



## PRESS RELEASE

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### **ASLAN PHARMACEUTICALS GRANTED ORPHAN DRUG DESIGNATION BY THE FDA FOR ASLAN003 FOR THE TREATMENT OF ACUTE MYELOID LEUKAEMIA**

**Singapore, 20 August 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 that the US Food and Drug Administration (FDA) has granted ASLAN003 Orphan Drug Designation (ODD) as a treatment for acute myeloid leukaemia (AML).

ASLAN003 is an orally active, potent inhibitor of human dihydroorotate dehydrogenase (DHODH) that has the potential to be first-in-class in AML. 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.

The US FDA grants orphan designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States. AML patients that have failed on standard of care chemotherapy in AML or do not respond to chemotherapy are termed relapsed/refractory and represent the majority of the total AML population. In 2016, the annual incidence of relapsed/refractory patients was approximately 13,000 patients in the United States. ODD status can provide ASLAN certain development and commercial incentives including a seven-year period of market exclusivity in the US after product approval, FDA assistance in clinical trial design and an exemption from FDA user fees.

ASLAN is currently conducting a phase 2 clinical trial in Asia to develop ASLAN003 in AML and expects to report interim data in the second half of 2018. In previous clinical studies, ASLAN003 has demonstrated potent inhibition of DHODH (up to two orders of magnitude stronger than first generation DHODH inhibitors), lack of toxicities associated with first generation inhibitors and other novel AML therapies, and the potential to induce differentiation in blast cells and applicability in a broad range of AML patients.

**ENDS**

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### **About ASLAN003**

ASLAN003 is an orally active, potent inhibitor of human dihydroorotate dehydrogenase, or DHODH, the enzyme controlling the rate limiting step in the de novo synthesis of pyrimidines, essential building blocks for the production of DNA and RNA in mammalian cells. DHODH also contributes to the production of adenosine triphosphate, or ATP. In cancer, increased levels of pyrimidines and ATP are required for tumor growth and survival. Inhibition of DHODH depletes the intracellular pool of pyrimidines and contributes to lower levels of ATP. This leads to the induction of the tumor suppressor p53, which at high levels of induction triggers apoptosis, or programmed cell death. ASLAN is currently conducting a phase 2 clinical trial in Asia to develop ASLAN003 in acute myeloid leukaemia.

### **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, Ammiral and CSL. For additional information please visit [www.aslanpharma.com](http://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.