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Novaliq, Jiangsu Hengrui focus on treatment of dry eye disease

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To develop, manufacture and commercialize the innovative, water-free drugs NOV03 and CyclASol(R)

Novaliq GmbH, a Germany based pharmaceutical company focusing on first- and best-in-class ocular therapeutics, and Jiangsu Hengrui Medicine Co, Ltd., a fully integrated biopharmaceutical company based in China, have announced the closing of an exclusive license agreement to develop, manufacture and commercialize the innovative, water-free drugs NOV03 and CyclASol(R) for the treatment of dry eye disease in the People's Republic of China (mainland China, Hong Kong, Macau and Taiwan).

Eighty-six percent of patients with dry eye show signs of Meibomian gland dysfunction (MGD). NOV03 (perfluorohexyloctane) is being developed as a treatment for patients with dry eye disease associated with Meibomian gland dysfunction and has a novel mode of action that has been confirmed in various studies. Several clinical trials have demonstrated that NOV03 stabilizes the tear film lipid layer and protects from excessive evaporation. In addition, it has been shown to penetrate into the meibomian glands and liquefy secretions there, improving the quality of the meibum and the tear film lipid layer. NOV03 is being developed in phase three for the treatment of dry eye disease associated with Meibomian gland dysfunction (MGD) in the USA.

CyclASol is an anti-inflammatory investigational drug for patients with moderate to severe DED with an inflammatory disease component. CyclASol contains cyclosporine A 0.1% in EyeSol(R) and holds the promise of unfolding cyclosporine A's full potential on the ocular surface, enabling clinicians to treat more patients successfully. CyclASol is in phase three development for the treatment of dry eye disease in the USA. Both investigational drugs have shown in recent late-stage clinical trials superior efficacy results, with early onset of action and excellent tolerability profile. They are perceived as breakthrough medicines for dry eye patients worldwide with an unprecedented benefit-risk profile.

"Dry eye disease is common in China, but treatment options are very limited in China. We are committed to serving this unmet need and feel excited about the partnership with Novaliq, a leading company in ophthalmology with the world's first water-free eye drop platform. We shall work closely together with Novaliq to allow patients in China to benefit from this platform," said Piaoyang Sun, Chairman of the Board of Hengrui Medicine.

"We are excited about this strategic collaboration with Jiangsu Hengrui Medicine. We believe that Jiangsu Hengrui Medicine, as a leading biopharmaceutical company in China, is the ideal partner for us to maximize the commercial potential of our innovative products NOV03 and CyclASol in the Chinese market," said Christian Roesky, PhD, CEO of Novaliq. "With great

benefits in terms of efficacy and tolerability, NOV03 and CyclASol can make a huge difference to the life of dry eye patients. We look forward to working with the team of Jiangsu Hengrui Medicine to bring these breakthrough medicines, if approved, to physicians and patients in the second biggest healthcare market in the most timely, efficient and effective way possible."

Under the terms of the agreement, Novaliq is eligible to receive an upfront payment of up to $9 million and up to $156 million in milestone payments linked to pre-defined development, regulatory and commercialization objectives. In addition, Jiangsu Hengrui Medicine will be obligated to pay Novaliq tiered percentage royalties on net sales of NOV03 and CyclASol in China. Thus, Jiangsu Hengrui Medicine secures exclusive rights to develop, manufacture and commercialize both drugs in China. Jiangsu Hengrui Medicine will be responsible for all development, regulatory and commercialization activities and related expenses in the territory.