PRESS RELEASE

New evidence of efficacy: Transcorneal electrical stimulation (TES) can slow progression in retinitis pigmentosa

- **New data show reduction of visual field progression/worsening in retinitis pigmentosa (RP)**
- **Early start of TES treatment can postpone onset of severe visual field loss**
- **Patients can apply stimulation therapy with OkuStim® at home: once a week for 30 minutes**

Reutlingen (April 25, 2023) Retinitis pigmentosa (RP) is a hereditary dystrophy of the retina and the choroid which manifests as a progressive visual field loss, in many cases leading to blindness. The recent explorative analysis (1) of an earlier clinical study (2) conducted by ophthalmologists from the University Eye Clinic Tübingen and the Eye Clinic of Stuttgart Medical Center has delivered further proof for the efficiency of this therapy. Those data show that this therapeutic approach – developed in Germany – slows down visual field progression in RP: retinal cells are stimulated via the surface of the eye by externally applied electrical impulses. The effects of the therapy, known as transcorneal electrical stimulation (TES), demonstrated in the study were irrespective of the degree to which the patient's visual field was already compromised at the initiation of the therapy.

A number of therapies have been tried in retinitis pigmentosa in the past. Currently, the focus of research is on gene therapy and stem cell therapy, although these options are not yet ripe for clinical routine management.

The non-invasive electrical stimulation therapy (OkuStim®), developed by Okuvision, a medical device company based in Reutlingen, Germany, has been used in 52 patients vs. placebo in the study. During TES, an electrode is placed on the lower lid and has contact with the eyeball at the inferior corneal limbus. Treatment with electrical impulses of max. 1 mA and 20 Hz takes 30 minutes, is performed once a week and can be applied by the patients at home after a short instruction and training by their physician.

Of the patients (average age: 46 years) enrolled in the study, 32 individuals received weekly electrical stimulation between 0.1 and 1.0 mA on one eye; 20 patients received sham treatment (placebo group). Following a year of treatment, the eyes that had undergone TES displayed a visual field loss of 2.1% while their untreated contralateral eyes had an average visual field progression of 5.8%. In the placebo group, however, the annual decline was 7.5%. Thus, the decrease in visual field area measured by kinetic perimetry was 64% less in the eyes treated with TES than in the untreated eyes (p=0.013) and 72% less than in the placebo group (p=0.103). Slowing of the progression was shown to be dose-dependent (p=0,047). In 23 of the treated eyes, dry eye symptoms were noticed as the most frequent ocular adverse event.

The prevalence of retinitis pigmentosa in Germany is about 1 person afflicted with the disease per 4,000 people. Nyctalopia (night blindness) is an early symptom of RP which in many cases occurs during childhood (with congenital blindness as an extreme form); milder versions can manifest at older age. Visual field loss usually starts in the periphery and progresses slowly but – until now – inexorably towards the center. Finally, there is then only a narrow remain of some central vision left, also referred to as tunnel vision, which renders the patient functionally blind – a fate that will happen to about half of RP patients by the age of 55 years. Decelerating this progression with a neuroprotective treatment, such as the TES, this is the study authors' conclusion, offers the chance to significantly delay severe visual loss and disability. The efficacy of TES in long-term use is being investigated in a testing-study (‘Erprobungsstudie') underway in Germany (3).

The exact mechanism of action of TES has not yet been fully understood. Experts suggest a neuroprotective effect that should be put to use in patients as early as possible and at a disease stage before visual function is compromised.

***Sources*:**

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2. Schatz A, Pach J, Gosheva M, Naycheva L, Willmann G, Wilhelm B, Peters T, Bartz-Schmidt KU, Zrenner E, Messias A, Gekeler F. Transcorneal Electrical Stimulation for Patients With Retinitis Pigmentosa: A Prospective, Randomized, Sham-Controlled Follow-up Study Over 1 Year. Invest Ophthalmol Vis Sci. 2017 Jan 1;58(1):257-269. doi: 10.1167/iovs.16-19906. PMID: 28114587.
3. Kahle N, Peters T, Braun A, Franklin J, Michalik C, Gekeler F, Wilhelm B; retina.net e. V.; TES-RP-Studiengruppe. Transkorneale Elektrostimulation bei Retinitis pigmentosa : Prüfplan einer multizentrischen, prospektiven, randomisierten, kontrollierten und doppelblinden Studie im Auftrag des Gemeinsamen Bundesausschusses (G-BA-Erprobungsrichtlinie) [Transcorneal electrostimulation in retinitis pigmentosa : Protocol of a multicentric prospective, randomized, controlled and double-masked trial on behalf of the Joint Federal Committee (G-BA pilot regulation)]. Ophthalmologe. 2021 May;118(5):512-516. German. doi: 10

About Okuvision

Okuvision is a medical device company based in Reutlingen, Germany. Okuvision manufactures and distributes the OkuStim® therapy system for electrical stimulation therapy in ophthalmology. OkuStim® – which is CE-marked – offers patients with retinitis pigmentosa and similar hereditary retinal dystrophies a non-invasive treatment that delays disease progression. OkuStim® is available from an increasing

distribution network, currently in nine European countries. Okuvision is in constant scientific and collaborative contact with leading eye hospitals.

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