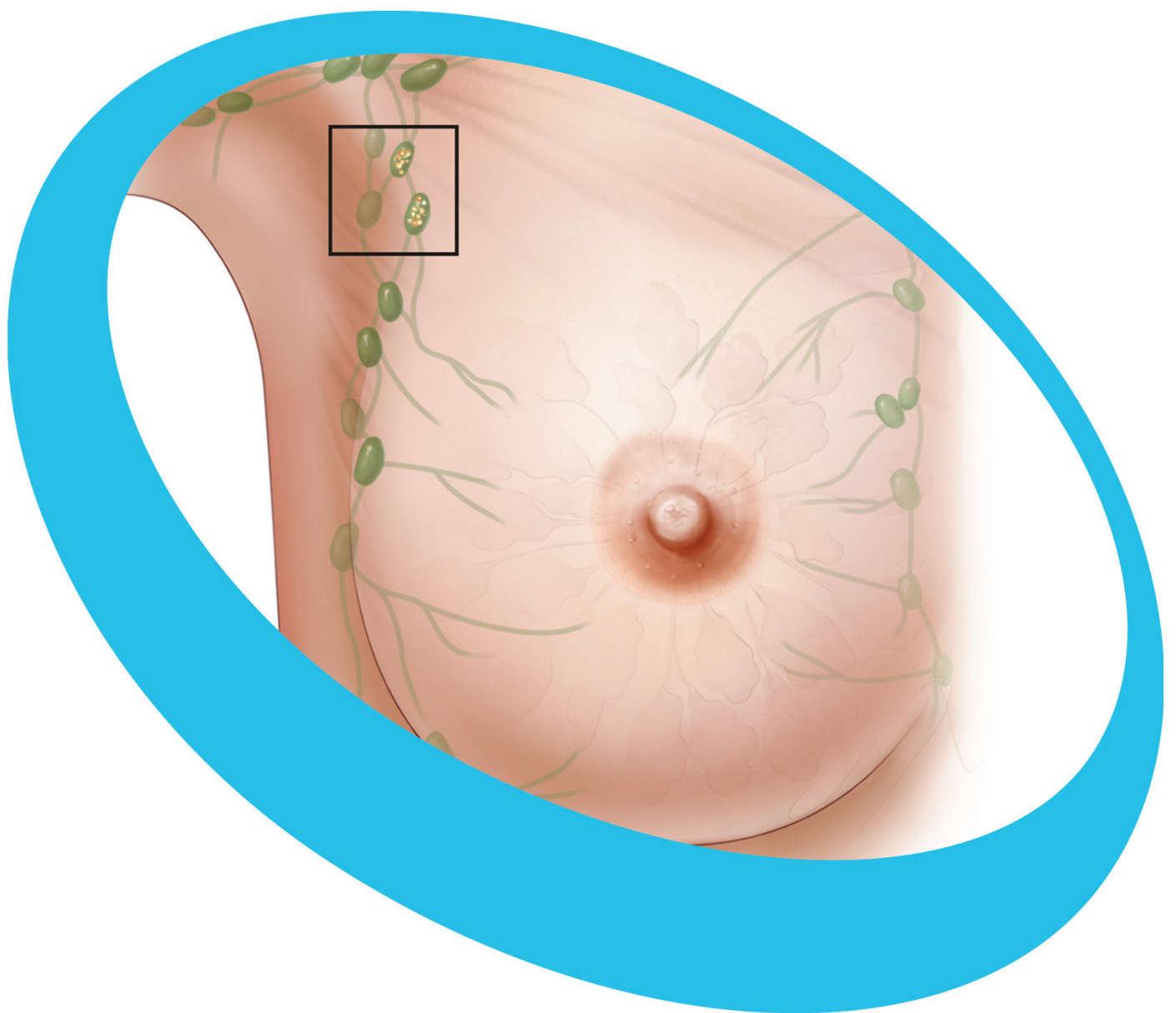


PHASE I

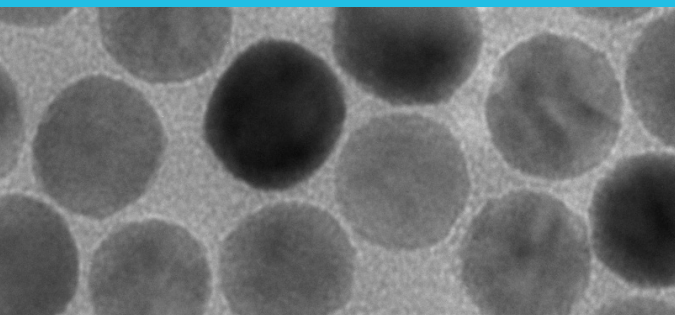
INVESTIGATIONAL STUDY OF A
NOVEL IMAGING AGENT FOR NODAL STAGING OF

HER2 BREAST CANCER



WHY IS THIS STUDY IMPORTANT?

