

Press Release

14 October 2020



Katairo Announces “Enrolment Completion” in STARTT Study of Remofuscin®.

STARTT: Stargardt Remofuscin® Treatment Trial: A multi-national, multi-center, double-masked, placebo-controlled, proof of concept trial to evaluate the safety and efficacy of oral soraprazan in adults with Stargardt disease.

Tübingen, October 14, 2020

Katairo GmbH, a biopharmaceutical company focused on discovering, developing and commercializing novel treatments for back of the eye diseases, today announced enrolment into this study has now been completed.

Dr Wolfgang Klein, Chief Executive Officer of Katairo GmbH said, “We are very happy to announce that, despite the challenges caused by the pandemic, we have now completed our enrolment in the STARTT study with 87 subjects randomized to receive either Remofuscin or its placebo. This is testament to the dedication and commitment of all the team involved most importantly the investigators and their staff. Treatment is scheduled to continue for a minimum of 12 months.”

“This is an important milestone for the STARTT study and a remarkable achievement” says Prof Carel Hoyng, from the Radboud University Medical Center and lead principal investigator. “Within this placebo-controlled study we will evaluate Remofuscin® in adults with Stargardt disease. The benefits will be explored by quantifying autofluorescence of lipofuscin in the retina, complemented by other more functional endpoints.”

The trial screened more than 110 Stargardt patients and of these 87 were randomized after meeting all the inclusion/exclusion criteria. Katairo is grateful to all those patients who have consented to participate in the trial, some of whom have to travel long distances to attend our investigative sites in the Netherlands, Germany, Italy and the UK. More information about the trial is available in the clinical trials register at www.clinicaltrialsregister.eu/ctr-search/trial/2018-001496-20/NL (EudraCT Number 2018-001496-20). The study is scheduled to end in 2021.

The multinational study received funding from the European Union’s Horizon 2020 programme and is coordinated by Dr. Thomas Wheeler-Schilling from the Institute for Ophthalmic Research in Tuebingen.

About Stargardt disease

Stargardt disease (STGD) is an orphan indication and genetic eye disorder that causes progressive vision loss leading to blindness by legal definition. The disorder affects the macula, an area of the retina responsible for color and sharp central vision. Individuals with the condition have abnormal accumulation of lipofuscin in the cells of the retinal pigment epithelium (RPE). Lipofuscin is auto-fluorescent and readily discernible with non-destructive/non-invasive, ophthalmic imaging methods. In advanced stages of STGD, the build-up of lipofuscin in the RPE results in the loss of the RPE. As the RPE provides support to photoreceptors, the overlying photoreceptors are lost too. People with STGD can also have problems with night

vision and color vision. The current treatment options are very limited and focus on preventive measures to avoid excessive light exposure.

About Remofuscin

Soraprazan, the active ingredient of Remofuscin®, was initially in development as an acid pump antagonist (APA) to treat gastro-esophageal reflux disease (GERD). The small molecule completed Phase I and Phase II clinical trials. Interestingly, soraprazan was also observed to result in removal lipofuscin of the RPE in non-human primates treated with Soraprazan.

The evidence in support of Remofuscin® as a potential medicinal product candidate for the treatment of STGD is compelling. Katairo GmbH has licensed data and related IP from the earlier developer. Remofuscin is protected by patents and orphan designation for use of soraprazan for the treatment of STGD.

About funding and collaborators

This project has received funding from the European Union's Horizon 2020 Research and Innovation program under Grant Agreement No 779317 "Soraprazan - a new regenerative therapy for Stargardt's disease".

The recipient of this grant is a consortium formed by the following institutions and principle investigators:

- Eberhard-Karls-Universität Tübingen, (Coordinator and trial site), Dr. Katarina Stingl
- Radboud University Medical Center, Nijmegen (trial site), Prof. Dr. Carel Hoyng
- Ospedale San Raffaele, Milano (trial site), Dr. Maurizio Battaglia Parodi
- Leiden University Medical Center (trial site), Prof. Dr. Camiel Boon
- Southampton University Hospital (trial site), Prof. Dr. Andrew Lotery
- Bonn University Eye Hospital (trial site), Dr. Philipp Herrmann
- Smerud Medical Research, Oslo (clinical research organization)
- Katairo (sponsor)

About Katairo

Katairo is a biopharmaceutical company focused on the development treatments for back of the eye indications. Katairo's lead development is Remofuscin® for the treatment of Stargardt Disease (phase 2). Katairo will also develop Remofuscin for the treatment of dry age-related macular degeneration (phase 2). For more information, visit www.katairo.com.

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