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NEW STUDY SHOWS UNIQUE DIETARY SUPPLEMENT WITH OMEGA FATTY ACIDS HOLDS PROMISE FOR 30 MILLION AMERICANS WHO SUFFER FROM DRY EYE

HydroEye® Effectively Halted Progression of Inflammation and Improved Ocular Irritation Symptoms in Dry Eye Patients

HOUSTON, TX.—July 25, 2013—Study* findings published online, ahead of print, in *Cornea* show that daily dietary supplementation with a unique combination of omega fatty acids (GLA, EPA and DHA) for six months is effective in improving ocular irritation symptoms and halting the progression of inflammation that characterizes moderate to severe dry eye.

The multicenter, double-blind, randomized, placebo-controlled clinical trial conducted at Baylor College of Medicine and Virginia Eye Consultants evaluated 38 post-menopausal women with tear dysfunction in both eyes. Participants randomly received a proprietary blend of omega fatty acids, antioxidants and other nutrients (HydroEye®), or a placebo every day. Patients were assessed at baseline, four-, 12- and 24-week intervals using a variety of disease parameters including Ocular Surface Disease Index (OSDI) symptom severity questionnaire, topographical indices (SAI and SRI), inflammatory biomarkers (HLA-DR and CD11c), Schirmer tear flow measurement, tear breakup time (TBUT), and conjunctival fluorescein and lissamine green staining. HydroEye was found to improve ocular irritation symptoms, suppress ocular surface inflammation, and maintain corneal surface smoothness. An irregular corneal surface contributes to both irritation and problematic visual symptoms.

“Prior to this study, clinical evidence showing that nutritional supplements were beneficial in treating dry eye was scarce. However, within three months, the group treated with HydroEye showed statistically significant improvements in irritation symptoms of dry eye, and no progression of ocular surface inflammation or corneal irregularity. The placebo group’s dry eye symptoms actually worsened over the six-month testing period.” said Stephen C. Pflugfelder, M.D., professor of ophthalmology, James and Margaret Elkins chair, director of The Ocular Surface Center, Baylor College of Medicine-Cullen Eye Institute and co-principal investigator of the trial. “HydroEye clearly had a positive impact on these patients with moderate to severe dry eye.”

*The HydroEye clinical trial was supported through an unrestricted research grant from ScienceBased Health and the Virginia Eye Foundation.

“Achieving statistical significance in a dry eye study is a remarkable accomplishment, especially given the extreme difficulty that many highly regarded pharmaceutical companies have had in bringing a prescription dry eye product to market,” said John D. Sheppard, M.D., M.M.Sc., president, Virginia Eye Consultants, professor of ophthalmology, clinical director of the Lee Laboratory for Ocular Pharmacology at Eastern Virginia Medical School, and co-principal investigator who initiated this research project. “This was a prospective, randomized, multicenter, placebo-controlled trial as would be any U.S. Food & Drug Administration registration clinical study.”

Dry eye is estimated to affect 30 million Americans, but the actual number of dry eye sufferers is thought to be much higher because cases of dry eye tend to be dramatically underreported. In the U.S. alone, the economic burden of dry eye totals \$3.84 billion in direct annual health care costs. When including the indirect costs of lost productivity, the societal burden of dry eye rises to \$55.4 billion annually in the U.S.

Moderate to severe dry eye can significantly deteriorate the quality of life for those who suffer from the condition. In fact, prior research concluded that the impact of dry eye on quality of life was rated as the equivalent to unstable angina (chest pain related to heart disease). Dry eye is associated with a number of risk factors including age, gender, computer use, smoking, exposure to dry environments, LASIK, contact lens wear, air pollution, many common medications, and diabetes mellitus. Ocular surface inflammation also contributes to the irritation symptoms and ocular surface disease that can develop in dry eye. Post-menopausal women are considered high risk for developing dry eye due to multiple risk factors.

“While this trial studied post-menopausal women, the largest group of dry eye sufferers, we think the benefits of HydroEye should apply to other populations suffering from dry eye since inflammation is believed to be a common thread in dry eye,” said Dr. Pflugfelder.

A wide variety of dry eye treatments are available; however, many have disadvantages or side effects. Oral prescription dry eye therapies such as secretagogues have a host of systemic side effects, such as intestinal cramping. Oral antibiotics such as doxycycline can cause gastrointestinal upset, sunburn sensitivity and tooth discoloration in younger patients. Topical therapies often present compliance, toxicity and cost issues, while some eye drops may sting, burn or cause allergic reactions.

“Given these parameters, HydroEye is among the safest, best tolerated, efficacious, and most cost-effective of all dry eye therapies,” said Dr. Sheppard. “I recommend HydroEye to all of my dry eye patients.”

About HydroEye®

HydroEye is a patented nutritional formulation that works from the inside out to provide continuous dry eye relief. HydroEye delivers a proprietary blend of omega fatty acids [gamma linolenic acid (GLA), eicosapentaenoic acid (EPA), and docosahexaenoic acid (DHA)], antioxidants and other key nutrients that work together to support a healthy tear film and dampen inflammation.

Much more potent than flaxseed oil or fish oil alone, HydroEye includes omega-3 EPA and DHA from highly pure USP®-verified fish oil and also provides the unique omega fatty acid, GLA, from black currant

seed oil. GLA has been found to play a key role in dampening dry eye symptoms in six other clinical studies. GLA is not found in flaxseed or fish oil and is not present at meaningful levels in the diet.

HydroEye is recommended by thousands of ophthalmologists and optometrists nationwide, including leading eye institutions.

For more information about this clinical trial or HydroEye, contact (888) 433-4726 or visit: www.SBH.com/HydroEyeTrial.

About ScienceBased Health®

ScienceBased Health®, a privately held company founded in 1997, develops and markets evidence-based nutraceuticals for eye health. The Company's featured formulations include: HydroEye®, a patented oral formulation for dry eyes; OcularProtect®, a comprehensive multivitamin for eyes and overall body health; MacularProtect Complete®-S, a powerful formulation to preserve macular and whole body health, based on AREDS, AREDS 2 and other advanced research; Optic Nerve Formula®, a powerful formulation to protect optic nerve health; and other high quality products.

The formulations are based on the latest science, made from premium ingredients and manufactured according to highest quality standards in NSF®-certified facilities. For more information, contact ScienceBased Health at: (888) 433-4726 or visit: www.SBH.com.

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