



April 17, 2025

Company Name: Rohto Pharmaceutical Co., Ltd.  
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### Announcement of Initiation of Phase II Clinical Trial in Japan for Ophthalmic Agent "ROH-001"

Rohto Pharmaceutical Co., Ltd. (Headquarters: Osaka; President and COO: Masashi Sugimoto) hereby announces the initiation of a Phase II clinical trial (hereinafter referred to as "the Trial") in Japan for the ophthalmic drug product-code, "ROH-001". The Trial is being conducted in collaboration with Tsubota Laboratory, Inc. (Headquarters: Shinjuku-ku, Tokyo; President and CEO: Kazuo Tsubota; hereinafter "Tsubota Laboratory") to evaluate a potential eye drop formulation intended to suppress the progression of myopia.

#### Details

In recent years, the widespread use of smartphones and increased exposure to digital devices have led to significant lifestyle changes, contributing to a growing prevalence of myopia among young people, and now recognized as a serious social issue. In response, Tsubota Laboratory and Rohto entered into a joint research agreement on October 1, 2020, to develop a drug intended to suppress the progression of myopia. Since then, we have been engaged in basic research. Following the confirmation of both efficacy and safety in the preclinical phase, as well as safety in a Phase I trial, the upcoming Phase II trial will evaluate efficacy and safety in patients with myopia, based on the findings of these earlier studies. We are actively advancing various research initiatives in the field of ophthalmology, with the aim of entering the prescription drug business. We will continue to deliver products and services that contribute to the advancement of ophthalmic medicine and people's eye health.

#### <About Tsubota Laboratory, Inc.>

Representative: Kazuo Tsubota, President and CEO

Location: Shinjuku-ku, Tokyo

Business Description: Research and development related to the prevention and treatment of myopia, dry eye, presbyopia, and other ocular and systemic diseases

URL: <https://tsubota-lab.com/>