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Exicure announces dosing of first patient in Ph1b/2 immuno-oncology trial

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Exicure, a clinical stage biotechnology company developing a new class of immunomodulatory and gene regulating drugs and a pioneer in gene regulatory and immunotherapeutic drugs utilizing spherical nucleic acid (SNA) constructs, announced today that it has dosed the first patient in its multicenter, open-label, Phase 1b/2 study of AST-008 combined with pembrolizumab. Enrollment in the trial is open to patients with superficial injectable tumors in advanced or metastatic solid tumor conditions including Merkel cell carcinoma, head and neck squamous cell carcinoma, cutaneous squamous cell carcinoma and melanoma.

“We believe that combining our immune system agonist drug with checkpoint inhibitors is an important strategy for leveraging the patient’s own immune system to fight cancer. We are excited to bring this approach into cancers like Merkel cell carcinoma, where patients have limited success using currently available treatments,” said Exicure CEO Dr. David Giljohann. “It is also an important milestone for Exicure in the development of our platform technology, which allows us to digitally design drug candidates and potentially bring them into clinic faster.”

The primary objective of the Phase 1b dose escalation stage is to assess the safety and tolerability of Exicure’s AST-008 drug alone and in combination with pembrolizumab, and to determine a dose for the Phase 2 stage of the study. Patients in the dose escalation stage may have previously been exposed to antibody checkpoint inhibitors, but not as a requirement for inclusion in the trial. In the Phase 2 portion of the study, Exicure will further evaluate AST-008 in combination with pembrolizumab in patients who have previously received but not responded to anti-PD-1 or anti-PD-L1 antibody therapy.

AST-008 is a toll-like receptor nine (TLR9) agonist oligonucleotide in a proprietary SNA format with immune-stimulatory properties. SNAs are dense, radial arrangements of nucleic acids (DNA) that have high cellular uptake and an enhanced presentation of the DNA for TLR9 agonism. AST-008 is designed to enter into and activate immune cells to elicit an immune response to treat solid tumors in combination with other agents such as checkpoint inhibitors. We observed that AST-008 showed potent antitumor activity as a monotherapy and synergized with anti-PD-1 antibodies in multiple preclinical tumor models. In a successful Phase 1 trial in healthy volunteers, AST-008 activated key immune cells and cytokines predictive for an anti-tumor effect in patients.