

September 24, 2024

**For Immediate Release**

OrphanPacific Inc.

## **Announcement of Marketing Authorization Transfer for Rabipur Intramuscular Injection**

OrphanPacific, Inc. (Headquarters: Minato-ku, Tokyo, Chairman, Representative Director, CEO: Takashi Kaneko, hereinafter referred to as "OrphanPacific"), a subsidiary of CMIC HOLDINGS Co., Ltd. is pleased to announce that, as of October 28, 2024, it will take over as the marketing authorization holder in Japan for the freeze-dried inactivated tissue culture rabies vaccine "Rabipur Intramuscular Injection" from GlaxoSmithKline Co., Ltd. (Headquarters: Minato-ku, Tokyo, President and Representative Director: Paul Lirette, hereinafter referred to as GSK).

"Rabipur Intramuscular Injection" was originally applied for marketing authorization by GSK and was approved in March 2019 for the indications of "prophylaxis and prevention of occurrence of rabies" in Japan. Since then, commercial activities have been conducted by GSK in Japan. However, Bavarian Nordic without a base in Japan acquired product rights for "Rabipur Intramuscular Injection". Therefore the marketing authorization will be transferred to OrphanPacific.

Rabies is an imported infectious disease that is classified as Group D (rare disease) among priority infectious diseases as defined by the Ministry of Health, Labor and Welfare. Although rabies is extremely rare in Japan, the overseas expansion of Japanese companies has led to an increase in travel abroad, and this has increased the need for pre- and post-exposure rabies vaccinations.

Rabipur Intramuscular Injection is the only rabies vaccine approved in Japan and protects people from virtually 100% fatal (once clinical symptoms appear). Through the Market Authorization transfer, OrphanPacific will further contribute to the treatment and prevention in the field of rare diseases.

For inquiries regarding this matter, please contact: OrphanPacific Co., Ltd.,  
Corporate Planning Department Tel: 03-6779-8151

**Reference:****1. Overview of Rabipur Intramuscular Injection**

Trade Name : Rabipur Intramuscular Injection

Generic Name : Freeze-dried Inactivated Tissue Culture Rabies Vaccine

Pharmacological Classification : Virus Vaccine

Indications : Prevention and onset inhibition of rabies

Dosage and Administration : Dissolve the product in the entire amount of the attached solvent (Japanese Pharmacopoeia Injection Water) and use as follows:

<Pre-exposure Immunization>

Administer 1.0mL as a single dose, with appropriate intervals, three times intramuscularly.

<Post-exposure Immunization>

Administer 1.0mL as a single dose, with appropriate intervals, four to six times intramuscularly.

Packaging: One vial [with 1mL of solvent (Japanese Pharmacopoeia Injection Water) attached]

**2. About Rabies**

Rabies is a disease that is almost 100% fatal once clinical symptoms appear. It is found worldwide, particularly in Asia and Africa. The virus is transmitted through the bites or scratches of infected animals such as dogs, foxes, raccoons, and bats. Vaccination is recommended for individuals who will be staying long-term in areas where rabies is common, researchers, and others who frequently come into direct contact with animals. It is also advised for those traveling to backcountry areas where immediate medical care may not be available.

Three doses of the vaccine are required within one month before potential exposure (prior to travel). Even if you have received the pre-exposure vaccination, it is crucial to get vaccinated again after exposure (if bitten or scratched by a suspected rabid animal), except in a few countries where rabies is not present. This is especially important in regions where rabies is prevalent. Proper post-exposure vaccination can prevent the onset of the disease.

Source: [https://www.forth.go.jp/moreinfo/topics/useful\\_vaccination.html](https://www.forth.go.jp/moreinfo/topics/useful_vaccination.html)

(Partially modified)

### **3. Company Overview**

#### **[About GSK (GlaxoSmithKline)]**

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. We prioritise innovation in vaccines and specialty medicines to prevent and treat disease. Find out more at <https://www.gsk.com/en-gb/> and <https://jp.gsk.com/ja-jp/home/> about GSK Japan.

#### **[About Bavarian Nordic]**

Bavarian Nordic is a fully integrated vaccine company with a mission to protect and save lives through innovative vaccines. Bavarian Nordic is a global leader in smallpox and mpox vaccines, supplied to governments to enhance public health preparedness, and have a strong portfolio of vaccines for travelers and endemic diseases. For more information visit [www.bavarian-nordic.com](http://www.bavarian-nordic.com).

#### **[About OrphanPacific Co., Ltd.]**

OrphanPacific is a Japanese pharmaceutical company dedicated to developing, manufacturing, and marketing treatments for rare diseases. Our mission is to bring smiles and happiness to patients with rare diseases and their families. With a commitment to “Leave No One Behind,” we actively engage in the development and provision of treatments for rare diseases with very few patients.

OrphanPacific is a 100% subsidiary of CMIC Holdings, a pioneering and leading CRO (Contract Research Organization) in Japan. We leverage the extensive experience and expertise of the CMIC Group in drug development, manufacturing, and marketing to introduce orphan drugs and support the entry of overseas pharmaceutical companies without a presence in Japan into the Japanese market.

For more details, please visit <https://www.orphanpacific.com/en/>

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