

ASLAN receives orphan drug designation for cancer drug

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Singapore: ASLAN Pharmaceuticals, Singapore based biotech company focused on the development of immunotherapies and targeted agents for Asia prevalent tumour types, has received orphan drug designation for pan-HER inhibitor ASLAN001 (varlitinib) by the US Food and Drug Administration (FDA) Office of Orphan Products Development (OOPD).

The indication for the Orphan Drug Designation is cholangiocarcinoma, a rare and very aggressive form of bile duct cancer which has no cure.

The FDA awards Orphan Drug Designation to advance the evaluation and development of drugs and products that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions. The OOPD evaluates scientific and clinical data submissions from sponsors to identify and designate products as promising for rare diseases and to further advance scientific development of such promising medical products. Orphan Drug Designation will provide ASLAN certain incentives including extended marketing exclusivity to develop ASLAN001 in cholangiocarcinoma.

ASLAN001 is currently being tested in phase 2 studies in breast cancer and cholangiocarcinoma. Studies in gastric cancer are also being planned.

"Cholangiocarcinoma is a very rare cancer in the USA, but one of the big killers in Asia. We became excited by some cases with remarkable responses in patients with cholangiocarcinoma taking part in our earlier studies with ASLAN001," said Dr Bertil Lindmark, chief scientific officer, ASLAN.

Cholangiocarcinoma is a heterogeneous cancer, which may show genetic variation in different populations, and its low prevalence in the West makes it difficult to study. In Asia, the incidence is over 10 times higher. The access to patients and physicians with knowledge of the disease will be key in studying the effects of ASLAN001 in this disease.

"The Orphan Drug Designation is an important step in the development of ASLAN001. With no approved targeted therapies for cholangiocarcinoma, the prognosis for patients in both Asia and the West is poor," said Dr Carl Firth, chief executive officer, ASLAN. He added, "In addition to our work in cholangiocarcinoma, we are progressing our portfolio of immunotherapies and targeted agents in other Asia prevalent tumour types, including gastric cancer and hepatocellular carcinoma."