



イノベーションで、世界をごきげんに、健康にする

Through innovation in health and medical fields,
we will make the world happier and healthier.

December 23, 2020

Tsubota Laboratory, Inc.

Phone: +81-3-6384-2866

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

Contact: inquiry@tsubota-lab.com

**A major step in the development of a medical device
for the suppression of myopia progression
Safety was confirmed in the exploratory clinical trial**

Tsubota Laboratory, Inc. is engaged in research and development to decrease the global myopia population by innovative and revolutionary technology development and application to medical devices.

Tsubota Laboratory is pleased to announce the achievement of primary outcome measures (*1) for safety assessment in the first exploratory clinical trial of a medical device for the suppression of myopia progression. This development utilizes violet-light technology and corresponding patents, and is based on the collaborative research with the Department of Ophthalmology, Keio University School of Medicine.

This exploratory clinical trial began in April 2019, titled “A Pseudo Placebo-controlled Parallel Group Comparative Exploratory Clinical Trial to Evaluate the Safety and Efficacy of TLG-001 (*2) on Schoolchildren with Myopia in a Randomized Double-Blind Study.”

After 6-month usage of this device by 41 subjects, no adverse events or defects occurred as a result of violet light use. The safety was accordingly confirmed.

Following this result, we are now proceeding to the next-phase confirmatory trial with efficacy as the primary outcome, aiming for marketing approval of the medical device.

Our CEO Kazuo Tsubota said, “We designed the TLG-001 with violet-light power based on the strength of sunlight in Tokyo, paying particular attention to its safety. I believe that the confirmation of its safety through this exploratory clinical trial is a major step toward the possible prevention of myopia. Myopia has been recently increasing among schoolchildren.



イノベーションで、世界をごきげんに、健康にする

Through innovation in health and medical fields,
we will make the world happier and healthier.

Most cases of myopia that develop during childhood are progressive, and the risk of visual impairment increases in middle-aged and elderly periods if it progresses to high myopia. Prevention of myopia progression is very important for those parents who are concerned about their children's myopia. Therefore, we will continue to strive to deliver it to society with clear evidence.”

*1 Primary outcome measures (safety assessment measures):

1. Visual acuity (corrected)
2. Intraocular pressure, assessed by a contactless measuring device
3. Ocular alignment
4. Use of corneal fluorescein staining to assess tear breakup time; subjective symptoms
5. Corneal endothelial cell density
6. Slit-lamp microscopy findings; funduscopy findings
7. Retinal morpho-structural evaluation using retinal optical coherence tomography (OCT)
8. Dermopathy (periocular skin)
9. Adverse events/defects

*2 TLG-001: The product code of the device that Tsubota Laboratory has been developing as a medical device for the suppression of myopia progression.



Company profile:

Company name:	Tsubota Laboratory, Inc.
Founded on:	February 19, 2015
Paid-in capital:	201,553,000 yen
Founding scientist and CEO:	Kazuo Tsubota, Professor, Department of Ophthalmology, Keio University School of Medicine
Address:	304 Toshin Shinanomachi-ekimae Bldg., 34 Shinanomachi Shinjuku-ku, Tokyo 160-0016 JAPAN
Phone:	+81-3-6384-2866



イノベーションで、世界をごきげんに、健康にする

Through innovation in health and medical fields,
we will make the world happier and healthier.

Inquiries to:

Tsubota Laboratory, Inc.

Address: 304 Toshin Shinanomachi-ekimae Bldg., 34 Shinanomachi
Shinjuku-ku, Tokyo 160-0016 JAPAN

Phone: +81-3-6384-2866

Contact: inquiry@tsubota-lab.com

Inquiry contacts: Shinichiro Kondo and Wakana Katabami