Ascend Biopharmaceuticals Announces Encouraging Phase I/IIa Interim Results of ASN-002 Treatment of Nodular Basal Cell Carcinoma (nBCC)

Overall objective response rate for medium and high dose cohorts was 100%

Melbourne, Australia, November 7, 2016 – Ascend Biopharmaceuticals Ltd, a clinical stage immuno-oncology company developing novel cancer treatments, today announced interim results from the first nine patient of its Phase I/IIa clinical trial evaluating the safety and clinical activity (as measured by clinical and histological clearance) of its lead candidate, ASN-002. The study is evaluating three escalating doses in nodular basal cell carcinoma (nBCC) patients, a common type of skin cancer.

The results showed that the treatment has a favorable safety profile and demonstrated encouraging signs of efficacy. The complete response (CR) rate in the high dose cohort was 100%. In the second medium dose cohort, 67% of patients achieved a CR with 33% achieving a partial response. The overall objective response rate observed for the medium and high doses was 100% and at the lowest dose administered, 33% of patients achieved a CR.

"The interim data shows a favorable safety profile and a clinical signal supportive of efficacy in nBCC patients," stated Dr. Clement Leong, CEO of Ascend Biopharmaceuticals. "Currently, there is no therapeutic approved for the treatment of nBCC, a common form of skin cancer and there is an opportunity for an alternative to surgery to address this important clinical need. Additionally, in these preliminary results, a patient with multiple lesions had regression of several non-injected lesions. We are encouraged by this development and the potential to treat patients with multiple lesions, such as those with Basal Cell Nevus Syndrome. Such patients develop many BCCs over their lifetimes."

Rodney Sinclair, MBBS, M.D., Professor of Medicine at the University of Melbourne, Director at Sinclair Dermatology and a principal investigator in the study said, "There is significant need for a new non-surgical treatment for nBCC. ASN-002 is an attractive potential therapeutic candidate. Basal cell carcinoma is the most common form of cancer worldwide. More than 3 million patients are diagnosed with BCC annually.

Nearly 2 million of those are diagnosed with nodular basal cell carcinoma. The prognosis is good if diagnosed early and surgically excised, but if left untreated, nBCC can cause significant morbidity and disfigurement. It is estimated that approximately 25-30% of patients with nBCC which is common in the elderly, are poor candidates for surgery due to age, other co-morbidities and the fact that they generally develop multiple primary nBCCs. Even those who are good candidates for surgery would welcome an effective non-surgical treatment alternative."

The trial is designed to assess the safety, tolerability and response of intra-tumoral injections of ASN-002 in 24 adult patients with nodular basal cell carcinoma. The trial design includes 3 cohorts where escalating doses of ASN-002 were administered via injection into the tumor. All cohorts received one injection per week for three weeks with follow-up visits at weeks 4, 8, 12 and 16. The primary endpoints for all cohorts are clinical and histological clearance and overall safety.

Ascend Biopharmaceuticals licensed ASN-002 from French biopharmaceutical company, Transgene, in 2013, with an exclusive world-wide license agreement to develop ASN-002 for multiple cancers including skin cancers and cutaneous B-cell lymphoma, CBCL (a B-Cell lymphoma that involves the skin).

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About Ascend Biopharmaceuticals

Ascend is a cancer immunotherapy company developing medicines to treat primary, recurrent and metastatic cancers. Ascend applies a number of different technologies and approaches utilizing viral vectors, and affinity agents that can be conjugated to deliver biologicals and small molecule (immune modulators or chemotherapeutics) payloads. We believe that applying a combination chemo-immunotherapeutic approach has the potential to materially improve therapeutic outcomes.

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