Nashoba Biotechnology, LLC

Overview

Immunotherapies are revolutionizing cancer treatment and outcomes. Approved drugs targeting the immune status of the tumour are already commanding billion-dollar markets. This latest evolution in this class of drugs has been termed "Immunotherapy 2.0" by the American Society of Clinical Oncology and features a set of therapies known as immune checkpoint inhibitors (ICIs). These drugs reactivate anti-tumor immune responses, for example "releasing the brakes" on T-cells in the suppressive environment of a tumor.

Most significantly, ICIs have achieved clinical results rarely seen before in cancer therapy: long term survival that is remarkably durable in patients with a wide variety of tumors. However, only a fraction of treated patients achieved these durable responses - generally only 20 to 30%. As a result, a major effort is underway to increase this fraction of durably responding patients by combining ICIs with other drugs whose mechanisms of action are complementary.

Nashoba Biotechnology, LLC is re-developing a clinical stage cancer therapeutic that has shown efficacy in early stage phase II clinical trials in metastatic renal cancer. There is now emerging evidence that when used in combination with approved immunotherapies, such as anti-VEGF antibodies or ICIs, Nashoba Biotech's NB-0039 will increase the durable response rates of these agents by precision editing of the tumor microenvironment. Thus, NB-0039 is a "helper drug" that assists approved therapeutics in achieving better clinical outcomes in cancer.

Nashoba seeks an initial investment of $30 million to complete step 1 with subsequent investment of an additional $70 million to complete step 2.

NB-0039 is a small molecule drug candidate that is orally available and well tolerated. Nashoba has acquired the regulatory files supporting the early phase II clinical trials and recruited a management team and advisors that include the people driving the original clinical program. The enzyme target of NB-0039, as well as downstream enzymes, have been shown to be independent prognostic indicators of overall survival in patients with cancer.

During the first two years of operation, Nashoba will establish pre-clinical proof-of-concept (POC) with a combination of NB-0039 and multiple, approved ICIs and other immunotherapies, such as Avastin and Keytruda. Nashoba will initiate discussions with the FDA to submit an IND for NB-0039 in phase II clinical trials in combination with approved ICIs for metastatic renal cancer. On approval of the IND Nashoba will, during the third, fourth, and fifth years of operation, conduct clinical trials sufficiently powered to establish the enhanced efficacy (durable OS) of the ICI when used with NB-0039.

Estimated costs of achieving these valuation inflection points are:

1. Preclinical POC of multiple combination therapies, companion Dx development, expansion of IP estate, updating CMC package, formulation development, advancing 2nd generation -0039 analogs, and filing of an IND for a phase II clinical trial of a combination of NB-0039 with an approved immunotherapeutic – $30 million
2. Completion of phase II clinical trials in metastatic renal cancer & allied activities and filing an IND for a 2nd clinical trial of a combination of NB-0039 with another ICI or anti-angiogenesis factor – an additional $70 million

Valuations of drug candidates successful in phase II clinical trials in cancer can exceed $750M.

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