Toregem Biopharma Co., Ltd

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Development of the World's First Tooth Generation Medicine Discovered by Dentist

Based on the research by Dr. Takahashi Katsu, the project aims to regenerate teeth by growing tooth buds that would normally degenerate from USAG-1, by suppressing it with antibodies. The aim is to extend the healthy lifespan of teeth by recovering missing teeth for patients, regenerating the 3rd dental ledge, and improving oral functions for the elderly.

Company Profile

◆ Business Overview

Toregem Biopharma Co., Ltd is a venture started at Kyoto Univ. to research, develop, and market tooth regeneration medicine. It is based on the research by co-founder Assoc. Professor Katsu Takahashi of Kyoto University Department of Dental and Oral Surgery (currently: Chief of Oral Surgery, Medical Research Institute Kitano Hospital). The discovery of a mouse model with excess teeth in 2007 led Dr. Takahashi to consider treating congenital and acquired tooth defects with a regeneration medicine, and create an antibody (mouse anti-USAG-1 antibody) that can restore teeth in mice. After confirming that teeth were increased in mice and ferrets, the antibody was humanized. The company is currently examining manufacturing methods and preparing for safety tests to implement human clinical trials. To contribute to the extension of a healthy life, we hope to develop a medicine for congenital edentulism, a condition of being born without 6 or more permanent teeth, and eventually create a medicine for acquired edentulism.

【Origin of Company Name】

Tooth Regeneration Medicine BioPharma

Toregem BioPharma

Features & Strengths

◆ Business Model Features

Our greatest strength is that we are the only company that has the technology to regenerate teeth by medicine.

Currently, dentures or implants are used to replace lost teeth. If our regeneration drug becomes available, it will be possible to restore teeth by injection. It has only been possible to achieve this groundbreaking research through a cooperative and supportive research environment. There were many difficulties while developing the regeneration drug, but Dr. Takahashi overcame the obstacles to pass on the baton to related authorities.

Our venture company originated from Kyoto Univ., but these results were brought forth through the Industry-Government-Academia collaboration, AMED (Japan Agency for Medical Research and Development). Being able to utilize this intellectual property that was cultivated by such a collaboration is our unique strength.

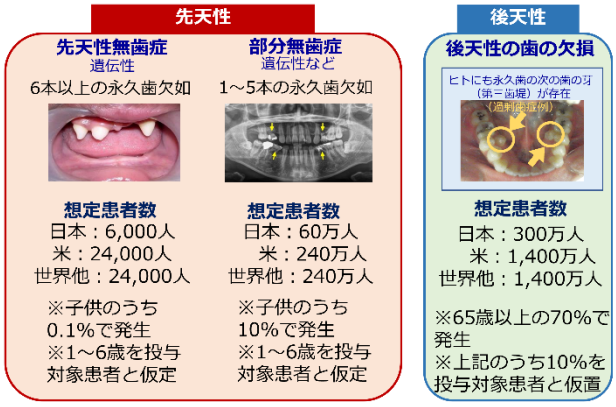
◆ Strengths

The strength of the tooth regeneration medicine we are developing is being able to add a new choice to existing treatments. Anodontia is genetic, so it is likely that the lack of permanent teeth is discovered in youth. Anodontia means losing at least 6 permanent teeth, so the condition affects

eating. It is possible to get dental implants in adulthood, but as a child, it is necessary to make new dentures with growth. In addition, if adults have surgery for implants, long-term treatment plans ranging from 10-20 years are needed due the various surgeries need to form the jaw bone and implant the teeth. By using the regeneration medicine we are developing, it is possible to naturally grow teeth by administering the medicine when first diagnosed as having anodontia. This treatment will not be a complete alternative to current treatment since it takes time to grow teeth, but it will most definitely be an effective option for anodontia if it is put to practical use.

Anodontia is losing more than 6 permanent teeth, but about 10% of children receiving dental care suffer from partial anodontia, which is the loss of 1-5 permanent teeth. It may be possible to use our regeneration medicine for patients who have partial anodontia, and there is increasing hope that the treatment options for those suffering from tooth loss will increase in the future.

【Reasons for Tooth Loss】



Background of Establishment

◆ Business View

Professor Katsu Takahashi, one of the co-founders, focused on the fact that mutating one gene can increase the number of teeth and conducted research for 30 years. From his background in molecular and developmental biology, believed that teeth can be regenerated by focusing on proteins to increase the number of teeth. This project was possible with the help of many advisors, seniors, colleagues and students, and the support from programs sponsoring venture businesses. Dr. Takahashi started the company with Mr. Takatani and Ms. Kiso, who had the same hope of developing a drug that will help patients who troubled due to loss of teeth.

Ms. Honoka Kiso, also one of the co-founders, lost 2 permanent teeth due to a disease of the jawbone when she was in junior high school. She decided to research tooth regeneration out of her appreciation to the doctor that treated her and the sadness of losing her permanent teeth. After entering graduate school in 2008, she has been researching under Dr. Takahashi.

There was a difficult time due to funding issues and lack of positive results. However, the strong will to produce a groundbreaking medicine that can regenerate teeth with only one injection encouraged the continuation of research and the startup of this company.

Vision for the Future

◆ Future Business Outlook

Our company is currently starting the preparation for GMP formulation and non-clinical safety studies. We first hope to be able to provide the world's first tooth regeneration medicine to patients with anodontia by 2030. Our future goal is to be able to treat patients who have lost teeth due to tooth decay and periodontal disease.

Toregem Biopharma's tooth regeneration medicine is a medicine that grows and extends tooth buds, so it can be expected to be effective for both congenital and acquired loss of teeth. However, since there are multiple antibodies, we plan to study whether the same antibodies can be applied to both congenital and acquired tooth loss. To do this, it is essential to make partnerships with pharmaceutical companies. While preparing for clinical trials, we are currently searching for companies to form partnerships with in order to commercialize our medicine as soon as possible.