Phase 2a Intratumoral Large Surface Area Microparticle Paclitaxel in Stage 3/4 Lung Cancer

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Results

• Median volume of tumor injected was 13.1cm³ (range 1.9-483.5cm³) and median volume of LSAM-PTX injected was 1.7ml (range 0.26-41.7ml). Disease Control Rate (CR + PR + SD per RECIST) for evaluable subjects at 3- and 6-months were 80% (8/10; 3 un evaluable) and 86% (6/7; 2 un evaluable), respectively.

• Eleven subjects received concurrent therapies including systemic chemotherapy (9), immunotherapy (9), and radiotherapy (1). Overall Survival at 3-, 6-, and 12-months post treatment initiation was 71% (12/17), 47% (8/17), and 25% (4/16; 1 LTFU), respectively.

• LSAM-PTX was well tolerated. There were a total of 217 TEAEs, of which 22 (15 systemic, 7 local) were possibly related to LSAM-PTX (Grade 1 - 9, Grade 2 - 12, Grade 4 - 1). There were 23 SAEs across 12 subjects, of which 1 was possibly related to LSAM-PTX. Of the 217 reported adverse events, one (0.5%) Grade 4 event of pulseless electrical activity was considered possibly related to LSAM-PTX administration and no TEAEs were considered definitely related to LSAM-PTX.

• Immunophenotyping of peripheral blood found no significant changes in absolute lymphocyte Tregs and immune suppressor cells, and complement systemic therapy without significantly increasing adverse events.

• Following up to three IT LSAM-PTX administrations, plasma pharmacokinetic analysis found low systemic paclitaxel exposure with dose proportionate increases and no apparent systemic accumulation, which is consistent with clinical trials of IT LSAM-PTX in other solid tumors.

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