



PRESS RELEASE

ASLAN PHARMACEUTICALS TO PRESENT POSITIVE *VARLITINIB* DATA IN FIRST-LINE BILIARY TRACT CANCER IN COMBINATION WITH CHEMOTHERAPY AT ASCO GI

- **Objective Response Rate of 60% and Disease Control Rate of 100% observed in 300mg dose cohort**
- **Data demonstrate increased activity of *varlitinib* in combination with *gem/cis* compared to standard of care**

Singapore, 15 January 2019 – ASLAN Pharmaceuticals (NASDAQ:ASLN, TPEX:6497), a clinical-stage biopharmaceutical company targeting cancers that are both highly prevalent in Asia and orphan indications in the United States and Europe, today announced positive data from an ongoing multicentre phase 1b/2 clinical trial (ASLAN001-007) of *varlitinib* plus *gemcitabine* and *cisplatin* (*gem/cis*) in first-line biliary tract cancer (BTC). *Varlitinib* in combination with *gem/cis* has been well tolerated in BTC patients and the data also demonstrate increased activity of *varlitinib* in combination with *gem/cis* compared to *gem/cis* alone. The data will be presented during a poster presentation at the upcoming American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO GI) in San Francisco on 18 January 2019.

Dr Carl Firth, Chief Executive Officer, ASLAN Pharmaceuticals, said: *“The responses we have seen with varlitinib in this clinical trial are impressive, especially when compared to historical data for the current standard of care, gem/cis for biliary tract cancer. Apart from combination chemotherapy, no progress has been made in the development of new treatment options for BTC patients. Based on these early results, varlitinib is demonstrating its potential to be the first targeted therapy in BTC, a disease with a poor prognosis.”*

As of 26 November 2018, the data cut-off date, 21 patients with advanced or metastatic BTC who had not received prior systemic therapy were enrolled in the phase 1b part of the trial. Patients received oral *varlitinib* twice daily (BID) at a dose of either 200mg or 300mg plus *gemcitabine* (1000mg/m²) and *cisplatin* (25mg/m²) on days one and eight of a three-week cycle.

16 patients completed the first cycle of chemotherapy with at least one post treatment scan and were evaluable for efficacy. Seven patients showed partial response (PR) and eight had stable disease (SD) for more than 12 weeks. The overall response rate (ORR) and disease control rate (DCR) for both cohorts were 43.8% and 93.8% respectively. In the 200 mg BID cohort, 4/11 patients achieved PR and 6/11 had SD with ORR and DCR of 36.4% and 90.9% respectively. In the 300 mg BID cohort, 3/5 patients achieved PR and 2/5 had SD with ORR and DCR of 60% and 100% respectively. These results compare favourably with the published historical results in the ABC-02 trial (Valle et. al., NEJM 2010) which reported ORR and DCR of 26.1% and 81.4% for patients dosed with *gem/cis*.

Varlitinib has been well tolerated in BTC patients treated to date. The incidence and severity of adverse events was comparable in both dose cohorts with the most frequently reported adverse events being decreases in platelet count and neutrophil count. ASLAN is continuing to recruit patients into the 300mg BID dose cohort to complete the phase 1b part of the clinical trial.

At ASCO GI, ASLAN will also present a poster on safety and efficacy data from a pooled analysis of three phase 1 clinical trials (ASLAN001-002, ASLAN001-002SG, and ASLAN001-007) of *varlitinib* in combination with various doublet chemotherapies (5-fluorouracil or *capecitabine* or *gemcitabine*) that contained a platinum-based regimen (cisplatin or oxaliplatin), in advanced BTC patients that were either: 1st line, 2nd line, 3rd line or >3rd line.



As of 26 November 2018, 43 advanced or metastatic BTC patients had been enrolled across the three clinical trials and the pooled patient safety, tolerability and efficacy data was assessed by ORR, DCR and the depth of tumour response. The analysis shows that *varlitinib* in combination with doublet chemotherapies that contain a platinum-based regimen had promising efficacy in highly advanced, metastatic BTC patients. The pooled ORR and DCR for the patients evaluable for efficacy from all three clinical trials was 33.3% and 81.5% respectively. In addition, *varlitinib* was shown to be well-tolerated at all dose levels in combination with doublet chemotherapies that contain a platinum-based regimen.

The full abstracts are available online via <https://meetinglibrary.asco.org> and copies of the posters will be available on ASLAN's website (www.aslanpharma.com) on 18 January.

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About *varlitinib* (ASLAN001)

Varlitinib (ASLAN001) is a highly potent, oral, reversible, small molecule pan-HER inhibitor that targets the human epidermal growth factor receptors HER1, HER2 and HER4. These receptors can be mutated or overexpressed in many tumors, which can cause excessive proliferative activity and uncontrolled growth. Therefore, by inhibiting the activation of the HER receptors, *varlitinib* could inhibit proliferation and control tumor growth. *Varlitinib* is currently being studied in biliary tract, breast and colorectal cancers. *Varlitinib* has been granted orphan drug designation in the United States for cholangiocarcinoma, a sub-type of biliary tract cancer, and was awarded orphan drug designation for the treatment of biliary tract cancer by the Ministry of Food and Drug Safety in South Korea.

About ASLAN Pharmaceuticals

ASLAN Pharmaceuticals (NASDAQ:ASLN, TPEX:6497) is a clinical-stage oncology-focused biopharmaceutical company developing novel therapeutics for global markets. ASLAN targets diseases that are both highly prevalent in Asia and orphan indications in the United States and Europe. Led by a senior management team with extensive experience in global and regional development and commercialization, ASLAN is headquartered in Singapore and has offices in Taiwan and China. ASLAN's portfolio is comprised of four product candidates which target validated growth pathways applied to new patient segments, novel immune checkpoints and novel cancer metabolic pathways. ASLAN's partners include Array BioPharma, Bristol-Myers Squibb, Ammirall and CSL. For additional information please visit www.aslanpharma.com.

Forward looking statements

This release and the accompanying financial information, if any, contains forward-looking statements. These statements are based on the current beliefs and expectations of the management of ASLAN Pharmaceuticals Limited and/or its affiliates (the "Company"). These forward-looking statements may include, but are not limited to, statements regarding the Company's business strategy, the Company's plans to develop and commercialise *varlitinib* for biliary tract cancer, the safety and efficacy of *varlitinib* for biliary tract cancer, the Company's plans and expected timing with respect to regulatory filings and approvals for *varlitinib* for biliary tract cancer, and the size and growth potential of the markets for the Company's product candidates. The Company's estimates, projections and other forward-looking statements are based on management's current assumptions and expectations of future events and



trends, which affect or may affect the Company's business, strategy, operations or financial performance, and inherently involve significant known and unknown risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation the risk that results of earlier studies and trials (including the results of the clinical trials described in this release) may not be predictive of future trial results, as well as the risk factors described in the Company's U.S. Securities and Exchange Commission filings and reports (Commission File No. 001-38475), including the Company's prospectus dated May 8, 2018 filed with the U.S. Securities and Exchange Commission on such date.

All statements other than statements of historical fact are forward-looking statements. The words "believe," "may," "might," "could," "will," "aim," "estimate," "continue," "anticipate," "intend," "expect," "plan," or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes are intended to identify estimates, projections and other forward-looking statements. Estimates, projections and other forward-looking statements speak only as of the date they were made, and, except to the extent required by law, the Company undertakes no obligation to update or review any estimate, projection or forward-looking statement.