



Northern Biologics Reports Phase I Data Update for MSC-1, an anti-LIF antibody, at ESMO

Toronto, Canada and Boston, USA - September 27th 2019

Northern Biologics Inc., a company focused on developing first-in-class oncology products, today announced the presentation of updated Phase 1a trial results of its lead antibody, MSC-1, at the European Society for Medical Oncology (ESMO) Congress in Barcelona, Spain.

MSC-1 is a humanized antibody against a soluble cytokine called LIF (see “About LIF” below). LIF plays a multi-faceted role in cancer, and antagonism of this molecule opens up two therapeutic avenues: reversal of tumor immunosuppression and modulation of cancer initiating cells (CICs) to promote tumor cell differentiation and sensitivity to chemotherapy.

The open-label, Phase 1a, dose escalation trial in the U.S., Europe and Canada is testing MSC-1 as monotherapy to determine safety and tolerability in patients with relapsed or refractory advanced solid tumors. The study completed enrollment in early March, with 41 patients enrolled in nine months, in dose cohorts ranging from 75 mg to 1,500 mg Q3W. The treatment was well-tolerated with no dose-limiting toxicities or tolerability issues observed at any dose. In addition, MSC-1 demonstrated a favorable PK profile, typical of an antibody. Durable saturation of peripheral LIF in a pharmacodynamic assay in patients supported the selection of the recommended Phase 2 dose for further development.

Prolonged stable disease (>16 weeks) was observed in nine patients, with five of these patients demonstrating progression-free survival with MSC-1 treatment longer than their most recent prior cancer therapy regimen. Finally, exploratory biomarker analysis of paired pre- and on-treatment tumor biopsies demonstrated a shift in macrophage populations in the tumor microenvironment to a more immunostimulatory phenotype, inhibition of STAT3 phosphorylation in the majority of patients, as well as increased CD8 T-cell infiltration in a subset of patients, supporting the proposed mechanism of action of MSC-1.

“The excellent safety profile of MSC-1 and the data from the Phase 1a study support the continued clinical development of MSC-1, and testing in combination with checkpoint inhibitors and chemotherapy,” said Erkut Borazanci M.D., M.S., Clinical Investigator at HonorHealth Research Institute. “We are excited to describe the effects of this first-in-class anti-LIF antibody on key biomarkers in the tumor microenvironment which are



consistent with the promotion of anti-tumor inflammation. We believe this molecule has the potential to bring benefit to individuals with cancer.”

“The encouraging clinical evidence of the effect of MSC-1 on the tumor microenvironment in heavily pre-treated patients, coupled with exciting preclinical data including recent publications in *Nature*, increase our conviction that targeting LIF can bring therapeutic benefit to cancer patients,” said Philip Vickers, Ph.D., CEO of Northern Biologics.

Poster Display Session 3 (ID 212). Session Date and Time: Monday, September 30th, 2019 12:00 PM - 1:00 PM Session Location: Poster Area (Hall 4), Fira Gran Via, Poster 1196P, Abstract 1950

About LIF

LIF, or leukemia inhibitory factor, is an exciting emerging target in the immuno-oncology space. Northern Co-Founder Joan Seoane first elucidated a role for the cytokine in cancer in a seminal 2009 publication in *Cancer Cell*. Since that time, several independent labs have demonstrated the role of LIF in many cancers including 3 recent publications in *Nature* (Shi et al. *Nature*. 2019, Pascual-Garcia et al. *Nat Commun*. 2019 and Wang et al. *Nat Commun*. 2019). LIF is hypothesized to contribute to tumor growth and progression by acting on multiple aspects of cancer biology, including immunosuppression within the tumor microenvironment (TME), and regulation of cancer initiating cells (CICs), which are thought to underpin tumor growth, metastasis and resistance to therapy.

About Northern Biologics

Northern Biologics was launched in June 2014 from Blueline Bioscience, a Canadian biotechnology incubator operated by venture capital firm Versant Ventures, in partnership with the University of Toronto and University Health Network’s Princess Margaret Cancer Centre. Headquartered in the MaRS Discovery District of Toronto, the company is developing a portfolio of antibody-based therapeutics based on relevant targets in the tumor microenvironment. Learn more at northernbiologics.com.

Media contact:

Steve Edelson

Versant Ventures

415-801-8088

sedelson@versantventures.com