Nobelpharma

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**Medical Device "Titanium Bridge" (for type II thyroplasty) Gets *SAKIGAKE* Designation from the Ministry of Health, Labor and Welfare for Fast-track Review**

The Ministry of Health, Labor and Welfare announced today five medical device and regenerative medicine products designated under its "sakigake" fast-track review system, one of which is the "titanium bridge (NPC-17)" for type II thyroplasty.

Type II thyroplasty using a "titanium bridge" for the treatment of adductor spasmodic dysphonia is a medical technique unique to Japan that was developed in 2001 before the rest of the world by Dr. Nobuhiko Isshiki, Professor Emeritus, Kyoto University, as a definitive treatment for the symptoms of adductor spasmodic dysphonia. For his long-standing contributions domestically and internationally including this type II thyroplasty, Dr. Isshiki received the "Isshiki Award" in 2011 from the Royal College of Surgeons of England.

This therapeutic device used in surgery called "titanium bridge" is manufactured by Wakayoshi Seisakusho Co., Ltd. (Sabae-shi, Fukui) with its exceptional technical skill in titanium processing.

Adductor spasmodic dysphonia is a type of focal dystonia, an intractable neurological disease of unknown cause common among young women. Due to prolonged interference with social ability, it may induce depression, social withdrawal, or even suicide attempt. Having no definitive treatment for this disease previously established anywhere in the world, the prompt practical use of this therapeutic technique is expected to be a major ray of hope for patients who suffer from adductor spasmodic dysphonia.

[SAKIGAKE Fast-track Review System]

A system, with the intention to provide state-of-the-art drug in Japan ahead of other countries, to grant SAKIGAKE fast-track review designation at an early development stage to innovative pharmaceuticals, medical devices, and regenerative medicines fulfilling certain criteria such as [1] innovativeness with new functional mechanism, [2] seriousness of target diseases, [ 3] extremely high efficacy for target diseases, and [4] inclination to early development and application in Japan ahead of other countries.

A designated product will be prioritized for consultation and reviews in the approval process and also adequately supported for the preparation of a manufacturing scheme and of smooth product supply to clinical settings in line with review schedule, further accelerating prompt practical application.

For the review period, reduction by half to 6 months from normal 12 months for medical devices is targeted by employing the expedited review processes.

Visit MHLW website for more information on "SAKIGAKE System."

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