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## PHASE II TRIAL OF NAB-PACLITAXEL (NANOPARTICLE ALBUMIN-BOUND PACLITAXEL (ABX)) + CAPECITABINE (XEL) IN FIRST-LINE TREATMENT OF METASTATIC BREAST CANCER (MBC)

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### Background

ABX and XEL both have substantial single agent activity in MBC. Taxane and anti-metabolite doublets improve response rate and TTP and longer survival. ABX administered weekly has an excellent safety and efficacy profile with maintenance of dose intensity. This study was designed to test the safety and efficacy of ABX + XEL given in a novel combination schedule.

### Methods

This phase II, multicenter open label study utilized ABX 125 mg/m<sup>2</sup> IV on day 1, 8 and with no premeds and capecitabine 825 mg/m<sup>2</sup> PO BID days 1-14 on a Q 3 week cycle. The primary endpoint is objective response rate, with evaluation performed after every 2 cycles. Entry criteria include

measurable MBC by RECIST criteria, age >18, PS 0-2, no prior chemo for metastatic disease, > 6 months since adjuvant fluoropyrimidine and/or paclitaxel.

### Results

The full sample of 50 patients (pts) have been enrolled; data from 43 pts are available for analysis. Median age is 58 (range 23.7-90.6). 37% received prior adjuvant anthracycline and 33% prior adjuvant taxane. Median number of metastatic sites is 2 (range 1-7), with most common sites of disease liver, 53.5%; bone, 51.2%; and lung, 14%. 226 cycles of therapy have been delivered. 5 pts required a dose reduction in XEL (3 pts to 650 mg/m<sup>2</sup>; 2 to 550 mg/m<sup>2</sup>) and 4 pts had dose reduction in ABX to 100 mg/m<sup>2</sup>. XEL dose reductions occurred due to hand-foot

syndrome (3), neutropenia (1), and fatigue (1). ABX dose reductions occurred due to mucositis, diarrhea, fatigue, and neuropathy (1 pt each). 10 pts had grade 3-4 non-hematologic AEs: 3 hand-foot syndrome, 4 fatigue, and 3 GI. Hematologic AEs included 4 with grade 3 and 1 with grade 4 neutropenia, and 2 with grade 4 febrile neutropenia. The most common AEs of any grade were GI (30), dermatological (23), fatigue (15), neuropathy (12), and hand-foot syndrome (11). The incidence of Grade 1-2 neuropathy was 25% (no grade 3-4). Of 38 pts available for analysis of response, the overall response rate is 47.5%: PR 39.5%, CR 8%. Total of 15 pts have stable disease, 20 pts have completed 6+ cycles. ★