



## **BTSCAN**

### **Overview**

BTSCAN is the product name for  $^{99m}\text{Tc}$ -Glucarate which is being developed as a breast tumor imaging agent. This compound has been shown to localize in breast cancer cells and certain other tumor types. The product has been administered to more than 200 patients in clinical trials for various indications, and shown to be safe and to have acceptable dosimetry. Preliminary clinical results suggest that BTSCAN might be a potential diagnostic modality adjunctive to mammography in patients suspected of breast cancer.

### **Introduction**

According to The American Cancer society, breast cancer affects an estimated one in eight American women. The disease is a leading cause of death for American women aged 35 to 54. In 2001 an estimated 192,200 new cases of invasive breast cancer occurred in women in the US, and about 40,200 women died from breast cancer.

Mammography has become the leading choice for breast cancer screening based upon its relatively low cost and overall high sensitivity. The sensitivity of breast examination plus mammography for cancer detection is about 90%. Estimates of mammography sensitivity range from 75% to 90% with specificity from 90% to 95%. However, for dense or abnormal breasts the sensitivity is significantly less. Some studies have indicated a false negative rate up to 75%. In most cases, additional tests lead to a final interpretation of normal.

Therefore, since mammography has a high sensitivity but questionable specificity, there is a need for adjunctive diagnostic approaches to enhance the specificity in the diagnosis of breast cancer and reduce the need for biopsy procedures. The company is hopeful that mammoscintigraphy using  $^{99m}\text{Tc}$ -Glucarate can fill this need for an adjunctive diagnostic for breast cancer.

### **Product Development Status**

The glucarate product is supplied as a lyophilized formulation in a 10 mL vial. The glucarate is labeled by adding  $^{99m}\text{Tc}$ -pertechnetate, which is obtained from readily available generators in nuclear medicine labs. After 10 minutes at room temperature the agent is ready to be administered to the patient.

The potential of  $^{99m}\text{Tc}$ -Glucarate for the scintigraphic detection of various tumors was preclinically demonstrated by distinct tumor uptake in human xenograft mouse models of breast tumors. The current hypothesis is that the localization might be mediated through the sugar transport system and uptake in cancer cells is due to the increased metabolic activity of the malignant cells.

Dr. Guiliano Mariani explored the potential of  $^{99m}\text{Tc}$ -Glucarate as an imaging agent in breast cancer patients in Italy. A total of 31 patients with ascertained or suspected breast cancer were enrolled in the study.  $^{99m}\text{Tc}$ -Glucarate kits were supplied by the company for the study. Some patients were also imaged with  $^{99m}\text{Tc}$ -Sestamibi and [ $^{18}\text{F}$ ]FDG for comparison. Both planar and SPECT images were obtained.  $^{99m}\text{Tc}$ -Glucarate was negative in all patients without cancer, while it was positive in 19 of 20 patients with confirmed breast cancer (mean tumor/background ratio was  $\sim 1.65$ ). In patients with advanced cancer,  $^{99m}\text{Tc}$ -Glucarate uptake was not strictly confined to the lesion, but also localized in some additional perilesional areas not detected by  $^{99m}\text{Tc}$ -Sestamibi.

Comparative SPECT images obtained in a 32 year-old breast cancer patient with  $^{99m}\text{Tc}$ -Sestamibi (MIRALUMA<sup>™</sup>),  $^{99m}\text{Tc}$ -GLA ( $^{99m}\text{Tc}$ -Glucarate), and [ $^{18}\text{F}$ ]FDG are show below. The ability of  $^{99m}\text{Tc}$ -Glucarate to detect both the primary and metastatic node is evident. These imaging results indicate that  $^{99m}\text{Tc}$ -Glucarate possesses diagnostic potential for scintimamography in patients with suspected breast cancer. Although this was a small, uncontrolled study, these preliminary results support further development of  $^{99m}\text{Tc}$ -Glucarate as a diagnostic modality adjunctive to mammography.

