



## PRESS RELEASE

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### ASLAN PHARMACEUTICALS INITIATES GLOBAL PIVOTAL STUDY FOR VARLITINIB IN BILIARY TRACT CANCER

**Singapore, 25 April 2017** – ASLAN Pharmaceuticals (ASLAN), a biotech company focused on the development of immunotherapies and targeted agents for Asia prevalent tumour types, today announced the commencement of a global pivotal study for its lead asset, *varlitinib*, in biliary tract cancer, following the approval of ASLAN's Investigational New Drug application by the United States Food and Drug Administration (US FDA).

The **TreeTopp (Treatment Opportunity with *varlitinib* in biliary tract cancer)** study is a global pivotal double-blind, randomised two-arm study that will be conducted in approximately 60 sites worldwide including the US, Japan, South Korea, China, Asia Pacific and Europe. Dr Milind Javle, a world-leading biliary tract cancer expert from the MD Anderson Cancer Center, will be leading the study.

The TreeTopp study design was agreed with the US FDA at an End of Phase 2 meeting, and will enrol 120 patients with biliary tract cancer who have failed first line therapy. The primary endpoint of the TreeTopp study will be Response Rate. Currently, there are no approved therapies for the treatment of biliary tract cancer, and the study will enable accelerated approval.

*Varlitinib* is a potent, reversible, small molecule pan-HER inhibitor and is currently being developed across multiple indications including biliary tract cancer, gastric cancer, metastatic breast cancer and metastatic colorectal cancer.

**Dr Bertil Lindmark, Chief Medical Officer, ASLAN Pharmaceuticals, said:** *“Existing scientific and clinical data on varlitinib indicate that the HER mechanism may be an important factor in biliary tract cancer, a disease with poor prognosis and few treatment options. Recognising this high unmet need, we are excited to begin enrolling patients in this setting. The TreeTopp study design builds on the positive phase 2 data we have generated with varlitinib and will enable us to explore the efficacy of the drug in a large patient population.”*

*Varlitinib* has been awarded Orphan Drug Designation by the US FDA for cholangiocarcinoma, and most recently received Orphan Drug Designation from the Korea FDA for biliary tract cancer.

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#### About *varlitinib* (ASLAN001)

*Varlitinib* (ASLAN001) is a potent small molecule inhibitor of the HER-family of receptor tyrosine kinases (RTKs). The type I RTK family consists of four distinct but closely related receptors: epidermal growth factor receptor (EGFR, ErbB1, HER1), epidermal growth factor receptor 2 (HER2, ErbB2), epidermal growth factor receptor 3 (HER3, ErbB3), and epidermal growth factor receptor 4 (HER4, ErbB4). *Varlitinib* is a potent, reversible, small molecule inhibitor of EGFR, HER2 and HER4. In a large variety of cancers, the overexpression and/or constitutive activation of EGFR and HER2 are often observed and frequently correlate with poor clinical prognosis. Therefore, by inhibiting the activation



of the HER receptors via *varlitinib*, effects such as shrinkage of the tumour and longer survival can be anticipated. *Varlitinib* is currently being studied in biliary tract, breast and gastric cancers. *Varlitinib* has been granted orphan drug status in United States for cholangiocarcinoma and gastric cancer and was awarded orphan drug status for the treatment of advanced biliary tract cancer after first line systemic therapy by the Korean MFDS.

#### **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 that reaches across the region via its offices in Taiwan, China and Australia, enabling the Company to conduct and support regional clinical development programmes. The Company is developing 5 drugs addressing multiple indications including biliary tract cancer, gastric cancer and breast cancer. ASLAN has several compounds in late stage development: *varlitinib* (ASLAN001), a pan-HER inhibitor which has completed phase 2 studies in gastric and breast cancer, and is entering pivotal studies for biliary tract cancer; and ASLAN002 (partnered with BMS), a RON and cMET inhibitor in phase 2 development for gastric and breast cancer. [www.aslanpharma.com](http://www.aslanpharma.com)