

**FOR IMMEDIATE RELEASE**

Tokyo, April 21, 2021

Torii Pharmaceutical Co., Ltd.

**Listing on the Japanese National Health Insurance Drug Price List and  
Launch of ORLADEYO Capsules 150mg  
for Suppression of HAE Attacks in Japan**

Torii Pharmaceutical Co., Ltd. (Torii) announced that drug price of ORLADEYO Capsules 150mg (generic name: berotralstat hydrochloride) (hereinafter “ORLADEYO”), a plasma kallikrein inhibitor indicated for the suppression of the onset of acute attacks in hereditary angioedema (HAE) in Japan, was placed on the Japanese National Health Insurance (NHI) drug price list as of today. Torii plans to launch the drug in Japan on April 23, 2021.

ORLADEYO is a drug developed in Japan by BioCryst Pharmaceuticals, Inc. ("BioCryst") and earned the Sakigake designation in October 2015, and the orphan drug designation in December 2018. The New Drug Application was filed by OrphanPacific, Inc.(OrphanPacific) under the contract with BioCryst. OrphanPacific has received manufacturing and marketing approval for this drug on January 22, 2021.

ORLADEYO is a new oral agent that is designed to suppress the onset of acute HAE attacks by specifically inhibiting the bradykinin-producing enzyme. The Phase 3 clinical studies conducted in Japan confirmed the efficacy and safety of ORLADEYO in HAE patients for the suppression of the onset of acute HAE attacks.

Torii expects ORLADEYO to be a new option for the treatment of HAE in Japan.

Based on the November 2019 agreement between BioCryst and Torii, Torii will pay BioCryst a milestone of US\$15 million. In addition, Torii will pay royalties to BioCryst according to product sales.

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## **Approval Summary**

Product Name	: ORLADEYO capsule 150mg
Generic Name	: berotralstat hydrochloride
Indications	: Suppression of the onset of acute attacks in patients with hereditary angioedema
Dosage and Administration	: The recommended dose of berotralstat for adults and children aged 12 years or older is 150mg (1 capsule) taken orally once daily.
Package	: 7 capsules (7 capsules (PPT) × 1 )
NHI Drug Price	: ¥ 74,228.20 per capsule
Approval Date	: January 22, 2021
NHI Pricing Date	: April 21, 2021
Launch Date	: April 23, 2021
Manufacturing and Distributor	: OrphanPacific, Inc.
Distributor	: Torii Pharmaceutical Co., Ltd.

### **ABOUT** hereditary angioedema (HAE)

HAE is a genetic disorder that develops by overproduction of bradykinin, a vasodilator substance, due to C1 inhibitor deficiency or functional decline and causes sudden edema to various regions of the body such as extremities, face, throat or digestive organ, resulting in swelling and pain that may affect the patients' quality of daily life.

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