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ASLAN reports Q1 2019 financial results

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ASLAN Pharmaceuticals, a clinical stage oncology and immunology focused biopharmaceutical company developing novel therapeutics for global markets, today reported financial results for the quarter ended 31 March 2019 and provided an update on its clinical activities.

Corporate updates

- In February, ASLAN entered into an agreement with BioGenetics Co Ltd that granted exclusive commercialisation rights for *varlitinib* in all indications in South Korea. ASLAN received an upfront payment of US$2 million and can receive up to US$11 million in sales and development milestones. ASLAN is also eligible to receive tiered royalties on net sales from the high-teens to the mid-twenties range.
- In March, ASLAN entered into a second agreement with BioGenetics Co Ltd that granted exclusive commercialisation rights for ASLAN003 in all indications in South Korea. Under terms of the agreement, ASLAN received an upfront payment of US$1 million and is eligible to receive up to US$8 million in sales and development milestones. ASLAN is also eligible to receive tiered royalties on net sales from the high-teens to the mid-twenties range.

First quarter 2019 financial results

- Cash used in operations for the quarter ended 31 March 2019 was US$7.2 million compared to US$10.0 million in the same period in 2018.

- Research and development (R&D) expenses were US$4.4 million and general and administrative (G&A) expense was US$2.3 million for the first quarter of 2019, compared to US$5.6 million and US$2.8 million, respectively, in the same period in 2018. The decrease in R&D expense was due to the completion of clinical studies and lower manufacturing expenses. The decrease in G&A expense was the result of the restructuring implemented in January 2019.

- Net loss for the first quarter of 2019 was US$4.3 million compared to a net loss of US$8.7 million for the first quarter of 2018. The narrower loss in the first quarter of 2019 was due primarily to recognition of the US$3 million upfront payment from the licensing agreements with BioGenetics Co Ltd and lower operational costs.
- Cash, cash equivalents and short-term investments totaled US$21.6 million as of 31 March 2019 compared to US$28.9 million as of 31 December 2018. Weighted average shares outstanding for the first quarter of 2019 was 160.2 million compared to 130.2 million for the first quarter of 2018. One American Depositary Share is the equivalent of five ordinary shares.

First quarter 2019 and recent business highlights

Clinical development

Varlitinib

- The *varlitinib* global pivotal TreeTopp (TREatmEnt OPPortunity) study completed patient enrolment ahead of schedule with the recruitment of 127 patients with biliary tract cancer (BTC) who failed first line therapy from 56 sites worldwide including the US, Europe, Australia, Japan, Korea, and other Asia Pacific countries. The trial is ongoing and proceeding according to plan.
- In January, positive *varlitinib* data was presented in first-line biliary tract cancer in combination with chemotherapy at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO GI). The data demonstrated a response rate of 44% across all evaluable patients and a 60% response rate in the highest dose cohort, compared to historical rates of 26% with current standard of care treatment.

ASLAN003

- Completed the third cohort (100mg BID) in phase 2a trial testing ASLAN003 in acute myeloid leukemia (AML). Six patients recruited into the fourth cohort (200mg BID). All patients are currently ongoing.

ASLAN004

- Completed the first part of the phase 1 single ascending dose (SAD) study testing the intravenous formulation of the first-in-class therapeutic antibody ASLAN004 in healthy volunteers. ASLAN004 is a fully human monoclonal antibody that binds to the IL-13 receptor ?1 subunit (IL-13R?1), blocking signalling of two pro-inflammatory cytokines, IL-4 and IL-13, which are central to triggering symptoms of atopic dermatitis, such as redness and itching of the skin. Analysis of downstream mediators demonstrated complete inhibition within one hour of dosing, which was then maintained for more than 29 days, suggesting monthly dosing may be achievable.
- Last patient dosed in the second part of the ongoing SAD trial on 27 March. ASLAN is testing a subcutaneous formulation and expects to report data from this part of the study in May. Initiation of a multiple ascending dose study in patients with moderate to severe atopic dermatitis is planned for the second half of 2019.

Dr Carl Firth, Chief Executive Officer, ASLAN Pharmaceuticals, said: "I am pleased with the pace of our accomplishments so far in 2019 and anticipate the achievement of additional key milestones later in the year. As reported, we completed recruitment for our pivotal study testing *varlitinib* in biliary tract cancer ahead of schedule and remain on track to report topline results in the second half of this year. Dosing of the fourth cohort in our phase 2 trial testing ASLAN003 in acute myeloid leukemia is continuing. In addition, we have completed dosing in the single ascending dose study of ASLAN004 and are on track to move into a multiple ascending dose study in patients with atopic dermatitis with this differentiated product candidate in the second half of 2019."

Anticipated upcoming milestones

- Topline global pivotal trial (TreeTopp) data on *varlitinib* as second line treatment for biliary tract cancer in the second half of 2019.
- Part 1 readout of ASLAN003 phase 2 trial in the second quarter of 2019.
- Completion of single ascending dose trial for ASLAN004 in atopic dermatitis in the second quarter of 2019.
- Initiation of a multiple ascending dose trial for ASLAN004 in patients with moderate to severe atopic dermatitis in the second half of 2019.