



Northern Biologics Reports Initial Phase I Data for MSC-1 at AACR

Toronto, Canada, March 29, 2019

Northern Biologics Inc., a company focused on developing first-in-class immuno-oncology products, today announced the presentation of [initial results](#) from the Phase I trial of their lead antibody, MSC-1, at the American Association for Cancer Research meeting in Atlanta, Georgia.

Session Title: Phase I Clinical Trials: Part 1

Session Date and Time: Sunday Mar 31, 2019 1:00 PM - 5:00 PM

Session Location: Georgia World Congress Center, Exhibit Hall B, Poster Section 16

Poster Board Number: 9

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 as a result of inhibiting the target 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, dose-escalation, dose-expansion Phase I trial in the U.S., Europe and Canada is testing MSC-1 as monotherapy in patients with relapsed or refractory advanced solid tumors. The primary objectives of the dose escalation part of the study are to evaluate the safety and tolerability of MSC-1 and determine the recommended dose for MSC-1 monotherapy in dose expansion. Secondary and exploratory objectives include assessing progression-free survival and characterizing the pharmacodynamic effects of MSC-1 in peripheral blood through stabilization of LIF levels and in tumor biopsies as measured by changes in the tumor microenvironment and cell signaling.

The dose escalation portion of the study completed enrollment in early March, with 41 patients enrolled in 9 months, in dose cohorts ranging from 75 mg to 1,500 mg. This includes expanded escalation cohorts being evaluated for additional safety, PK/PD and biomarker analyses, including studying the tumor microenvironment in matched pre- and post-treatment tumor biopsies. There have been no dose-limiting toxicities or tolerability issues observed at any dose.

Six patients have been treated for 16 weeks or longer. Moreover, some patients displayed decreases in tumor biomarkers CA19-9 and CA125. MSC-1 has shown a favorable PK profile, typical of an antibody, and evidence of durable peripheral LIF stabilization.



“We are pleased with the preliminary safety profile of MSC-1 in this trial that has enrolled patients at a very rapid pace,” said Joan Seoane, Ph.D., ICREA Professor and Director of Translational Research at Vall d'Hebron University Hospital's Institute of Oncology (VHIO). “We are excited to report on the effect of this first-in-class molecule on multiple measures in hopes of bringing benefit to patients with advanced cancers.”

“These clinical results, coupled with exciting preclinical data, increase our conviction that targeting LIF can bring therapeutic benefit to defined populations of cancer patients,” said Philip Vickers, Ph.D., CEO of Northern Biologics. “We now have a deep understanding of the biology underlying our first-in-class antibody.”

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. 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.

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