**A PHASE 2 STUDY OF DOCETAXEL IN COMBINATION WITH INDOXIMOD FOR METASTATIC BREAST CANCER**

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**Background:** Indoleamine 2,3-dioxygenase (IDO) is a tryptophan-catabolizing enzyme that plays a key role in the regulation of immune tolerance. Tumors also employ this mechanism to induce a state of immunosuppression, evading immune mediated destruction. Indoximod (D-1-methyltryptophan) is a broad IDO pathway inhibitor as it has been shown to potentially interfere with multiple targets within the IDO pathway. Preclinical studies in MMTV-neu mouse models have shown that indoximod combined with chemotherapy was more effective in causing tumor regressions than either agent alone. A phase 1 trial combining docetaxel and indoximod demonstrated safety and responses in metastatic breast cancer patients. Based on this data a phase 2 trial in first line metastatic breast cancer was initiated.

**Trial design:** The study is a 1:1 randomized, placebo controlled two arm phase 2 study. The study treatment is docetaxel 75mg/m2 IV D8 plus indoximod 1200mg PO BID D1-14 every 21 days or matching placebo. Primary endpoint is progression free survival. Secondary endpoints include overall survival, response rate, and immune response correlative assays. Patients with measurable, histologically confirmed metastatic breast cancer, no prior chemotherapies (hormonal therapies allowed) in the metastatic setting, ER+ or ER –, HER2 –, ECOG PS 0-1, no active CNS disease, no active autoimmune disease are eligible. Target enrollment is 154 patients. The trial is currently open at multiple clinical sites all around the US and actively enrolling patients. Expansion to the EU is underway. NCT01191216.

**Disclosure:** E.P. Kennedy: Employee of NewLink Genetics who is the sponsor for this clinical trial; G. Rossi: Author is an employee of NewLink Genetics; N. Vahanian and C. Link: Author is an officer and employee of NewLink Genetics. All other authors have declared no conflicts of interest.