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PHASE II CLINICAL TRIAL, TESTING THE EFFICACY OF A HUMANIZED MONOCLONAL ANTIBODY AGAINST THE LEWIS-Y ANTIGEN (LE Y)

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Background: The Lewis-Y (Le y) antigen is a blood group-related antigen expressed in over 70% of epithelial cancers. It is expressed in 44% of breast cancers. **Objectives:** The primary endpoint was to evaluate the clinical efficacy of hu3S193, a humanized monoclonal antibody against the Lewis-Y antigen, in advanced hormone positive breast cancer after failure of at least one line of endocrine therapy. **Methods:** This multicenter, single arm, phase II trial enrolled eligible patients to receive hu3S193 weekly at a dose of 20 mg/m2, intravenously. Efficacy was measured as clinical benefit rate (objective response or stable disease for at least 24 weeks). **Results:** Of 49 patients screened, 27 (55%) were Le y positive. Of these 27, only 20 were eligible for efficacy analysis. No complete or partial responses were observed. Four patients had stable disease for 24+ weeks (clinical benefit rate 20%). One patient remains on study drug maintaining stable disease for over 2 years. This patient had high expression of Le y. The most common treatment-related adverse events were headache (50%), cough (45,5%) and nausea/vomiting (31,8%). Hu3S193 lacked sufficient activity in is trial and the investigators stopped accrual at the first interim analysis. High expression of Le y might play a role in selecting patients to this strategy.