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Announcement for Completion of the PMDA Investigation of CTN (Clinical Trial Notification) for TRG035 Phase IIa Trial

Toregem BioPharma Co., Ltd. (Headquarters: Kyoto City, President and CEO: Honoka Kiso) has submitted CTN to PMDA (Pharmaceuticals and Medical Devices Agency) regarding an exploratory trial (clinical trial protocol number: TR-002, hereinafter referred to as "this clinical trial") of an antibody drug (development code: TRG035) for congenital tooth agenesis, and we are pleased to announce that the PMDA has completed the required investigation today.
Going forward, after review by IRB (Institutional Review Board) of the clinical trial site, we plan to enroll subjects and begin administering the investigational drug.
The outline of this clinical trial is as follows:

【Overview of this clinical trial】

Clinical trial title	TRG035 Phase IIa trial in pediatric patients with severe congenital partial anodontia –Open label dose finding trial–
Phase of clinical trials	Phase IIa
Target diseases	Children with severe congenital partial anodontia
Clinical trial design	Non-comparative, open-label, multi-center study
Target number of subject	24

As announced on September 29, 2025, in the document TRG035 for sever congenital partial anodontia designated as an Orphan Medicinal product by MHLW (the Ministry of Health, Labor and Welfare).

This rare disease significantly impacts patients' quality of life (QOL) through effects on chewing function and speech, as well as aesthetic and psychological burdens. If administration of TRG035 enables tooth formation, patients will be able to eat using their own teeth throughout their lives, thereby providing a curative treatment for patients with congenital anodontia.

【About TRG035】
TRG035 is the world's first antibody drug that neutralizes the protein "USAG-1," which suppresses tooth development. This antibody is expected to activate dormant tooth buds and promote the eruption of new teeth.
The drug's effectiveness has been confirmed in animal models, and Phase I clinical trials have been completed in Japan. The TRG035 development project for congenital anodontia was selected in June 2024 for the Japan Agency for Medical Research and Development (AMED*)'s "Drug Discovery Venture Ecosystem Strengthening Program (Drug Discovery Venture Call for Proposals)."

*This project is supported by AMED (“Drug Discovery Venture Ecosystem Enhancement Project” :Subsidy Project Name: "Development of Novel Antibody Drugs to Regenerate Missing Teeth in Patients with Congenital Anodontia").

【About congenital anodontia】
Congenital anodontia is a condition in which even one tooth is missing from birth, regardless of the type of tooth. Patients with congenital anodontia are dentition from a young age, but because this is a period of jawbone development, dentures and dental implants are difficult to apply.
Furthermore, oral frailty during the growth period can negatively impact nutrition and growth. Because teeth are missing during the growth period, the jawbone that supports the teeth also atrophies, and in cases of multiple tooth loss, long-term specialized treatment, including jawbone reconstruction, becomes necessary in adulthood.
Existing treatments are limited to alternative therapies using dentures or dental implants for adults, and there is a strong desire for the development of tooth regeneration therapy as a curative treatment.

【About Torgem BioPharma Co., Ltd.】
Our company, a bio-venture originating from Kyoto University, is engaged in the research and development of a tooth regeneration drug called "Tooth Growth Drug." In particular, our goal is to provide a groundbreaking treatment for patients suffering from tooth loss, such as congenital anodontia and acquired anodontia. We are currently conducting research and clinical trials with the aim of commercializing "Tooth Growth Drug," and in the future, we also envision developing a treatment that can address acquired tooth loss caused by cavities and periodontal disease.
Our company aims to become a comprehensive pharmaceutical research and development manufacturer in the dental field, contributing to people's health and well-being by providing therapeutic drugs in this area.

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