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Toregem BioPharma Co., Ltd.  
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**Toregem Raises Approximately USD 5.3 Million (JPY 850 Million) in Pre-Series C Financing;  
Total Past Funding Exceeds USD 29 Million (JPY 4.6 Billion)**

Toregem BioPharma Co., Ltd. (Kyoto City, President and CEO: Honoka Kiso; hereinafter referred to as "Toregem") raised approximately USD 5.3 million (JPY 850 million) in Pre-Series C financing round of an allocation of J-KISS-type stock acquisition rights to a new investor and also a third-party allotment of new shares with subscribing companies including JIC Venture Growth Investments (VGI). Through this funding, Toregem's cumulative equity financing has reached approximately USD 16 million (JPY 2.6 billion), and its cumulative funding, including grants and subsidies, has exceeded USD 29 million (JPY 4.6 billion). With this Pre-Series C funding, Toregem will conduct Phase II clinical trials of TRG035, a humanized anti-USAG-1 antibody, in Japan, prepare for future clinical development in the United States, and further accelerate the clinical development.

This financing will primarily be used for promoting the global development of the lead pipeline, research and development for additional promising pipeline programs, strengthening corporate governance, and expanding organizational capabilities through recruitment.

Toregem has received approximately USD 12 million (JPY 1.9 billion) in grant funding from the 2024 "Drug Discovery Venture Ecosystem Enhancement Project" (4th round) of the Japan Agency for Medical Research and Development (AMED) as a supporting drug discovery venture company, together with other grants and subsidies, total non-dilutive funding has reached approximately USD 12.5 million (JPY 2.0 billion).

**Investors in the Pre-Series C Financing**

Existing Investor : JIC Venture Growth Investments (VGI)

New Investors : Osaka University Venture Capital Co., Ltd. (OUVC) , BI Holdings Co., Ltd., SHOFU INC.,  
SIIF Impact Capital Inc., Chushin Venture Capital co., Ltd.

For details regarding the AMED program, please refer to the following:

“Drug Discovery Venture Ecosystem Enhancement Project (Drug Discovery Venture Open Call)” (4th round) of the Japan Agency for Medical Research and Development (AMED)

#### **【Background】**

Toregem is a biopharmaceutical startup in the dental field originating from Kyoto University. Established in May 2020, the company is based on many years of research by Associate Professor Katsu Takahashi of the Department of Oral and Maxillofacial Surgery, Kyoto University Graduate School of Medicine, who currently serves as Chief of the Department of Dentistry and Oral Surgery at Kitano Hospital, The Tazuke Kofukai Medical Research Institute.

Dr. Takahashi and his team revealed that the molecule USAG-1, which inhibits the function of BMP, a bone-forming protein, is involved in the process of tooth development and that tooth loss can be regenerated along with alveolar bone in an edentulism model animal by neutralizing antibody USAG-1.

TRG035 is expected to offer a new radical therapeutic approach for patients who currently have limited treatment options with dentures or implants, and we set our goal to obtain Japanese approval for launch as a new treatment.

We are in the process of researching and developing a therapeutic for patients with congenital tooth agenesis, first. Congenital tooth agenesis is a rare disease for which no curative treatment currently exists, and patients are mainly children whose jawbones are still developing, so often have difficulty using dentures or implants until they become adults. Nowadays, there is no choice but to obtain long-term preservation treatment until adulthood but tooth loss adversely affects nutrition and growth. As a result, development of a curative treatment is strongly needed. By enabling the regeneration of a patient’s own teeth, our treatment improves quality of life (QOL). Furthermore, USAG-1 antibodies are also expected to induce the development of a “third dentition” following permanent teeth, we hope to develop treatment to improve oral frailty in elderly people and widely contribute to dental care.

#### **【Purpose of fundraising and utilization】**

Toregem has utilized the funds raised from investors for the non-clinical safety clinical trials of TRG035(humanized antibody of USAG-1), manufacture of clinical trial formulations (GMP formulation), regulatory consultations with the Pharmaceuticals and Medical Devices Agency (PMDA) and TRG035 Phase I clinical trial in humans.

The company will initiate Phase II clinical trials of TRG035 in Japan, prepare for global clinical development, strengthen organizational capabilities through recruitment, and further accelerate the advancement of what could become the world's first therapy for tooth regeneration.

#### **【Company information】**

- Establishment date: May 12, 2020
- Address: 448-5 Kajiicho, Kawaramachi-dori Imadegawa-sagaru, Kamigyo-ku, Kyoto 602-0841

- Representative: Honoka Kiso
- Business description: Development of dental regenerative medicine
- Official website: <https://toregem.co.jp/en/>