September 20, 2019

Press Release (Translation)

Nobelpharma Co., Ltd.

Marketing Approval Granted for Retympa® 250 μg Set for Otology, for Treatment of Tympanic Membrane Perforation

Nobelpharma Co., Ltd. (Head office: Tokyo, President: Jin Shiomura) announces today that the manufacturing and marketing approvals have been granted for Retympa® 250 μg set ("Retympa®") for the indication of tympanic membrane perforation.

Perforation of the tympanic membrane is caused by otitis media, insertion of a tympanic tube, or traumatic injury. Perforation of the tympanic membrane can cause hearing impairment, weaken listening comprehension, affect the ability to communicate, and significantly reduce QOL. For perforation of the tympanic membrane without spontaneous closure, the following procedures have been performed: tympanoplasty, in which connective tissue and cartilage fragments are collected from the back of the patient's ear and transplanted to the site of perforation of the tympanic membrane; tympanic membrane perforation closure, in which a tympanic membrane perforation is closed with an artificial material.
However, in tympanoplasty, there were problems such as high invasiveness, the possibility of hearing loss due to shallow or thickened tympanic membranes, and in tympanic membrane perforation closure, the tendency of the implanted prosthesis to detach due to poor fixation.

Retympa® is a topical liquid formulation (Note 1) containing trafermine (genetic recombination) as an active ingredient, which is licensed from Kaken Pharmaceutical Co., Ltd. Gelatin sponge infiltrated with Retympa®, which come in a package (Note 2), is placed at the perforated tympanic membrane and the treatment is less invasive. It promotes regeneration of the tympanic membrane, has demonstrated efficacy and safety in tympanic membrane perforation, and is expected to be effective in improving hearing.
We believe Retympa® will provide one of the new treatment options for perforation of the tympanic membrane.

Dr. Shin-ichi Kanemaru , Department of Otolaryngology - Head and Neck Surgery, Kitano Hospital, Tazuke Kofukai Medical Research Institute, devised the treatment method using Retympa®. With the support of the Translational Research Center for Medical Innovation (TRI) of the Foundation for Biomedical Research and Innovation at Kobe, Kyoto University Hospital, Keio University Hospital, and Advanced Medical Center Hospital, a public interest foundation (now Kobe City Medical Central General Hospital), conducted a physician-led clinical trial, and Nobelpharma Co., Ltd. applied for approval on September 27, 2018.
There are no other countries or regions where the drug is approved for the indication of tympanic membrane perforation.

We will endeavor to continuously contribute to society by providing pharmaceuticals and medical devices for unmet needs.

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(Note 1) Trafermine (genetic recombination), the active ingredient of drug, is an active ingredient produced by genetic recombination of human basic fibroblast growth factor (bFGF). It is believed to act on the fibroblast growth factor receptor present in the epithelium of perforated tympanic membrane to stimulate the proliferation and differentiation of endothelial cells, fibroblasts, and keratinocytes and promote the rapid proliferation of subepithelial connective tissue to repair the perforated tympanic membrane.

(Note 2) This is a packaged product that comes with trafermine (genetic recombination), which promotes wound healing, and gelatin sponge, which is used as scaffolding material for cells involved in wound healing. We have developed a new gelatin sponge for tympanic membranes that is easy to process according to the size and shape of the perforation, and have also developed a dedicated container (patent pending) that can prevent infection with clean procedures by fully infiltrating the gelatin sponge for tympanic membranes with trafermine (genetic recombination) so that it can easily cover complicated perforations and large perforations.