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Aurinia Initiates Phase 2 Clinical Trial for Voclosporin Ophthalmic Solution for the Treatment of Dry Eye Syndrome

VICTORIA, British Columbia--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH/TSX: AUP), a clinical stage biopharmaceutical company focused on the global immunology market, today announced the initiation of its Phase 2 trial evaluating voclosporin ophthalmic solution (VOS) for the treatment of dry eye syndrome (DES).

VOS, which is a proprietary nanomicellar formulation, enables high concentrations of voclosporin to be incorporated into a clear aqueous, preservative-free solution for local delivery to the ocular surface. This patented formulation has the potential to result in improved efficacy, dosing frequency, and tolerability versus the current treatments for DES.

This Phase 2 study is evaluating the ocular tolerability of VOS 0.2% versus Restasis® (cyclosporine ophthalmic emulsion 0.05%) at four weeks in subjects with mild to moderate DES. This robust head-to-head trial is recruiting 90 patients in sites across the United States, and the study is expected to complete at the end of 2018. Key secondary endpoints include Ocular Surface Disease Index (OSDI), System Assessment in Dry Eye (SANDE), Individual Symptom Severity Assessments and Drop Discomfort Visual Analog Scale (VAS) scores, Fluorescein Corneal Staining (FCS), and Schirmer Tear Test (STT).

“Topical calcineurin inhibition is thought to be a mainstay of treatment for dry eye, and based on its unique profile, we believe that VOS has the potential to compete in the multi-billion-dollar prescription dry eye market,” said Richard M. Glickman, Aurinia’s Chairman and Chief Executive Officer. “Our goal with this program is to develop a best-in-class treatment option, and upon completion, we will look to evaluate strategic alternatives for this asset.”

VOS has demonstrated safety and tolerability in a human Phase Ib study (n=35), supporting its development for the treatment of DES. It has also previously shown evidence of efficacy in canine studies, which are being conducted by Merck Animal Health.

About Aurinia

Aurinia Pharmaceuticals is a clinical stage biopharmaceutical company focused on developing and commercializing therapies to treat targeted patient populations that are suffering from serious diseases with a high unmet medical need. The company is currently
developing \textit{voclosporin}, an investigational drug, for the potential treatment of lupus nephritis, focal segmental glomerulosclerosis, and dry eye syndrome. The company is headquartered in Victoria, British Columbia and focuses its development efforts globally. For further information, see our website at \url{www.auriniapharma.com}.

About Voclosporin Ophthalmic Solution (VOS)

VOS is an aqueous, preservative free nanomicellar solution containing 0.2\% voclosporin intended for use in the treatment of DES. Studies have been completed in rabbit and dog models, and a single Phase I has also been completed in healthy volunteers and patients with DES. VOS has IP protection until 2031.

About Dry Eye Syndrome (DES)

Dry eye syndrome (DES) is characterized by irritation and inflammation that occurs when the eye’s tear film is compromised by reduced tear production, imbalanced tear composition, or excessive tear evaporation. The impact of DES ranges from subtle, yet constant eye irritation to significant inflammation and scarring of the eye’s surface. Discomfort and pain resulting from DES can reduce quality of life and cause difficulty reading, driving, using computers and performing daily activities. DES is a chronic disease. There are currently two FDA approved therapies for the treatment of dry eye; however, however there remains a large opportunity to improve on efficacy and tolerability.

Forward-Looking Statements

Certain statements made in this press release may constitute forward-looking information within the meaning of applicable Canadian securities law and forward-looking statements within the meaning of applicable United States securities law. These forward-looking statements or information include, but are not limited to statements or information with respect to; the safety and tolerability of VOS; the timing for commencement of a Phase 2 tolerability study of VOS; the timing for completion of the Phase 2 tolerability study of VOS and strategic considerations for this asset. It is possible that such results or conclusions may change based on further analyses of these data Words such as “anticipate”, “will”, “believe”, “estimate”, “expect”, “intend”, “target”, “plan”, “goals”, “objectives”, “may” and other similar words and expressions, identify forward-looking statements. We have made numerous assumptions about the forward-looking statements and information contained herein, including among other things, assumptions about: the market value for the DES program; that another company will not create a substantial competitive product for Aurinia’s DES business without violating Aurinia’s intellectual property rights; Even though the management of Aurinia believes that the assumptions made, and the expectations represented by such statements or information are reasonable, there can be no assurance that the forward-looking information will prove to be accurate.

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