Ascend Biopharmaceuticals completes ASN-002 Nodular Basal Cell Carcinoma (nBCC) Trial, key regulatory milestones and recruits US Clinical Advisors

Melbourne, Australia, December 14, 2017 – Ascend Biopharmaceuticals Ltd, a clinical stage immuno-oncology company developing novel cancer treatments, announced the completion of its dose escalation phase 1/2 clinical trial in nodular basal cell carcinoma patients treated with ASN-0021. The study included both sporadic BCC and Gorlin Syndrome or Basal Cell Nevus Syndrome (BCNS) patients and reported excellent clinical outcomes. Overall, histological clearance rates in both the intermediate and high dose cohorts were 83% (5/6 eligible patients in each of the intermediate and high dose cohorts). Lesions that did not result in complete histological clearance had partial responses and evidence of on-going regression in excision biopsies. The overall response rate for this study was therefore 100% (ORR – histological clearance/complete response or partial responses). In addition, abscopal regression was also observed in patients with multiple lesions. Five patients on study had greater than one BCC comprising a total of 20 non-treated lesions of which 70% (14/20) showed clinically measurable regression. Overall ASN-002 was reported to be well tolerated in all cohorts.

Ascend has also been granted an Orphan Designation for ASN-002 to treat BCNS patients and has an active IND with the FDA allowing the company to commence clinical studies in the United States (US) planned for 2018. The company has also completed a Type C meeting with the FDA in November and has received important guidance on the design and endpoints acceptable to the FDA for a BCNS registration study.

Ascend has expanded its US clinical advisors ahead of planned late stage US studies, to include Drs George Hruza, Bruce Smoller and Murad Alam. Dr. George Hruza has an MD from New York University and fellowship at Harvard Medical School. He is president-elect of the American Academy of Dermatology and clinical professor of dermatology and otolaryngology at St. Louis University. Dr. Bruce Smoller has an M.D. from University of Cincinnati and is currently the chair and professor, Department of Pathology at the University of Rochester School of Medicine and Dentistry. Dr. Murad Alam received his MD from Yale University and training at Columbia University and Harvard Medical School and is Professor of Dermatology and Chief of Cutaneous and Aesthetic Surgery at Northwestern University. Dr Alam is on the Board of Directors of the American College of Mohs Surgery.
About Ascend Biopharmaceuticals

Ascend is a cancer immunotherapy company developing medicines to treat local and metastatic cancers. The company has a near term pipeline focused on cutaneous cancers that need improved treatment options and a medium-term objective to develop combination immunotherapies that can both induce a potent immune response and alter the local tumor microenvironment to engender clinical benefit in advanced cancer patients.

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