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Japanese NHI price listing triggers $15 M milestone payment to BioCryst

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ORLADEYO is the first and only approved prophylactic therapy for HAE in Japan

US based BioCryst Pharmaceuticals, Inc. has announced that the Japanese National Health Insurance System (NHI) has approved the addition of oral, once-daily ORLADEYO ™ (berotralstat) to the NHI drug price list.

Oral, once-daily ORLADEYO was approved in Japan in January 2021 for prophylactic treatment of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older. ORLADEYO is the first and only prophylactic HAE medication approved in Japan.

ORLADEYO will be commercialized in Japan by BioCryst's partner, Torii Pharmaceutical Co., Ltd. Torii plans to launch ORLADEYO following the NHI drug price listing.

"Our goal is to bring ORLADEYO to HAE patients around the world who want a new oral, once-daily option to prevent their attacks. In Japan, ORLADEYO is the first approved prophylactic HAE medication, which has the potential to significantly impact the lives of HAE patients," said Jon Stonehouse, president and chief executive officer of BioCryst.

The NHI price listing triggers a $15 million milestone payment from Torii to BioCryst. In addition, BioCryst will receive tiered royalties ranging from 20 percent to 40 percent of Japanese net sales.

BioCryst received Orphan Drug and Sakigake designation for ORLADEYO in Japan. The APeX-J trial in Japan met its primary endpoint ($p=0.003$) of a reduction in HAE attacks from baseline for ORLADEYO 150 mg compared to placebo, and ORLADEYO was safe and generally well-tolerated in the trial. In APeX-2, ORLADEYO also met its primary endpoint ($p<0.001$) for ORLADEYO 150 mg compared to placebo and was safe and generally well-tolerated.