

Enabling Studies Program

Advanced preclinical development of the oncolytic vaccine platform to prepare requirements for a clinical trial of patients with HPV-associated cancers

July 1, 2015 to Mar. 31, 2017 **Highlights** · Potential to put BioCanRx on the international landscape \$462,264 for oncolytic virus from BioCanRx clinical trials new cases of these cancers • Builds upon considerable in 2015 expertise to orient the Canadian-made oncolytic vaccine platform for the treatment of HPV-\$85,000 \$300,000 positive cancers \$60,000 · High likelihood the BioCanRx network will successfully move this deaths from these program into clinical cancers in 2015 \$120,000 trials Ontario HPV-E6/E7 MG1 Maraba/HPV-E6/E **About the project** oncolytic virus Human Papilloma Virus (HPV) causes about 5% of the world's cancer burden and every year it results in more than 250,000 deaths globally. While virtually all cases of cervical cancer can be attributed to prior infection by HPV, we are now learning that this virus can cause other cancers. In fact, head and TURNSTONE neck cancer is often caused by HPV and there are more of these HPV-associated (HPV+) cases diagnosed each year in North America than cervical cancer. This project proposes using another virus, called Maraba, to attack and kill HPV+ cancer. The very fact that these cancers are caused by a virus makes them more sensitive to killing by the therapeutic Maraba virus. More importantly, the cancer-killing Maraba virus is also designed to educate the patient's own immune system, teaching it to find and kill any cancer cells that the Key in Ke Maraba virus is unable to kill directly. This combination of attack by Maraba and by the patient's immune system may be able to significantly benefit patients with this class of cancers when other therapies have failed. Funding for this project will enable the final steps required before the clinical testing of this new therapy can proceed in Canadian cancer patients. Dr. Brian The technology being advanced represents a highly promising new twist on cancer immunotherapy that brings together oncolytic viral and viral-vectored vaccine technologies in a way that has led to unprecedented T-cell responses in rodent and non-human primate studies. This Enabling Study will allow the team to complete work that has traditionally proven the most difficult to fund, namely preclinical animal testing and GMP manufacturing. Specifically, the project

team will conduct the required preclinical animal testing and manufacturing of the GLP and GMP toxicology study lots, master virus banks (MVB) and bulk drug product that are required to complete

and submit a clinical trial application (CTA) to Health Canada.

