



PRESS RELEASE

NEW DATA ON ASLAN003 PRESENTED AT ASH ANNUAL MEETING SHOWS FIRST SIGNS OF CLINICAL ACTIVITY OF A DHODH INHIBITOR IN ACUTE MYELOID LEUKAEMIA

Singapore, 3 December 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 the presentation of new positive data from the ongoing phase 2a study of ASLAN003 for the treatment of acute myeloid leukaemia (AML) at the 60th American Society of Hematology (ASH) Annual Meeting in San Diego, US.

ASLAN003 is an orally active, potent inhibitor of dihydroorotate dehydrogenase (DHODH) that has the potential to be first-in-class in AML. As of 16 November 2018, 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 8 evaluable patients, 4 patients showed clinical signs of efficacy: 2 patients (1 in the 100mg once daily [QD] cohort and 1 in the 200mg QD cohort) exhibited evidence of myeloid differentiation and 1 patient in the 100mg QD cohort developed suspected differentiation syndrome. Overall, 4 patients had stable disease for more than 3 months.

ASLAN003 has been well tolerated in patients treated to date. The most commonly occurring related adverse events were leukocytosis, nausea and rash, with grade 3 / 4 leukocytosis in 1 patient. The study contains 4 cohorts for the optimum dose determination (100 mg, 200 mg QD, and 100 mg, 200 mg BID with planned enrolment of 6 patients for each cohort), and an additional expansion cohort with the selected optimum dose (20 patients).

Dr Carl Firth, CEO of ASLAN Pharmaceuticals, commented: *“This study is the first time that a DHODH inhibitor has been tested in this subset of AML patients and we are encouraged to observe signs of clinical activity and safety, even at the lowest dose, in patients who have limited treatment options and poor clinical outcomes. We continue to dose cohorts and hope to see further promising signs of efficacy as we optimise the dose.”*

AML is a rapidly progressing blood cancer that is characterised by the uncontrolled proliferation of immature blast cells in the bone marrow. The five-year cancer survival rate for AML patients is 26.9%¹. The majority of AML patients relapse or present with refractory disease and have overall poor prognosis².

The primary outcome of the phase 2a study is to determine the optimum monotherapy dose of ASLAN003 and provide a preliminary estimate of efficacy evaluated by overall complete remission rate (OCRR). A phase 1 trial showed that ASLAN003 demonstrated dose proportional pharmacokinetics and was safe and well tolerated in healthy volunteers compared to the side effect profiles of existing AML induction and maintenance chemotherapies. 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. The US Food and Drug Administration has granted ASLAN003 Orphan Drug Designation as a treatment for AML.

¹ [National Cancer Institute](#)

² [Szer, J. ASH. The prevalent predicament of relapsed acute myeloid leukemia](#)



ASLAN will also present new data from a preclinical study evaluating the effects of ASLAN003 on cell growth, differentiation, apoptosis, and gene expression changes in AML cell lines and primary bone marrow cells from patients with AML.

Posters presented at ASH:

Poster Number: 2676

Abstract Title: *Preliminary Results of a Phase 2a Dose Optimization Study of ASLAN003 (DHODH inhibitor) in Acute Myeloid Leukemia (AML) Patients Who Are Ineligible for Standard Therapy; Early Signs of Activity*

Session Title: 613. Acute Myeloid Leukemia: Clinical Studies: Poster II

Date/Time: Sunday, December 2, 6:00 PM - 8:00 PM PST

Location: San Diego Convention Center, Hall GH

Poster Number: 4047

Abstract Title: *ASLAN003, a Novel and Potent Dihydroorotate Dehydrogenase (DHODH) Inhibitor, Induces Differentiation of Acute Myeloid Leukemia*

Session Title: 616. Acute Myeloid Leukemia: Novel Therapy, excluding Transplantation: Poster III

Date/Time: Monday, December 3, 6:00 PM - 8:00 PM PST

Location: San Diego Convention Center, Hall GH

Copies of the posters presented at ASH will be available to download from the Publications section of ASLAN's website.

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About ASLAN003

ASLAN003 is an orally active, potent inhibitor of 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 (ASLAN, 6497.TT, Nasdaq: ASLN) 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 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.