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Neoadjuvant talazoparib (TALA) for operable breast cancer patients with a BRCA mutation (BRCA+).

Presented Monday, June 4, 2018

Authors:
Jennifer Keating Litton, Marion Scoggins, Kenneth R. Hess, Beatriz Adrada, Carlos Hernando Barcenas, Rashmi Krishna Murthy, Senthil Damodaran, Sarah Marie DeSnyder, Abenaa M. Brewster, Alastair Mark Thompson, Gary J Whitman, Nuhad K. Ibrahim, Stacy L. Moulder, Jill Schwartz-Gomez, Elizabeth A. Mittendorf, Banu Arun; The University of Texas MD Anderson Cancer Center, Houston, TX; Department of...

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Abstract Disclosures

Background:
TALA has demonstrated efficacy in patients (pts) with BRCA+ metastatic breast cancer. We previously reported a window trial with median 88% tumor volume reduction after 2 months for early stage breast cancer. This study expanded to evaluate the pathologic response of TALA alone x 6 months in BRCA+ pts and operable breast cancer.

Methods:
The study was approved by the Institutional Review Board. Eligibility included ≥ 1 cm tumor and BRCA+. HER2+ tumors were excluded. Twenty pts underwent a pre-treatment biopsy, 6 months of once daily oral TALA (1 mg), followed by definitive surgery. Pts received adjuvant therapy at physician's discretion. Endpoint was residual cancer burden (RCB). With 20 patients, the RCB0 + RCB1 response rate can be estimated with a 95% confidence interval with half width < 20%.

Results:
All 20 planned pts have enrolled from 08/2016-09/2017: median age = 38 (range 23-58); BRCA1+ = 16 and BRCA2+ = 4; 17 patients had triple negative breast cancer (TNBC, ER/PR < 10%) and 3 had hormone+ disease; Clinical stage I = 5, stage II = 12, Stage III = 3 including 1 patient with inflammatory breast

carcinoma (IBC) and 1 with metaplastic chondrosarcomatous carcinoma (MpBC). One pt chose to receive chemotherapy prior to surgery so no RCB obtained. To date 18 pts have completed TALA and 17 surgery. This report will be updated with the final 2 patients scheduled for surgery in 03/2018. RCB0 = 9 (including the 1 pt with IBC and 1 pt with MpBC, 8 pts had TNBC and 1 with ER+ invasive lobular). RCBI = 1; RCB II = 5, RCBIII = 2. RCB0/1 rate = 10/17 = 59%, 95% CI = (36%, 78%). There was 1 grade 4 toxicity of thrombocytopenia. Grade 3 toxicities included: anemia = 8; neutropenia = 3, UTI = 1. Most common grade 1/2 toxicities included: nausea, fatigue, neutropenia, alopecia, dizziness and dyspnea. Toxicities were managed by dose reduction and transfusions. Nine pts required dose reduction.

Conclusions:

Single agent oral TALA once daily given preoperatively without chemotherapy produced significant pathologic complete responses with manageable toxicity. This pilot trial exceeded our expectations and is novel to demonstrate RCB0 in TNBC by a single targeted therapy. These results warrants a larger study for this pt population. Clinical trial information: NCT02282345