on VT. In the largest Phase 2 study to date, it was found that budiodarone reduced atrial fibrillation burden in a dose-dependent fashion. Due to the high unmet need for an alternative anti-arrhythmic agent for the treatment of refractory atrial fibrillation and VT in patients with ICDs, Armetheon is pursuing development of budiodarone in these patient populations.

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 and cardiac arrhythmias. 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. Armetheon is also developing its anti-arrhythmic drug candidate, budiodarone, for the potential treatment of refractory atrial fibrillation (AF), defined as those patients who have failed at least one first line therapy with anti-arrhythmic drugs or catheter ablation as well as ventricular

tachycardia (VT) in patients with implantable cardioverter defibrillators (ICDs). For more information: www.armetheon.com.

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