

Castle Creek Pharmaceuticals Announces License of Exclusive US Rights for Arlevert® from Hennig Arzneimittel GmbH

Important addition to Castle Creek's portfolio addresses major medical need in ear nose and throat (ENT) space

PARSIPPANY, N.J. -- December 13, 2016 -- Castle Creek Pharmaceuticals, LLC (CCP), a global company dedicated to delivering transformative therapies to patients with dermatologic and head/neck orphan diseases and underserved conditions, today announced completion of an exclusive license agreement for all U.S. rights to Arlevert® from Hennig Arzneimittel GmbH & Co. KG. Arlevert is a fixed-dose oral combination of cinnarizine and dimenhydrinate. Arlevert is approved in multiple European Union countries where it is indicated for the treatment of patients with vertigo of various origins.

“We are very pleased to license Arlevert for the U.S., as vertigo is a complex problem, and combining two molecules with different modes of action could be important for addressing both the peripheral and central effects of vertigo,” said Dr. Greg Licholai, President and Chief Scientific Officer at Castle Creek Pharmaceuticals. “Our goal is to expedite the development of Arlevert in the U.S. by building on the European patient experience of over 11 million prescribed doses and its track record of effectiveness, safety and tolerability. Arlevert will be an important addition to our pipeline, as it addresses a significant need for patients who suffer from the debilitating effects of vertigo.”

Previous well-controlled clinical studies have demonstrated that Arlevert has a significant efficacy profile, as measured by validated mean vertigo scores compared with placebo^{7,9}, betahistine^{1,2,5,6,7,11} and the component mono-therapies^{3,4,9,10}. Arlevert has also been well-tolerated with minimum sedation^{2,10}.

“I am very happy that the possibility of a treatment modality available to the rest of the world is now being developed for patients in the United States,” said Dr. Sujana Chandrasekhar, MD, FACS, FAAO-HNS; past president of American Academy of Otolaryngology-Head and Neck Surgery; neuro-otologist and clinical professor at Hofstra-Northwell School of Medicine; and clinical associate professor at Icahn School of Medicine at Mount Sinai. “Our patients can be utterly debilitated due to vertigo and they could benefit from a medication that allows them to function better.”

About Vertigo

Vertigo is a sensation caused by an imbalance in the signals from the body's sensory balance organs, including the eyes and inner ears, or by the way such signals are interpreted by the

brain. It is commonly perceived as instability, a feeling of rotation or the sensation of dizziness, and it is often associated with lack of balance, nausea and vomiting. Vertigo is caused by a wide number of underlying conditions, including benign paroxysmal positional vertigo, vestibular neuropathy, vertebrobasilar insufficiency, vestibular migraine and Menière's disease. Vertigo is a common condition, and in recent studies, vertigo and dizziness together were found to affect 5-10 percent of the entire U.S. population and as much as 40 percent of the U.S. population over the age of 40 years.

About Arlevert®

Arlevert is a fixed-dose oral combination tablet containing 20 mg cinnarizine and 40 mg dimenhydrinate, to be taken three times daily. It is approved in multiple European Union countries for the treatment of vertigo of various origins⁸. When these two substances are used together, they are more effective than either of its component drugs alone. The active ingredients work together both peripherally and centrally to reduce the symptoms of vertigo. Cinnarizine is a calcium channel antagonist which peripherally affects the vestibular hair cells of the inner ear and dimenhydrinate is an antihistamine which centrally affects the vestibular nuclei of the brainstem. Dimenhydrinate also reduces nausea which is a symptom of acute vertigo.

About Castle Creek Pharmaceuticals

Castle Creek Pharmaceuticals (CCP) is a high-growth biopharmaceutical company that has rapidly assembled a robust and diversified late-stage pipeline of products backed by strong science and focused on meeting patient needs in the treatment of rare and debilitating dermatologic and head and neck conditions.

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About Hennig Arzneimittel

HENNIG ARZNEIMITTEL is an independent, family-run, mid-sized German pharmaceutical company with more than 118 years of experience in the manufacturing and marketing of pharmaceutical products. Over the past 35 years, the company has specialized in the treatment of vertigo and vestibular disorder. In this indication, HENNIG ARZNEIMITTEL is German market leader with Arlevert, its original drug for the treatment of patients with vertigo of various origins. By hosting the biannual HENNIG-Vertigo-Symposium, Europe's largest event in this therapeutical area and tendering the HENNIG-Vertigo-Award, HENNIG ARZNEIMITTEL fosters research and scientific exchange among investigators in this field of study. By supporting continued education for practitioners, ENT-physicians and neurologists, the company promotes better vertigo diagnosis and therapy. With its more than 300 highly qualified employees, state-of-the-art technologies and its own on-site production facilities, HENNIG ARZNEIMITTEL stands for the highest quality.

Footnotes

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For more information, visit: www.castlecreekpharma.com.