Press Release

June 7, 2021
QD Laser, Inc.

Completion of the clinical trial in Europe of RETISSA Medical

QD Laser, Inc. announced today the completion of the clinical trial in Europe to assess the safety and performance of the Retinal Imaging Laser Eyewear, named "RETISSA_Medical."

The Clinical trial has been performed under the principal investigator, Prof. Dr. med. Anja Eckstein in University Eye Clinic Essen, sponsored by QD Laser Deutschland GmbH for three years since August 2018. Twenty-one patients over 18 to 85 years old with visual impairment caused by corneal diseases participated in the trial.

The main objective was to improve visual acuity by RETISSA in patients with visual impairment caused by corneal diseases, including Keratitis, corneal scars and opacities. The secondary objectives consisted of assessing safety after continuous usage, reading ability, and vision-related quality of life. The study was divided into Phase I (core study for performance evaluation) and Phase II (extended follow-up phase, where four patients completed continuous use of RETISSA for one year in their daily life.).

The Clinical Study Report (CSR) concluded that RETISSA improved the patients' near and distant visual acuity compared to best-corrected visual acuity and the patients' reading ability, while showing no side effects. Remarkable was that only 19% of patients could read with the best correction, while more than 80% could read with RETISSA.

The follow-up phase showed that, besides improving the ability to read, the device enabled doing fine two-handed work such as needlework, talking with others while recognizing their face, using computer, and watching TV, etc. These advantages are expected to considerably improve the quality of life (QOL) of visually impaired patients.

The End of Study was notified from CRO to the German Federal Institute for Drugs and Medical Devices (BfArM) on June 4th with the final Clinical Study Report (CSR).