

**Non-technical Abstract of Protocol AGS-004-001**

Argos Therapeutics, Inc, a biotech startup company, is developing a cellular therapy based on proprietary technology (Arcelis™) for HIV infection. The purpose of this current study is to find out what effect the immunotherapy product Arcelis™ for HIV, AGS-004, has on the amount of HIV virus in the blood of infected individuals, as well as to assess whether it is well tolerated in subjects. Argos manufacturing and clinical protocols are subject to review and approval by ethics committees and regulatory bodies, such as the FDA and Health Canada. Argos is gathering all necessary approvals from these bodies and is in compliance with all applicable associated regulations.

The Arcelis™ product is custom-made for each subject since it uses each subject's own white blood cells as well as some of each subject's blood to prepare the cell therapy product. The Arcelis™ product may help the subject's own immune system/body to fight the HIV infection. Special white blood cells, called dendritic cells, are collected from each subject by a process called leukapheresis, which is similar to giving blood. When these special cells are mixed with the subject's own viral material, the dendritic cells may learn to fight the infection specific for that subject. After mixing, these cells are injected back into the body where they may train other cells to find and kill infected cells. To make the product, a short-lived labile material, ribonucleic acid (RNA), is purified from each subject's blood sample, and 4 specific HIV RNAs, Gag, Vpr, Rev and Nef, are converted to another form of genetic material called deoxyribonucleic acid (DNA) that is then used to make a larger quantity of the RNA. In addition, another RNA, called CD40L RNA, is prepared from recombinant DNA and is added it is known to have the potential to stimulate the immune response. The RNAs are kept frozen and can be used to produce several batches of Arcelis™ product if necessary.

The subject's white blood cells collected during leukapheresis are grown in sterile containers at the Argos facility to produce dendritic cells. These cells are then mixed with the RNAs. The resulting subject specific product is called Arcelis™ and is stored frozen at Argos in single dose vials. A single vial is then shipped to the clinical site for each scheduled dosing visit. Subjects will receive 6 doses injected into their skin during the first 6 months followed by a booster every 3 months, which can continue until confirmation that the virus is replicating again. Subjects are also carefully monitored for safety and any associated immune response by taking small amounts of blood throughout the study. The use of the Arcelis™ technology allows subject specific treatment targeted directly to each subject's own viral infection and if successful will lead to the availability of well-tolerated patient-specific anti-HIV therapies that may limit the necessity for taking other anti-HIV daily medications.