

Development of GMP-Grade Anti-Nectin-4 Radioimmunoconjugates, and Clinical Trial Enabling Studies for Phase 1 Trial Against Nectin-4 Positive NSCLC and TNBC

Project duration: 2025-3-1 to 2028-2-29

Targeted cancer type:

Triple negative BC (TNBC) and non-small cell lung cancer (NSCLC)

The team will be conducting enabling studies for the clinical-grade development of their novel radiolabeled antibody targeting Nectin-4 for ultimate use in a Phase 1 clinical trial.

5
Partners



Canadian Nuclear Laboratories

Laboratoires Nucléaires Canadiens



CIHR
IRSC

Canadian Institutes of Health Research
Instituts de recherche en santé du Canada



National Research Council Canada

Conseil national de recherches Canada

Key Investigators:

Project lead:

Dr. Humphrey Fonge



Biotherapeutic:
Antibody

Project value:

\$3,137,450

BioCanRx Contribution:

\$730,000

About the project:

Triple negative BC (TNBC) and non-small cell lung cancer (NSCLC) are two of the leading causes of cancer deaths indicating more effective treatments are in urgent need.

Nectin-4 is a protein that is overexpressed in many cancers including in 60-70% of TNBC and 60% of NSCLC, and no radiotherapeutics targeting this antigen have been reported. The team has developed novel radiolabeled antibody targeting Nectin-4 and showed it is effective against these cancers in mice. In addition, the radiolabeled antibody was

even more effective when combined with an immune checkpoint inhibitor (ICI). After treatment with the radiolabeled drug and ICI, mice rejected engraftment when re-challenged with same cancer cells, indicative of adaptive immunity. The team's goal is to produce clinical-grade drug product and conduct a Phase 1 trial. The ultimate milestones are to develop "research cell bank", "master cell bank", clinical-grade anti-Nectin-4 antibody and radiolabeled antibody conjugates that meet regulatory

guidelines. The deliverables include chemistry manufacturing control (CMC) of the drugs and a phase 1 trial package.

This "homemade" radiolabeled anti-Nectin-4 antibody with a market potential >\$15B can result in unprecedented socioeconomic benefits.



Partners:

Canadian Nuclear Labs

CHU de Quebec
(Cyclotron Facility)

Center for Probe Development
and Commercialization

CIHR

National Research Council
of Canada

Total Pledged Partner Contributions: \$1,857,450

Total Pledged Matched Contributions: \$250,000 Total

Total Leveraged Partner Contributions: \$1,607,450

Key Deliverables

1. Research cell bank and master cell bank characterization reports
2. Chemistry Manufacturing Control (CMC) of final drug substances of the anti-Nectin-4 antibody
3. CTA package CMC of the diagnostic and radio therapeutic agents

The power to kill cancer lies within us. Let's tell our bodies how.