News Release

Santen Presents Phase I/II Data on DE-122 (Carotuximab) in Patients with Refractory Wet Age-Related Macular Degeneration

Single Intravitreal Injection of DE-122 Was Well-Tolerated

Emeryville, CA, February 12, 2018 – Santen Inc. today announced that the topline results from the Phase I/II study of DE-122 (carotuximab) for refractory wet age-related macular degeneration (AMD) were presented at the 15th Annual Angiogenesis, Exudation, and Degeneration, a medical symposium presented by Bascom Palmer Eye Institute of the University of Miami Miller School of Medicine.

The open-label, dose-escalation, sequential-cohort Phase I/II study assessed the safety, tolerability, and bioactivity of a single intravitreal injection of DE-122 at four dose levels in 12 subjects (n=3 per dose) with wet AMD refractory to vascular endothelial growth factor (VEGF) inhibitors. Subjects were followed up to 90 days.

No serious adverse events were reported. The study results also suggest bioactivity of DE-122 in refractory wet AMD patients, as measured by mean change in central retinal subfield thickness (CST) based on the spectral domain optical coherence tomography (SD-OCT).

“Wet AMD continues to be a leading cause of blindness and is responsible for severe loss of vision in most patients. The opportunity remains for new therapies to address this significant unmet need,” said Victor H. Gonzalez, M.D., study investigator and founder of Valley Retina Institute in McAllen, Texas. “The study results are very encouraging and support the ongoing clinical development of DE-122 as a potential treatment for patients with wet AMD.”

About DE-122 (carotuximab)
Carotuximab is a novel antibody to endoglin, a protein overexpressed on endothelium essential for angiogenesis and upregulated by anti-VEGFs. DE-122, a novel ophthalmic formulation of carotuximab, is active in preclinical choroidal neovascularization (CNV) models and expected to enhance the effect of anti-VEGF agents used to treat wet AMD. DE-122 is being investigated in a Phase 2a randomized controlled trial (NCT03211234) assessing the efficacy and safety of intravitreal injections in combination with Lucentis® (ranibizumab) compared to Lucentis monotherapy in patients with wet AMD.

About Wet AMD
Wet AMD is the leading cause of blindness in the elderly in the world and is caused by excessive growth and leakage of blood vessels in the back of the eye that leads to a sudden, often substantial, loss of central vision. Existing therapies for the disease are limited to treatments targeting the VEGF pathway.

About Santen

As a specialty company dedicated to the ophthalmic field, Santen carries out research, development, marketing, and sales of pharmaceuticals. Santen is the market leader in Japan for prescription ophthalmic pharmaceuticals and sells products in approximately 60 countries. As a leading company in the field of ophthalmology, Santen aims to contribute to society by supplying valuable products and services to satisfy unmet medical needs. For more information, please visit Santen websites www.santen.com (Japan headquarters) and www.SantenUSA.com (United States).

Forward Looking Statements

Information provided in this press release contains so-called "Forward-looking Statements." The realizations of these forecasts are subject to risk and uncertainty from various sources. Therefore, please note that the actual results may differ significantly from the forecasts. Business performance and financial condition are subject to the effects of change in regulations made by the governments of Japan and other nations concerning medical insurance, drug pricing and other systems, and to fluctuations in market variables such as interest rates and foreign exchange rates.

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