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Taiwan accepts CANbridge's NDA for Alagille Syndrome

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CANbridge Pharmaceuticals CAN108 New Drug Application/Orphan Drug Registration (NDA/ORD) for Alagille Syndrome accepted by the Taiwan Food and Drug Administration



CANbridge Pharmaceuticals Inc. has announced that the Taiwan Food and Drug Administration (TFDA) has accepted the New Drug Application/Orphan Drug Registration (NDA/ODR) for CAN108 (maralixibat oral solution (LIVMARLI)) for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older. LIVMARLI (maralixibat) oral solution was recently approved by the US Food and Drug Administration (FDA) for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older. CANbridge recently received an acceptance letter for a CAN108 NDA the same indication from China's National Medical Products Administration.

CANbridge and Mirum Pharmaceuticals signed an exclusive license agreement for the development, commercialization and manufacture, under certain conditions, of maralixibat (CAN108) in Greater China last year. Under the terms of the agreement, CANbridge has the right to develop and commercialize CAN108 for three indications: Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC) and biliary atresia (BA) in Greater China.