



## PRESS RELEASE

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### **ASLAN PHARMACEUTICALS RECEIVES SECOND ORPHAN DRUG DESIGNATION FROM THE FDA FOR *VARLITINIB* (ASLAN001) IN GASTRIC CANCER**

**Singapore, 24 June 2016** – 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 its pan-HER inhibitor *varlitinib* (ASLAN001) by the US Food and Drug Administration (FDA) Office of Orphan Products Development (OOPD) for gastric cancer. *Varlitinib* previously received Orphan Drug Designation for cholangiocarcinoma in August 2015.

Gastric cancer is an aggressive form of cancer that is most often diagnosed when it is already in its advanced stage. Prognosis for the disease remains poor despite it being the third leading cause of cancer deaths globally. Worldwide, gastric cancer has one of the highest incidence rates, with 952,000 new cases diagnosed in 2012<sup>1</sup>. In Asia, gastric cancer is the third most common cancer after breast and liver, and is the second most common cause of cancer deaths in Asia<sup>2</sup>.

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 *varlitinib* in gastric cancer.

ASLAN is currently conducting phase 2 studies of *varlitinib* in gastric cancer, cholangiocarcinoma and breast cancer.

**Ends**

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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 inhibitor of EGFR, HER2 and HER4. In a large variety of cancers, the overexpression and/or constitutive activation of EGFR and HER2 are often

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<sup>1</sup> World Cancer Research Fund Institute. Stomach cancer. <http://www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/stomach-cancer-statistics>

<sup>2</sup> Rubayat Rahman, Akwi W Asombang, and Jamal A Ibdah. World Journal of Gastroenterology. 2014. Characteristics of gastric cancer in Asia. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4000485/>



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 tumor and longer survival can be anticipated. *Varlitinib* is currently being studied in cholangiocarcinoma and breast and gastric cancer.

#### **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, China and Australia, 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](http://www.aslanpharma.com)