



PRESS RELEASE

ASLAN PHARMACEUTICALS PROVIDES UPDATE ON TIMELINES FOR CLINICAL TRIAL OF VARLITINIB IN BILIARY TRACT CANCER IN CHINA

Management will host a conference call and webcast today, Monday, 17 September at 8:30am ET/8:30pm SGT.

Singapore, 17 September 2018 – 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 an update to its planned timelines for the ongoing single-arm clinical trial in China testing *varlitinib* plus *capecitabine* in patients with advanced or metastatic biliary tract cancer (BTC). The open-label study planned to enrol 68 patients with BTC who had progressed on at least one line of prior chemotherapy.

Based on a review of patients recruited to-date and discussions with key investigators, it was agreed that a protocol amendment should be submitted to local authorities to modify enrolment criteria and to ensure the study will provide an accurate evaluation of *varlitinib*'s efficacy. Review and implementation of the voluntary amendment is expected to take approximately 4 months. In the interim, ASLAN will continue to recruit patients into the study and provide a further update on study timelines in early 2019.

ASLAN's global pivotal study in second line BTC, TREETOPP, remains on track to complete patient enrolment in early 2019. TREETOPP is a randomised, double-blind, placebo-controlled clinical trial in second line BTC comparing *varlitinib* and *capecitabine* to placebo and *capecitabine*. If positive, data from the TREETOPP study will be used in regulatory approval submissions for *varlitinib* globally.

Patients enrolled into the second line study in China appear to have performed significantly worse, prior to recruitment, in the first line setting than observed in published global studies. In the first 27 patients enrolled, the first line response rate was approximately 7% and progression free survival (PFS) was 2.7 months. In comparison, the ABC-02¹ study that compared *cisplatin* plus *gemcitabine* to *gemcitabine* alone, the current standard of care for first line treatment of patients with advanced BTC, showed a first line response rate of 26% and PFS of 8 months for patients on *cisplatin* and *gemcitabine*.

In the 14 patients that received a 6-week scan in the study, 1 partial response and 6 patients with stable disease were reported based on site assessment. For the same 14 patients in the first line setting, there were 2 partial responses and 4 patients with stable disease.

Dr Mark McHale, Chief Operating Officer, ASLAN Pharmaceuticals said: *"Based on our team's experience developing drugs such as gefitinib and afatinib that showed differences in outcomes between US and Chinese patients, we have been monitoring the China study closely. This has allowed us to identify significant differences in the patient population compared to historical studies and take measures to ensure this study will provide an accurate evaluation of varlitinib's efficacy. Single-arm studies are inherently prone to these risks and we do not see any impact on our other ongoing placebo-controlled studies. We are working closely with some of China's leading biliary tract cancer experts to understand the differences in disease outcomes we are seeing."*

¹ [ABC-02 NEJM](#)



ASLAN Pharmaceutical's management will host a conference call and webcast for analysts and investors on Monday, 17 September at 8:30am ET/8:30pm SGT.

US: 1 866 519 4004

United Kingdom: 0808 234 6646

Singapore: +65 6713 5090

Hong Kong: 800 906 601

Taiwan: 0809 091568

Conference ID: 1148366

A live webcast of the call will be available online in the investor relations section of the company website at www.aslanpharmaceuticals.com and will be archived there for 30 days.

ENDS

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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 gastric, biliary tract, breast and colorectal cancers. *Varlitinib* has been granted orphan drug designation in the United States for gastric cancer and 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 commercialisation, 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 its product candidates, the safety and efficacy of the Company's product candidates, the Company's plans and expected timing with respect to regulatory filings and approvals, 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 factors described in the Company's US Securities and Exchange Commission filings and reports (Commission File No. 001-38475), including the Company's prospectus dated May 8, 2018 filed with the US 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.