

**Non-technical Abstract of Protocol AGS-003-006**

Argos Therapeutics, Inc, a biotech startup company, is developing a cell-based therapy based on proprietary technology (Arcelis™) for metastatic kidney cancer. Metastatic kidney cancer is kidney cancer that has spread to other parts of the body outside of the kidney. The purpose of this current study is to find out what effect the immunotherapy product, Arcelis™, has on metastatic kidney cancer (called renal cell carcinoma) as well as to assess whether it is well tolerated in patients who are also receiving a tyrosine kinase inhibitor, a drug approved by FDA to treat this condition. 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 has gathered 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 tumor to prepare the cell therapy product. The Arcelis™ product may help the subject's own immune system/body to fight the tumor cells from their kidney cancer. 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 tumor material, the dendritic cells may learn to fight the cancer cells specific for that subject. After mixing, these cells are injected back into the body where they may train other cells to find and kill cancer cells. To make the product, a short-lived labile material, ribonucleic acid (RNA), is purified from each tumor sample and converted to another form of genetic material called deoxyribonucleic acid (DNA) that is then used to make a larger quantity of the tumor RNA than could be purified from the tumor itself. In addition, another RNA, called CD40L RNA, is prepared from recombinant DNA and is added to the tumor RNA because CD40L 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 tumor RNA and with the CD40L RNA. 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 5 doses injected into their skin during the first 6 months followed by a booster every 3 months, which can continue until confirmation that the tumor has either responded or that it has started growing again (i.e., disease progression). 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 patient specific treatment targeted directly to each patient's own tumor and, if successful, will lead to the availability of well-tolerated patient-specific anti-tumor therapies that could be utilized throughout the anti-cancer therapeutic spectrum.