



PRESS RELEASE

ASLAN PHARMACEUTICALS RECEIVES ORPHAN DRUG DESIGNATION IN KOREA FOR *VARLITINIB* (ASLAN001) IN BILIARY TRACT CANCER

Singapore, 20 February 2017 – 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 Korean Ministry of Food and Drug Safety (MFDS), for the treatment of advanced biliary tract cancer after first line systemic therapy. This is the third Orphan Drug Designation for *varlitinib* which has previously received orphan status for cholangiocarcinoma and gastric cancer from the United States Food and Drug Administration (FDA).

The MFDS awards Orphan Drug Designation to advance the development of drugs targeted for treating rare diseases that do not have any available treatments in Korea. Biliary tract cancer is a heterogeneous cancer and has over 5,000 newly diagnosed patients per year in Korea¹.

The Orphan Drug Designation will provide ASLAN certain incentives including faster regulatory approval for clinical trials involving *varlitinib* in biliary tract cancer in Korea, as well as marketing exclusivity in Korea for 10 years.

ASLAN is currently conducting pivotal studies of *varlitinib* in biliary tract cancer, and phase 2 trials in gastric and breast cancers.

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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.

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

¹ Oh, C.-M., Won, Y.-J., Jung, K.-W., Kong, H.-J., Cho, H., Lee, J.-K., ... The Community of Population-Based Regional Cancer Registries. (2016). Cancer Statistics in Korea: Incidence, Mortality, Survival, and Prevalence in 2013. *Cancer Research and Treatment: Official Journal of Korean Cancer Association*, 48(2), 436–450.



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