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ASIA EDITION

Taiwan approves first and only treatment for rare genetic disorder

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CANbridge announces marketing approval of CAN108 (/LIVMARLI) in Taiwan for the treatment of cholestaticpruritus in patients with Alagille Syndrome

CANbridge Pharmaceuticals, a global biopharmaceutical company with a foundation in China, has announced the marketing approval of CAN108 (Maralixibat Chloride Oral Solution /LIVMARLI) by the Taiwan Food and Drug Administration (TFDA).

LIVMARLI is a minimally absorbed ileal bile acid transporter (IBAT) inhibitor, and the first and only treatment approved medication in Taiwan for the treatment of cholestatic pruritus (itching caused by slowed or stalled bile flow) in patients with Alagille syndrome (ALGS) aged one year or older.

ALGS is a rare genetic disorder that can lead to end-stage liver disease and death. ALGS is characterized by paucity of the bile ducts, which causes cholestasis, and involvement of extrahepatic organs, such as the kidneys, eyes, as well as bones and the cardiovascular system. Cholestatic pruritus is the most burdensome symptom in ALGS, greatly reducing quality of life.

LIVMARLI has recently been approved in Hong Kong, mainland China and Canada. It has also been approved in the United States for patients with ALGS aged three months and older, and in Europe for patients with ALGS aged two months and older.

CANbridge holds an exclusive license with Mirum Pharmaceuticals, Inc. for the development, commercialisation, and manufacturing, under certain conditions, of LIVMARLI in Greater China for three rare liver disease indications: Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC), and biliary atresia (BA), along with other selected indications. LIVMARLI is currently being evaluated in an ongoing Global Phase 2 study known as EMBARK for the treatment of BA, which completed patient enrolment in China in May 2023.