

Frequently Asked Questions about Genetic-Engineered Tumor Cell Vaccine Research Study

A Phase 1-2 Study for Stage IV Breast and HER2/neu Positive Cancers to Evaluate the Safety and Efficacy of a Vaccine Using Whole Cells from the SV- BR-1-GM Cell Line Genetically Engineered To Produce Granulocyte-Macrophage Colony Stimulating Factor

1. How is the vaccine made?

Tumor cells were collected from a breast cancer patient. The cells were modified to produce GM-CSF, a biological medication widely used to stimulate the bone marrow production of white blood cells. The tumor cells are grown in special flasks and frozen. Just before use, the cells are thawed, the cell preparation is diluted, and then given a treatment with x-rays to nullify any further cell growth.

2. How is the vaccine given?

The vaccine is injected into the skin in four places, two on the abdomen, and two on the thighs.

3. How often is it given?

The vaccine is given every 2 weeks for 3 doses. Then the subject has repeat scans and/or x-rays to see any possible effect. Depending on the tumor response, the subject may then go onto a monthly booster schedule for more injections.

4. Do I have to be in the hospital?

No, the vaccine is designed to be given in a doctor's office

5. What is GM-CSF and why is it needed?

GM-CSF is a biological medication widely used to stimulate the bone marrow production of white blood cells. There is, however, new data that this agent can also help generate a more effective immune response.

6. What are the side-effects of the vaccine?

Side effects are uncommon. We have had no life-threatening events and have only rarely seen allergic reactions or incision infections. These have been mild and self-limited. You will not lose your hair or have vomiting from the vaccine. Nausea after the priming medicine, if it occurs, is manageable with some of the newest anti-vomiting medicines. The vaccine is checked carefully for contamination, viruses, or infectious microbes. In theory, there is always a slight chance of some undiscovered or unpredicted side-effects.

7. Am I being experimented on?

Yes. As a research subject, you should know that this study was reviewed by a registered Institutional Review Board for compliance with medical ethics, safety, and scientific justification. The programs are then reviewed by the F.D.A. and the National Cancer Institute. You should understand clearly that this program is a research investigation. We are trying to develop a new treatment, learn as much as possible, and hopefully help the patients who come to us. But this is a research program, we cannot guarantee it will benefit you, and we must always be on the lookout for unpredicted or unexpected effects.

8. What is “informed consent?”

Before you decide to be in the study or begin any study procedures you will be given a document which explains in detail the program and any known or theoretical side effects as mentioned above. The document must be signed to indicate that you have been told the details of the program, that you enter into it freely without pressure or deception, that you have been informed you can at any time ask further questions, and that you also have been informed about your rights and responsibilities as a research subject. A useful supplemental booklet will be provided from the National Cancer Institute entitled, “A Guide to Informed Consent.” Signing the consent form does not take away any of your rights, including the right to change your mind. The consent process actually helps protect your rights and it also protects the ethical intent of our research.

9. How much does the vaccine cost?

We do not charge for the vaccine. Wiseman Research is supported by gifts, donations, the Wiseman Cancer Research Foundation, Wiseman Research Initiatives, LLC and others. You should be aware that there will be costs and charges, according to standard fees, for most study procedures including medical visits, for the doctor’s visits where the vaccine and other study drugs are given, for laboratory and imaging tests, and for the supplies, needles and syringes, medications, etc. used in the study.

10. Will my insurance or Medicare cover these fees?

Generally, third-party payers routinely cover doctors’ visits and routine charges. Depending on circumstances, some carriers will reimburse for expenses associated with the experimental vaccine, but we cannot predict or guarantee you will be covered for all or part of the expenses. Wiseman Research and your doctors are committed to minimizing costs and to providing care and working with all eligible patients. The vaccine study is NOT subsidized by Federal funds, however. If you have special circumstances please be sure to discuss these with your doctors.

11. I’d like to be part of this study. What do I do next?

Notify our office and information will be provided. We will need medical records, pathology reports, x-rays and scans, etc. We frequently like to discuss your medical situation with your personal physician. In evaluating your case we will try to make our recommendations as responsibly as possible.

USEFUL PHONE NUMBERS:

Wiseman Research Initiatives, LLC (Study Sponsor)
Phone: 213-483-8464

Lasika Senneveratne MD (Principal Investigator)
Phone 213-977-1214

You may also call the National Cancer Institute's Cancer Information Service at:

• 1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

You may also visit the NCI Web site at <http://cancer.gov/>

• For NCI’s clinical trials information, go to: <http://cancer.gov/clinicaltrials/>

• For NCI’s general information about cancer, go to <http://cancer.gov/cancerinfo/>