

Japan's JCR Pharma receives marketing authorisation in UAE for IZCARGO to treat Hunter Syndrome

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This marketing authorisation is the first for IZCARGO outside of Japan



JCR Pharmaceuticals Co., a global specialty biopharmaceutical company dedicated to developing therapies for rare and genetic diseases, has announced that IZCARGO™, a blood-brain barrier-penetrating enzyme replacement therapy (ERT) for Hunter syndrome developed using JCR's proprietary J-Brain Cargo® technology, received marketing authorisation in the United Arab Emirates (UAE).

This marks the first marketing authorisation for IZCARGO™ outside of Japan. IZCARGO™ was approved and launched in Japan in 2021 and is currently being evaluated in an ongoing global Phase III clinical trial.

JCR has been working to expand access to IZCARGO™ outside of Japan while advancing its global clinical development programme. As part of this effort, JCR entered into a distribution agreement with Taiba Middle East FZ LLC and pursued regulatory approval in the UAE based on the product's marketing authorisation in Japan.

Under this agreement, JCR will also seek marketing authorisation for IZCARGO™ in countries across the Middle East and North Africa (MENA) region, while Taiba will be responsible for sales and distribution in the relevant territories.

Hunter syndrome (mucopolysaccharidosis type II, or MPS II) is an X-linked recessive lysosomal storage disorder caused by a deficiency of iduronate-2-sulfatase, an enzyme that breaks down complex carbohydrates called glycosaminoglycans (GAGs, also known as mucopolysaccharides) in the body. Hunter syndrome, which affects an estimated 2,000-3,000 individuals worldwide, gives rise to a wide range of somatic and neurological symptoms.