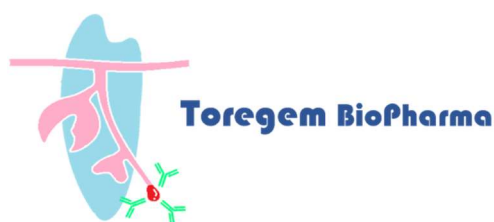


September 29th,2025



Toregem BioPharma Co., Ltd.
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**Toregem's Anti-USAG-1 Antibody “TRG035” for severe congenital partial anodontia
designated as an Orphan Medicinal Product
by Japan's Ministry of Health, Labour and Welfare**

Toregem BioPharma Co., Ltd. (Head Office: Kyoto City; CEO: Honoka Kiso; hereinafter referred to as Toregem)’s investigational anti-USAG-1 antibody 'TRG035’ has been designated by the Ministry of Health, Labour and Welfare as an orphan drug for the target disease “severe congenital hypodontia”.

【Background of the Designation】

Severe congenital partial anodontia is a rare congenital disorder characterised by the absence of six or more permanent teeth from birth. It significantly impacts patients' quality of life (QOL), affecting chewing function, speech, and causing aesthetic and psychological burdens. Currently, only prosthetic solutions such as dentures or implant treatments are available; no fundamental cure exists.

【Features of TRG035】

TRG035 is the world's first antibody drug that neutralises the protein “USAG-1”, which inhibits tooth development. This antibody is expected to activate dormant tooth buds and promote the eruption of new teeth. Its efficacy has been confirmed in animal models, and a Phase I clinical trial is currently underway in Japan. In June 2024, the development program of TRG035 for the treatment of congenital hypodontia was selected by the Japan Agency for Medical Research and Development (AMED) under its FY 2024 Venture Ecosystem Enhancement Project for Drug Discovery Project*.

【Significance of Orphan Drug Designation】

This designation enables access to support measures such as tax incentives, grant funding, and prioritised review, which is expected to accelerate development. Furthermore, it broadens the potential to offer patients suffering from severe congenital partial edentulism the world's first fundamental treatment option: the regeneration of teeth.

【Future Prospects】

Toregem aims to accelerate the clinical development of TRG035 while collaborating with research and medical institutions both domestically and internationally to deliver dental regenerative medicine to patients. Furthermore, development will proceed with a view to expanding indications not only for congenital conditions but also for acquired tooth loss.

※ This project is supported by AMED (Project ID: 25qfb127013j0002), under the sub-project titled “Development of a novel antibody drug to regenerate missing teeth in patients with congenital anodontia.”

【About Toregem BioPharma Co., Ltd】

Founded in 2020 based on groundbreaking research at Kyoto University, Toregem is a biotechnology startup dedicated to pioneering regenerative therapies for tooth loss. With a mission to “For the realization of a society where people are not afraid of losing their teeth,” Toregem is developing innovative antibody drugs centered on anti-USAG-1 technology.

Company: Toregem BioPharma Co., Ltd.

Headquarters: Kyoto, Japan

CEO: Honoka Kiso

Founded: May 2020

Business: Development of tooth regenerative medicine

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