

A&G Pharmaceutical

Breast cancer theranostic biomarker

Project Manager: Ginette Serrero, Ph.D.; **Principal Investigator:** Katherine Tkaczuk, M.D., UMB

Location: Columbia, Maryland - Howard County; **Project Start Date:** 8/1/2008

Business Description

A&G Pharmaceutical discovers, develops, and commercializes innovative personalized medicine products that improve the screening, monitoring, and targeted treatment of cancer and other human diseases. Ginette Serrero, CEO and co-founder of A&G, has discovered and patented (over 130 patents filed worldwide, >40 issued patents) its unique and novel biomarker, called GP88, and also known as progranulin. This protein is produced and required by cancer cells and enables them to proliferate and survive. GP88 is not produced by normal cells, thus GP88 is identified as a novel biomarker target for diagnostic and therapeutic product development. A&G is developing diagnostic tissue and serum test kits based on GP88 that will improve the early detection, diagnosis, and monitoring of breast cancer. One of the diagnostic products—a test kit validated for assessing GP88 in tumor biopsies—will also serve as a companion diagnostic to anti-GP88 immunotherapy. Both the tissue and serum tests have been validated at the University of Maryland Greenebaum Cancer Center and supported by grants from MIPS and the National Cancer Institute Small Business Innovation Research (SBIR) program.

Precision Antibody™, A&G's wholly owned, highly automated service unit, generates revenue to fund the drug development effort by providing customized antibodies to leading pharmaceutical and biotechnology companies, as well as federal laboratories, and is recognized worldwide as a provider of high-quality, antibody-based products.

Challenge

Ginette Serrero demonstrated that GP88 had the potential to be a biomarker for breast cancer, as increasing GP88 serum levels positively correlated with advancing disease. This initial observation needed clinical validation in breast cancer patients.

"The MIPS program has been instrumental to the GP88 blood test. It's helped the company tremendously."

– Michael Keefe, COO, A&G

MIPS Role

Dr. Kate Tkaczuk, from the University of Maryland Greenebaum Cancer Center (GCC), performed a clinical study with newly diagnosed breast cancer patients stages 1 to 4. The two objectives of the study were to determine if: serum GP88 could be used to detect breast cancer by measuring GP88 serum and tissue levels at the time of diagnosis; and GP88 serum levels could be used to follow the therapy response and progression of the disease in stage 4 patients undergoing therapy. GP88 assays were conducted at A&G.

Results

Correlations of GP88 serum levels with clinical parameters such as stage, therapy response and survival, established the clinical utility of the GP88 serum assay to



Pictured, left to right: Jun Hayashi, Co-Founder and VP of Research & Development; Ginette Serrero, Co-Founder and CEO; and Michael Keefe, Chief Operating Officer, A&G Pharmaceutical

detect the disease and to monitor response to therapy, disease progression and recurrence in breast cancer patients.

In 2010, A&G Pharmaceutical received a \$1.2 million Phase II Small Business Innovation Research (SBIR) grant from the National Cancer Institute (NCI) for the program "Novel Targeted Therapy for Breast Cancer," focused on the development of a neutralizing therapeutic antibody against a novel cancer-associated protein, GP88. A&G has since raised \$12 million in equity capital.

OncoStain 88 is currently in use as a tissue-based diagnostic test to predict the risk of recurrence in early stage breast cancer patients.

Dr. Ginette Serrero is a UMB professor who left her academic position to start A&G and commercialize her discovery of GP88. She is looking forward to the culmination of her work, which could result in a robust and accurate blood test for the early detection of breast cancer.



"I can see the benefits and the strengths of having Maryland companies working with University of Maryland faculty. The MIPS program was very useful and powerful in getting it [GP88] to the next level."

– Dr. Ginette Serrero,
CEO, A&G Pharmaceutical