DIAGNOSTEAR ANNOUNCED POSITIVE RESULTS IN A LARGE CLINICAL STUDY EVALUATING ITS TEARX™ DRY EYE TEST

Results indicate robust detection of Dry Eye Syndrome, detection of severe MGD, and prediction of response to Cyclosporin, suggesting new potential uses

REHOVOT, ISRAEL. April 21st, 2024 (EIN NEWSWIRE) – DiagnosTear Ltd. today announced it has received results of a large clinical trial to test its TeaRx™ product that was conducted in LV Prasad Eye Institute (LVPEI) in Hyderabad, India. The TeaRx™ product is planned to become a tool for Point-of-Care diagnosis and analysis of Dry Eye Syndrome (DES), by quantifying 5 protein biomarkers in the tear fluid. As reported by DiagnosTear, analysis of the raw data collected from ~500 subjects defined as eligible DES patients and ~100 subjects that were defined as eligible healthy controls, indicated the following outcomes:

(1) TeaRx™ differentiated between severe DES subjects (Grades 3-4) vs. non-severe patients and healthy controls (Grades 0-2) at sensitivity, specificity, and accuracy levels of 80.6%, 66.7% and 68%, respectively.

(2) TeaRx™ differentiated between DES subjects at all severity levels (Grades 1-4) vs. healthy controls at sensitivity, specificity, and accuracy levels of 72%, 63% and 70.1%, respectively.

(3) TeaRx™ identified the presence of severe Meibomian Gland Disfunction (MGD, the most common underlying cause of evaporative DES, as classified by meibography grades 3-4) vs. Non-MGD (meibography grade 0), within the group of eligible DES patients, at sensitivity, specificity, and accuracy levels of 80.6%, 61.3% and 76%, respectively.

(4) Analysis of the data from 35 eligible DES patients which were prescribed with topical Cyclosporin A (CysA) therapy at baseline, and for whom independent, objective data was gathered 3 and/or 6 months after initiation of therapy, revealed that the product is capable to predict at baseline responders vs. non-responders at sensitivity, specificity, and accuracy levels of 94%, 63% and 77%, respectively. Notably, the negative predictive value (NPV) achieved was 92.3%, indicating the potential of the product to identify non-responders and further increase the ability to select patients with the best chance to respond for therapy.

To the best knowledge of DiagnosTear, these results are based on the widest and most diverse cohort of subjects ever studied for diagnostics of DES.

Dr. Shimon Gross, DiagnosTear's CEO, stated: "We are very pleased with the results of the study. The TeaRx™ non-invasive, multi-parametric test exhibited good diagnostic performance in the diagnosis of DES, assessment of its severity, prediction of the presence of severe MGD, and prediction of the therapeutic outcome of topical CysA therapy. We believe these results pave the way for additional studies aimed at prediction of outcome of DES therapies with different mechanisms of action, and also linking such outcomes with the different clinical subtypes of the disease."

"Biolight Life Sciences Ltd. Created and Invested lots in DiagnosTear – one of its major subsidiaries. We are excited to see that our hope for rapid, multi-parameter Point-of-Care test provided results that are very promising and will hopefully provide tools to better diagnose and treat the huge number of DES patients across the world" said Yaacov Michlin, CEO of BioLight, and Chairman of the Board of DiagnosTear.

About DIAGNOSTEAR

DiagnosTear is a leading ophthalmic company developing and commercializing disruptive diagnostic solutions for better management of eye diseases. DiagnosTear's TeaRx™ technology is a diagnostic platform intended for rapid, Point-of-Care Testing (POCT) of ophthalmic pathologies through multi-parameter analysis of non-invasively collected tear fluid. The first CE-IVD, and Israeli MoH-approved test based on the TeaRx™ platform is intended for diagnosis of DES (TeaRx™ Dry Eye). This product is not FDA-cleared yet. Beyond DES, DiagnosTear is developing innovative tests based on the TeaRx™ platform for additional ophthalmic indications. Among others, DiagnosTear's pipeline includes TeaRx™ Red Eye; The first test of its kind test for differential assessment of adenoviral conjunctivitis, Herpetic Keratitis and Allergic conjunctivitis. For additional information about DiagnosTear, please visit https://diagnostear.com

About BIOLIGHT

BioLight Life Sciences Ltd. is a leading company investing in companies and managing projects in the field of eye diseases and ocular treatments. BioLight's portfolio companies engage in advanced medical devices, medications, diagnostics, and digital medicine and all exemplify the enormous

potential of Israeli innovation in these fields. For additional information about BioLight, please visit https://bio-light.co.il.

About DRY EYE SYNDROME

Dry Eye Syndrome (DES) is a common disorder in which there is a decline in tear production or tear quality is impaired. Moderate and severe DES may cause pain and discomfort, and impair vision quality. In extreme cases, DES may even cause permanent blindness. Some 340 million people worldwide have DES, including some 40 million in the US. Symptoms associated with DES account for about one third of patients' complaints to ophthalmologists in the US. Despite its widespread prevalence, DES is complex and difficult to diagnose and treat since it may be caused by many underlying factors, resulting in diverse and distributed sub-populations suffering from the syndrome. Multi-parameter analysis of the tear film proteins may provide insights as per the underlying pathophysiology (e.g., evaporative, aqueous deficient, inflammatory DES) and may assist the ophthalmologist in prescribing the optimal treatment matched to the underlying cause of the disease.