# PRESS RELEASE

## ASLAN PHARMACEUTICALS ANNOUNCES IND SUBMISSION FOR ASLAN003 TO U.S. FDA AND CONCLUSION OF 30-DAY REVIEW PERIOD

**- ASLAN003 is an orally active, potent inhibitor of DHODH that has the potential to be first-in-class in AML**
**- Positive interim Phase 2a data for ASLAN003 in AML was presented at the 2018 ASH Annual Meeting**

**Singapore, 4 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 that the U.S. Food and Drug Administration (FDA) has concluded its 30-day review of the Investigational New Drug (IND) application for ASLAN003. The company plans to evaluate ASLAN003 in the United States as part of an ongoing Phase 2 clinical trial. ASLAN003 is a potential treatment for acute myeloid leukaemia (AML), for which the FDA has previously granted Orphan Drug Designation.

ASLAN plans to enrol patients in the United States as part of a 20-patient expansion cohort for its ongoing trial, to be conducted once an optimum dose of ASLAN003 in AML has been established. In the United States, clinical sites have been selected and we expect the clinical trial to begin in the first half of 2019. Patients will also be enrolled in the expansion cohort in Singapore and Australia, where the Phase 2a clinical trial is ongoing.

**Dr Carl Firth, CEO of ASLAN Pharmaceuticals, commented:** "We're excited to begin enrolling U.S. patients in our ASLAN003 Phase 2 clinical trial. We have been encouraged to see half of our evaluable patients recruited to date in our lower dose cohorts show signs of clinical activity. We expect our clinical trial activity in the United States and Asia to be supportive of potential approval in major markets and to fulfil our desire for a submission of a robust, comprehensive and compelling data package."

ASLAN recently presented interim data from its Phase 2a clinical trial of ASLAN003 in AML at the 2018 American Society of Hematology (ASH) Annual Meeting. As of the 16 November 2018 data cut-off, 14 patients with AML ineligible for standard treatment (including relapsed, refractory and treatment naïve) had been enrolled in the multicentre dose optimisation study to evaluate ASLAN003 monotherapy administered as a 28-day cycle. Eight patients had received at least one post-treatment assessment at the cut-off date and were evaluable for efficacy. Of the eight evaluable patients, four patients showed clinical signs of efficacy: two patients (one in the 100mg once daily [QD] cohort and one in the 200mg QD cohort) exhibited evidence of myeloid differentiation and one patient in the 100mg QD cohort developed suspected differentiation syndrome. Overall, four patients had stable disease for more than three months with ASLAN003 being well tolerated by patients.

**Ends**

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**About ASLAN003**
ASLAN003 is an orally active, potent inhibitor of human dihydroorotate dehydrogenase (DHODH) that has the potential to be first-in-class in acute myeloid leukaemia (AML). Licensed from Almirall in 2013, ASLAN has global rights for all non-topical and non-dermatological
indications. AML is a cancer of the myeloid line of blood cells, characterised primarily by the rapid growth of abnormal white blood cells that build up in the bone marrow and interfere with the production of normal blood cells. ASLAN is conducting a Phase 2 clinical trial to develop ASLAN003 in AML and also exploring other solid tumour types where DHODH may be relevant.

**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, Almirall 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 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 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.