Sumitomo Dainippon Pharma

News Release

February 15, 2018

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Announces Amends the License Agreement for Obeticholic Acid (DSP-1747)

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Masayo Tada) announced today that it has agreed with Intercept Pharmaceuticals, Inc. (Head Office: New York, U.S.A.) ("Intercept") to return the exclusive rights to develop and commercialize obeticholic acid (generic name, development code: DSP-1747) (“OCA”) in Japan and Korea, which was licensed from Intercept, and the two companies have entered into an amendment to the license agreement for OCA.

Under the new terms of the license agreement, Sumitomo Dainippon Pharma returns the exclusive rights to develop and commercialize OCA in Japan and Korea, and retains the exclusive rights to develop and commercialize OCA in China. Sumitomo Dainippon Pharma will pay milestone payments based on the development and commercialization and royalties based on sales of OCA in China.
The amendment of the license agreement will not materially affect Sumitomo Dainippon Pharma’s consolidated financial results of the fiscal year ending March 31, 2018.

(Reference)

About Obeticholic Acid
Obeticholic Acid is an agonist for farnesoid X receptor (FXR) whose ligand is the primary human bile acid chenodeoxycholic acid, the natural endogenous FXR agonist.
In March 2011, Sumitomo Dainippon Pharma entered into an exclusive license agreement with Intercept for the development and commercialization of OCA for nonalcoholic steatohepatitis (NASH) and primary biliary cholangitis (PBC) in Japan and China, and added Korea to its territory thereafter.
Sumitomo Dainippon Pharma conducted a Phase 2 study of OCA for NASH in Japan and we have been considering the development plan, and we have decided not to continue the development for OCA in Japan.

About Primary Biliary Cholangitis (PBC)
PBC is an autoimmune chronic liver disease that primarily afflicts women in their 50s and 60s. Chronic inflammation destroys small intrahepatic bile ducts, causing bile to accumulate in the liver and damage to the liver.

About Nonalcoholic Steatohepatitis (NASH)
NASH is steatohepatitis with necrosis/inflammation/fibrosis in hepatic tissue without alcohol drinking or hepatitis virus infection. In a report of a 5-10 year follow-up study, up to 25% of NASH patients progressed to cirrhosis of the liver.

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