



PRESS RELEASE

ASLAN Pharmaceuticals receives Orphan Drug Designation from the FDA for ASLAN001 (*varlitinib*) in cholangiocarcinoma

Singapore, 13 August 2015 –ASLAN Pharmaceuticals (ASLAN), a biotech company focused on the development of immunotherapies and targeted agents for Asia prevalent tumour types, today announced the Designation as an Orphan drug of their pan-HER inhibitor ASLAN001 (*varlitinib*) by the U.S. 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 of 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 of 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."*

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About ASLAN Pharmaceuticals

ASLAN Pharmaceuticals is an oncology focused biotechnology company developing a portfolio of immunotherapies and targeted drugs, focusing on Asia prevalent tumour types. Led by a highly experienced management team with global pharmaceutical expertise, ASLAN is headquartered in Singapore with a platform which reaches across the region via its offices in Taiwan and China, enabling the Company to conduct and support regional clinical development programmes. The Company's proprietary pipeline of 4 development-stage candidates addresses multiple indications including gastric and breast cancers and inflammatory diseases. ASLAN's most advanced compounds are in phase 2: ASLAN001, a pan-HER inhibitor with phase 2 data in gastric cancer, being developed in cholangiocarcinoma, breast cancer and gastric cancer; and ASLAN002, which targets RON, an immune checkpoint inhibitor, and cMET. www.aslanpharma.com