



PRESS RELEASE

ASLAN PHARMACEUTICALS REPORTS POSITIVE TOP-LINE RESULTS FOR PHASE 2 CLINICAL TRIAL OF VARLITINIB IN METASTATIC BREAST CANCER

Second-Line Treatment with Varlitinib Demonstrated Significant Tumour Shrinkage in HER2-positive Breast Cancer Patients

Singapore, 9 February 2017 – ASLAN Pharmaceuticals (ASLAN), a biotech company focused on the development of immunotherapies and targeted agents for Asia prevalent tumour types, today announced positive phase 2 results for its lead drug candidate *varlitinib* (ASLAN001) in combination with capecitabine as second-line treatment for metastatic HER2-positive breast cancer patients progressing on trastuzumab (Herceptin®). *Varlitinib* is a reversible potent small molecule inhibitor of the HER-family of receptor tyrosine kinases (RTKs).

The multinational, randomised open-label study compared the effects of *varlitinib* combined with capecitabine versus that of lapatinib (Tykerb™) combined with capecitabine on tumour shrinkage at week 12. Top-line data showed significantly greater tumour shrinkage at week 12 of the treatment cycle in patients who were on therapy for more than a month, receiving 400 mg *varlitinib* (36.4%) twice daily compared to 1,250 mg lapatinib (17.8%) once daily (p=0.075). A total of 50 patients were enrolled in the study.

While the study was not powered for objective response rate (ORR), it found that patients dosed with *varlitinib* showed higher ORR compared to patients on lapatinib (60% versus 46%). There were no differences in progression-free survival (PFS) or overall survival (OS) in the study. Adverse events reported included nausea, vomiting and diarrhoea, and occurred at similar frequency in both arms. The incidence of grade 3 diarrhoea was 12.5% in the *varlitinib* group and was clinically manageable. There were no instances of grade 4 diarrhoea. No anti-diarrhoea prophylaxis was mandated for patients in the *varlitinib* group.

"The positive results from this study continue to demonstrate the robust anti-tumour capabilities of varlitinib," said Dr Bertil Lindmark, Chief Medical Officer, ASLAN Pharmaceuticals. "We believe that varlitinib has great potential across tumour types, and it is the first of several novel agents that we are committed to developing to treat Asia prevalent cancers."

Varlitinib is also being developed in other indications, including gastric and biliary tract 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 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