

# **VYLUMA announces positive results from PHASE III CHAMP Study of NVK002 for treatment of myopia in children**

**October 11, 2023** – Vyluma Inc announced positive top-line results from the second stage of its Phase III CHAMP (Childhood Atropine for Myopia Progression) clinical study of its lead compound, NVK002 (low dose atropine 0.01%), a proprietary, investigational, preservative-free eye drop administered nightly and intended for patients ages 3 to 17.

NVK002 currently is under FDA review with a Prescription Drug User Fee Act (PDUFA) date of January 31, 2024 set. With the completion of the second and final phase of CHAMP, Vyluma continues its progress towards bringing NVK002 forward as an important new, first-in-class pharmaceutical treatment option for children with myopia.

**Analysis of the results of this multi-center, international study conducted after 4 years of treatment and follow up, demonstrated strong safety, the absence of rebound upon washout of the study drug, and continued efficacy for NVK002 as a potential treatment for myopia in children.**

CHAMP was a 3-arm, randomized, double-masked, placebo-controlled Phase III clinical study conducted across the US and Europe in nearly 600 children and adolescents aged 3 to 17 years at enrollment. The study consisted of 2 stages: a completed 3-year treatment period to evaluate the safety and efficacy of NVK002, after which enrolled patients were re-randomized for a masked, ongoing 1-year treatment period to characterize cessation of therapy.

The company noted in its news release that during the 4th year of the study, both doses of NVK002 -- the 0.01% and 0.02% concentrations -- continued to exhibit a strong safety profile with a low level (8% incidence) of Treatment Emergent Adverse Events (TAES) and no evidence of meaningful rebound in subjects who had discontinued active treatment and were washed out over one year.

CHAMP is the largest and longest placebo-controlled, prospective pediatric myopia study conducted to date, the top-line results represent a significant landmark in myopia management and signify a potential new and more hopeful era on the horizon.

