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PHASE 3 TRIAL OF SHR8058 EYE DROPS (PERFLUOROHEXYLOCTANE) CONDUCTED BY JIANGSU HENGRUI PHARMACEUTICALS IN THE PEOPLE'S REPUBLIC OF CHINA SHOWS STATISTICALLY SIGNIFICANT TOPLINE RESULTS

HEIDELBERG, Germany, and CAMBRIDGE, MA, USA, December 16, 2021 – Novaliq, a biopharmaceutical company focusing on first- and best-in-class ocular therapeutics based on the unique EyeSol® water-free technology, today provided a development update on the phase 3 trial of SHR8058 eye drops (perfluorohexyloctane) for the treatment of dry eye disease (DED) associated with Meibomian gland dysfunction (MGD) conducted by Jiangsu Hengrui Pharmaceuticals Co., Ltd. ("Hengrui Pharma") (SSE: 600276) in the People's Republic of China showing statistically significant topline results compared to 0.6% sodium chloride solution.[1]

Hengrui Pharma has completed the Phase 3 clinical trial (SHR8058-301) which enrolled 312 patients at 17 clinical sites in the People's Republic of China. SHR8058-301 was a multi-center, randomized, double-masked, saline-controlled clinical trial and was designed to evaluate the efficacy and safety of SHR8058 eye drops (100% perfluorohexyloctane) for the treatment of signs and symptoms of DED associated with Meibomian gland dysfunction. SHR8058-301 evaluated its primary efficacy at eight weeks.[2]

The trial met its prespecified primary sign endpoint improvement of total corneal fluorescein staining (tCFS) and its prespecified primary symptom endpoint improvement of eye dryness score of the Visual Analogue Scale (VAS) at eight weeks with high statistical significance. The trial showed an excellent safety and tolerability profile for SHR8058 eye drops (perfluorohexyloctane) comparable to placebo.

Hengrui Pharma expects to submit a pre-NDA communication application to the National Medical Products Administration (NMPA)'s Center for Drug Evaluation (CDE) in the People's Republic of China in the near term future.

About SHR8058 eye drops (perfluorohexyloctane)

SHR8058 eye drops is an investigational, proprietary, water-free and preservative-free solution, based on Novaliq's EyeSol® technology. In 2019, Hengrui Pharma and Novaliq announced a strategic collaboration under which Hengrui Pharma secured exclusive rights to develop, manufacture, and commercialize NOV03 (local drug name SHR8058 eye drops) and CyclASol® (local drug name SHR8028 Eye Drops) in China.

About Novaliq

Novaliq is a biopharmaceutical company focusing on the development and commercialization of firstand best-in-class ocular therapeutics based on EyeSol®, the worldwide first water-free technology. Novaliq offers an industry-leading portfolio addressing today's unmet medical needs of millions of patients with eye diseases. Novaliq GmbH is headquartered in Heidelberg, Germany and Novaliq Inc. has an office in Cambridge, MA, USA. The long-term shareholder is dievini Hopp BioTech holding GmbH & Co. KG, an active investor in Life and Health Sciences companies. More on www.novaliq.com.

References

- 1. Jiangsu Hengrui Pharmaceuticals Co., Ltd. reported the progress of the drug clinical trial through the Shanghai Stock Exchange with announcement no. Lin 2021-175 on November 30th, 2021.
- 2. Clinical trial information available at <u>www.chinadrugtrials.org.cn</u> with identifier CTR20210154.

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