

TOREGEM BIOPHARMA CO., LTD.

Developing the world's first antibody-based tooth regeneration medicine as a new alternative dental treatment to dentures and dental implants

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Founded in 2020
Co-founder & CEO: KISO Honoka, D.D.S., Ph.D.
No. of employees: 10
Type of Ownership: Private
Stock Exchange: N/A

October 2024: Aiming to commercialize a groundbreaking antibody drug for tooth regeneration invented by Dr. TAKAHASHI Katsu of Kyoto University, Cofounder & CTO. Venture Valuation (VV) interviewed Dr. KISO Honoka, D.D.S., Ph.D., Co-founder & CEO.



VV: Dr. Takahashi discovered that the USAG-1 (Uterine Sensitization-Associated Gene-1) protein limits the growth of teeth. And he proved in preclinical studies¹ that a neutralizing antibody which blocks this protein's function can grow missing teeth and alveolar bone.

Kiso: We have already effectively grown new teeth in mice, ferrets and dogs. If the clinical trials, which are planned to start this year, are successful, our antibody-based tooth regeneration drug will become a new option in addition to dentures and dental implants.

The major advantage of antibody-based tooth regeneration is a treatment with a systemic single injection while dental implants require invasive procedures while dentures need periodical cleaning and maintenance.

VV: Your priority is to treat children with hypodontia who are born without the ability to grow teeth.

Kiso: As an oral and maxillofacial surgeon, I treat children with hypodontia, the cause of which is mostly heredity. It is classified as a rare disease. Current treatments include bridges, dentures, dental implants and orthodontics. Dentures should be adjusted periodically until adulthood, when their jaws stop growing and the implants can be adjusted.

¹ <https://www.science.org/doi/10.1126/sciadv.abf1798>

Our technology allows patients to grow their own teeth. We primarily aim for patients congenitally missing more than six teeth, No.1 indication; then patients with fewer than five missing teeth, No.2 indication. (See below)

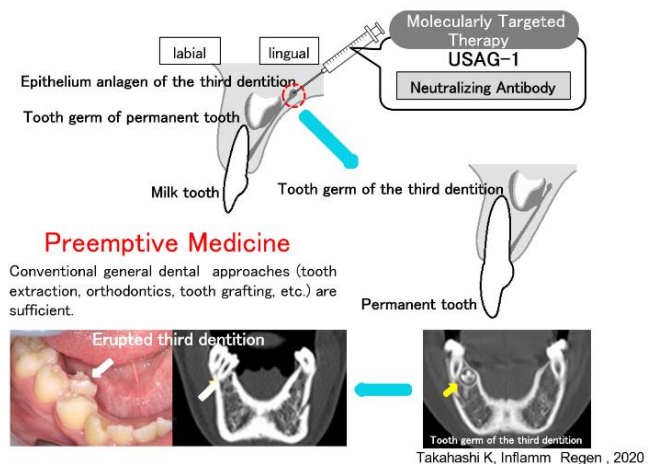
Target patients and business scale			
	No. 1 indication	No. 2 indication	No. 3 indication
	Congenitally missing teeth (hypodontia) (6 or more) (Permanent tooth birth defect)	Congenitally missing teeth (hypodontia) (5 or less) (Permanent tooth birth defect)	Acquired tooth defects
Cause	Hereditary etc.	Hereditary and others	caries, periodontal disease, etc.
Treatment target	Permanent tooth germ		Third dentition Stem cell
Current treatment	Mainly dentures until adulthood	tooth when jaw growth stops	Dental Implants / dentures
Incidence rate (in Japan)	About 0.1%	About 10%	65 years old ~: About 70%
Number of patients	Japan 1,000 people / year US 4,000 people / year Other 4,000 people / year	Japan 100,000 people / year US 400,000 people / year Other 400,000 people / year	Japan 30 million people / year US 140 million people / year Other 140 million people / year
Sales start time	Scheduled for 2030	Scheduled for 2033	To be decided

We are hoping to provide our antibody-based tooth regeneration medicine to those patients, predominantly small children, in 2030 to 2033.

VV: Your ultimate objective is No.3 indication, that is, to treat any person who has lost teeth due to caries, periodontal disease, and other reasons.

Kiso: For instance, around 70% of over 65 years old people in Japan have dental implants and/or dentures. That is approximately 30 million people.

Dr. Takahashi provided evidence that the start of a third set of teeth is already embedded in our mouths. As the image shows, a tooth germ of the third dentition appears behind the permanent tooth.



We are conducting research on activating the third set of buds with the antibody administration encouraging teeth regrowth.

VV: You are in the process of planning Phase 1 physician-led clinical trials and Phase 2a trials this year.

Kiso: Phase 1 trials will be with 30 male adults having healthy dental condition. After the drug safety is confirmed, Phase 2a trials will assess effectiveness, with the treatment administered to patients aged 2 to 7.

We expect our antibody-based tooth regeneration drug will be available to patients with hypodontia from 2030 to 2033.

VV Comments after the interview:

Tooth loss affects human health. Toregem's tooth regeneration technology has potential to improve overall quality of life for everybody in the future.

It will mostly give great hope and self-esteem to patients suffering with hypodontia for which no comprehensive treatment exists. Around 2.3–10% of the world's population is affected.²

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Venture Valuation specializes in the independent assessment and valuation of technology-driven companies in growth industries, such as the Life Sciences (Biotech, Pharma, and Medtech), ICT, Femtech, Nanotech, Cleantech and Renewable Energy. In addition to valuation products, Venture Valuation offers high-quality, focused information services like the Global Life Sciences Database, Biotechgate.com and this "*Let's Interview Series*" with companies with interesting technologies and services. We select and interview thriving companies and organizations especially in Switzerland and Japan.

² <https://www.sciencedirect.com/science/article/pii/S1991790220302105>