Every day someone new is confronted with the difficult experience of being diagnosed with breast cancer. We understand that when faced with the diagnosis of cancer your focus will be on working with your doctor to find the best treatment options for you.



This study aims to show if this new imaging agent has the potential to non-invasively stage breast cancer by determining if the cancer has spread to the lymph nodes. The physicians and investigators at the participating study institutions believe this new MagSense® HER2 imaging agent holds promise for aiding doctors in treating breast cancer and avoiding biopsies for future patients

By participating in this study, you will be joining the breast cancer research community and contributing to the understanding of the possible impact of this new imaging agent.

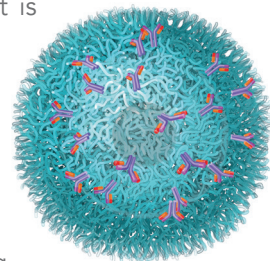
The treatment plan you and your doctor decide is the best one to treat your breast cancer will not be affected by your participation in this study.



WHAT IS THE IMAGING AGENT?

Imaging agents are frequently used with imaging methods like MRI and CT to enhance the image of tissue by adding contrast.

The MagSense® HER2 imaging agent is specially designed for patients with HER2 – positive breast cancer. The imaging agent is an injectable solution of tiny magnetic nanoparticles that attach to HER2 tumour cells. When attached they can be seen by the imaging machine and provide a non-invasive way to avoid a biopsy of lymph nodes.



IS IT SAFE?

This Phase I study is the first time the MagSense® HER2 imaging agent will be used in humans. The imaging agent has been shown to be safe in animal studies. Similar nanoparticles have been shown to be safe and well tolerated for therapeutic and diagnostic uses. Possible side-effects may be redness, swelling or itchiness around the injection site (where the agent is given) and discolouration of this area, which usually disappears over time. You will be observed for side-effects throughout your participation in the study.

WILL THE STUDY AFFECT MY CARE OR TREATMENT?

This study can work with the course of treatment that you and your doctor decide upon. Your doctor will be responsible for ensuring the study activities fit around your treatment schedule.

There are no costs to you if you participate in this study. All medication, tests and medical care will be provided to you free of charge. You will be compensated for your participation and you may be reimbursed for any reasonable travel, parking or other expenses you have during your participation.

Your decision whether to take part or not to take part, will not affect your treatment, your relationship with those treating you, or your relationship with the hospital.

WHAT'S INVOLVED IF I **PARTICIPATE?**

If you choose to take part in the study, you will meet with the study doctor and be given complete information about the study and the risks of participation to be sure the study is right for you. An examination and some routine tests will be included.

Once you start the study, you will have a magnetic resonance imaging (MRI) scan of the breast followed by an injection of the MagSense® HER2 imaging agent. The agent is injected below the skin near the breast cancer lump. Over the next 2-3 days you will have two more MRI scans and a small biopsy of tissue will be collected from one of your lymph nodes.

About 28 days later you will return for an examination and consultation with your doctor to check your condition and any response to the MagSense® HER2 imaging agent.



WHY IS A NEW IMAGING AGENT **NEEDED?**

Once a breast cancer tumor has been identified it is important to determine if the cancer has spread to another part of the body. This is known as staging. One area that the cancer cells can go to is the lymph nodes, which are part of the body's immune system and help the body fight infections and disease. For breast cancer, the axillary lymph nodes, which are located in and around the armpit, are the most likely location to detect if the breast cancer has spread.

Unfortunately, detection of breast cancer cells in the lymph nodes can be difficult or impossible using the normal radiology/x-ray imaging techniques. While ultrasound, x-rays, CT and MRI scans may be used to identify swollen or enlarged nodes, they cannot confirm if breast cancer cells are present.

Most patients have no nodal disease, but a biopsy is required to find that out.

Today the only way to confirm if cancer cells have spread to the lymph nodes is to do a biopsy, either removing the node altogether or taking a sample of the tissue from a suspicious lymph node.

Since the majority of patients turn out to have no cancer cells in their lymph nodes, the MagSense® HER2 imaging agent would provide a simpler way to identify if breast cancer cells are present in the lymph nodes and could eliminate the need for biopsies for those patients that have no cancer cells in their lymph nodes.

IF I'M
INTERESTED
HOW DO I LEARN MORE?

Thank you for your interest and consideration of this study. For more information about the study, what's involved and your eligibility, please consult your doctor managing your treatment.

You can contact Imagion Biosystems, the study sponsor, directly at:

☎ 1800 749 262

✉ HER2Imaging@imagionbio.com



www.imagionbiosystems.com.au