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Nevakar Announces First Subject Dosed in its Phase 3 Clinical Trial of NVK-002 for the Treatment of Myopia in Children

BRIDGEWATER, NJ, November 21, 2017 – Nevakar LLC, a privately-held specialty pharmaceutical company developing innovative therapies within the injectable and ophthalmic space, today announced that the first subject has been dosed in a Phase 3 clinical trial of NVK-002, the company's investigational, topical ophthalmic solution intended to slow the progression of myopia (nearsightedness) in children. If successful in Phase 3 and then in obtaining approval from the U.S. Food and Drug Administration (FDA), NVK-002 would represent the first pharmacologic eye drop for this patient population.

Navneet Puri, Ph.D., founder and chief executive officer of Nevakar, noted, "Dosing of the first Phase 3 subject with NVK-002 is a key milestone for the company and we are excited about this product's potential to improve the quality of life for millions of children."

Dr. Puri continued, "According to industry sources, the prevalence of myopia is expected to affect over 50% of the global population by the year 2050, with the number of people experiencing high myopia, the most severe form of the disease, reaching over 900 million. Given that the condition progresses the fastest during early childhood and adolescence, treatment at this stage is of critical concern. Without effective intervention, patients are at increased risk of developing vision-threatening conditions later in life including blindness related to maculopathy, and retinal detachment, among others. Unfortunately, simple corrective lenses do not halt disease progression, and there is currently no FDA-approved eye drop to treat and slow down advancement of the disease. If successful in Phase 3 and approved, NVK-002 would offer an important therapeutic option to this underserved population, improving quality of life, and alleviating the associated economic burden on society."

The Phase 3 trial will enroll approximately 500 subjects aged 3 to 17 years with myopia Spherical Equivalent Refraction (SER) of at least -0.50 D and no greater than -6.00 D in each eye. The three-arm, randomized, multicenter, double-masked, placebo-controlled trial will be conducted in two stages.

Stage one will evaluate the safety and efficacy of two concentrations (low dose and high dose) of NVK-002 as compared to placebo for slowing the progression of myopia over a three-year period. Stage two will be a randomized cross-over phase of one year in duration.

NVK-002 will be evaluated against the primary endpoint of a statistically significant overall between-group difference from baseline in the proportion of subjects who show <-0.50 D progression at the month 36 visit. As key secondary endpoints, NVK-002 will be evaluated to determine whether it meets preset criteria for: between-group difference in the mean progression rates at 12, 24 and 36 months of treatment; between-group difference in the proportion of subjects who show <-0.75 D progression at the month 36 visit; and, between-group median time to a change in myopia of <-0.75 D.

About Myopia and Children

Myopia, or nearsightedness, is a common, progressive vision disorder in which the eye grows too long from front to back. Instead of focusing images on the retina—the light-sensitive tissue in the back of the eye—the lens of the eye focuses the image in front of the retina. In some cases, myopia occurs because the cornea – the eye's outermost layer- is too curved for the length of the eyeball, or a lens that is too thick.

Myopia currently affects about 40% of the United States population and its prevalence worldwide is growing rapidly (Vitale, Sperduto et al. 2009). A 2015 joint World Health Organization-Brien Holden Vision Institute report noted that, by 2050, approximately half of the world's population (nearly five billion people) will suffer from myopia, and approximately 925 million will suffer from high myopia (<-6.0 D).

Progression can start in early childhood, advancing rapidly in some individuals until late adolescence or early adulthood. Patients with high myopia are at higher risk for serious eye disorders later in life including cataracts, glaucoma, maculopathy, retinal detachment, and blindness. Although corrective glasses and standard contact lenses can be used to improve impairments in vision caused by myopia, they do not treat the underlying cause. Refractive surgeries, such as LASIK and others, carry their own limitations and associated risks. As a result, additional treatment options are needed. According to the World Health Organization-Brien Holden Vision Institute report noted above, reducing the rate of myopia progression by 50%, could potentially lower the prevalence of high myopia by up to 90%.

About Nevakar

Nevakar is a specialty pharmaceutical company focused on therapies within the injectable and ophthalmic space. Our goal is to develop enhanced products that address unmet clinical and/or commercial needs of currently FDA-approved molecules, through intensive R&D and clinical efforts. Nevakar has a comprehensive infrastructure for product development at its New Jersey facilities. More information about Nevakar can be found at www.nevakar.com.

References

Vitale, S., R.D. Sperduto and F.L. Ferris, 3rd (2009). "Increased prevalence of myopia in the United States between 1971-1972 and 1999-2004." Arch Ophthalmology 127(12): 1632-1639.

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