

Press release

Diagnoptics receives Japanese market approval for AGE Reader mu.

Groningen, the Netherlands – September 11, 2015

Diagnoptics has received a Todokede registration from the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) for the AGE Reader mu in Japan. This allows Diagnoptics to market the AGE Reader mu in Japan as a General Medical Device (class I).

This approval means entry to another important market for the AGE Reader mu. Japanese healthcare professionals are now allowed to use the AGE Reader mu in general clinical practice. The AGE Reader SU was already available in Japan for clinical research since 2009 and will continue to be available for this purpose.

The AGE Reader provides an immediate cardiovascular risk prediction for major chronic diseases, such as diabetes, cardiovascular disease and renal failure. The AGE Reader yields a real time and non-invasive assessment of cardiovascular risk in 12 seconds. The method is convenient, easy to use and validated. The AGE Reader measures tissue accumulation of Advanced Glycation Endproducts (AGEs) by means of fluorescence techniques (skin autofluorescence). AGEs play a key role in the pathogenesis of many age-related diseases, such as diabetes, cardiovascular disease and renal failure.

Bart van den Berg, CEO of Diagnoptics, said, “This Todokede registration is another milestone in the history of Diagnoptics and fits in our strategy to increase the daily clinical use of the AGE Reader. It allows Diagnoptics and its partners to start selling the AGE Reader mu in the Japanese healthcare sector.”

Diagnoptics was the first company worldwide to introduce a technology to non-invasively measure the tissue accumulation of AGEs by means of fluorescence techniques (AGE Reader). The AGE Reader has been used in clinical practice and research since 2006. Since the introduction of the AGE Reader over 140 peer reviewed scientific papers have been published.

About Diagnoptics

Established in 2003, Diagnoptics is the pioneer and inventor of cutting edge diagnostic devices that can non-invasively diagnose and assess the risk of diabetes and its complications. Its technological advance in detecting fluorescence of Advanced Glycation Endproducts (AGEs) has led to the invention of the AGE Reader - a state of art diagnostic device that can determine the tissue accumulation of AGEs in 12 seconds. Since the CE certification on the first AGE Reader in 2006, Diagnoptics has been marketing this medical device to thousands of clinics around the world. Currently the company is working on obtaining additional regulatory approvals in other regions and is engaged in new product development activities. The head office of Diagnoptics Technologies BV is in Groningen, the Netherlands.

About AGE Reader

The AGE Reader provides an immediate cardiovascular risk prediction for major chronic diseases, such as diabetes, cardiovascular disease and renal failure. The AGE Reader yields a real time and non-invasive assessment of cardiovascular risk in 12 seconds. The method is convenient, easy to use and validated. The AGE Reader measures tissue accumulation of Advanced Glycation Endproducts (AGEs) by means of fluorescence techniques (skin autofluorescence). AGEs play a key role in the pathogenesis of many age-related diseases, such as diabetes, cardiovascular disease and renal failure. Since the market introduction in 2006, the AGE Reader has been clinical validated extensively in over 140 peer reviewed scientific publications.

AGEs are essential biomarkers of metabolic and glycemc stress and have been implicated as causative factors in the progression of a host of age-related diseases, such as atherosclerosis, diabetes, renal failure and Alzheimer. The level of AGEs in tissue reflects the glycometabolic memory and is a valuable predictor of (pre)diabetes and cardiovascular complications.

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