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NASDAQ-listed Aurinia Pharmaceuticals Inc has announced that after constructive interactions with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), the company will initiate a study of voclosporin in healthy Japanese volunteers.

Voclosporin is a calcineurin inhibitor (CNI). It is made by a modification of a single amino acid of the cyclosporine molecule (a CNI approved for use in transplant patients since 1983). This modification results in a more predictable pharmacokinetic and pharmacodynamic relationship, an increase in potency vs. cyclosporine, an altered metabolic profile, and potential for flat dosing.

With positive results from the pending phase 2b AURA-LV study in lupus nephritis (LN) and supportive safety, tolerability, pharmacokinetic and pharmacodynamic data from this clinical study, the Company hopes to be able to incorporate Japanese patients into future global voclosporin studies, eliminating the need to conduct a stand-alone Japanese trial.

"Japan represents a substantial market opportunity for the Company," said Charlie Rowland, CEO of Aurinia Pharmaceuticals Inc. "This Japanese study has the potential to reduce development timelines for voclosporin in this major market. With voclosporin's product attributes, we're confident that we may be able to offer Japanese patients suffering from LN a more suitable treatment approach compared to the current therapies."

"Our interactions with the PMDA to date have been beneficial," stated Lawrence Mandt, Vice President of Regulatory and Quality for the Company. "We're looking forward to continued productive discussions in order to bring voclosporin to Japanese LN patients as quickly as is practical."