

Zoledronic Acid (ZA) Effectively Inhibits Cancer Treatment-induced Bone Loss (CTIBL)

in Postmenopausal Women (PMW) with Early Breast Cancer (BCa) Receiving Adjuvant Letrozole (Let) 12 mos BMD results of the Z-FAST trial [533]

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Background: Aromatase inhibitors (AIs) are effective therapies for PMW with BCa. Their use has been associated with increased bone resorption markers and bone loss at the lumbar spine (LS)/total hip (TH). This multicenter open-label randomized study evaluates the efficacy and safety of ZA in preventing CTIBL in PMW with early BCa

who are receiving AI therapy.

Methods: 602 PMW with stage I-IIIa ER+ and/or PR+ BCa starting Let (2.5 mg qd x 5 yrs) were randomized to upfront ZA (4 mg IV infusion q 6 mos) vs delayed ZA in 93 centers in the US and Canada. The delayed group will receive ZA when either post-

baseline T-score decreases <-2 SD or in case of fracture. The primary endpoint is the percent change in LS BMD at 12 mos.

Results: Baseline characteristics were similar between groups. 343 of 602 pts (170 upfront/173 delayed) are evaluable for 12

Continued on Page 31

A Phase II Trial of Letrozole and Trastuzumab for ER and/or PgR and HER2 Positive Metastatic Breast Cancer

Final results [596]

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Background: About 50% of HER2+ breast cancers exhibit ER coexpression and HER2 signaling may impair responses to endocrine treatment. A Phase II trial was therefore conducted to examine trastuzumab (TRAS) with letrozole (LET) in patients with ER and HER2 positive advanced disease.

Methods: Postmenopausal women with ER and/or PR+, HER2 IHC 2-3+ or FISH+, measurable (WHO) metastatic breast cancer, ECOG 0-2 and LVEF greater than 50%. Loading dose TRAS within 28 days of initiating aromatase inhibitor (AI). Patients who had been started on other AI were

switched to LET. The exclusion criteria were prior AI > 28 days, prior TRAS, cumulative anthracycline > 360 mg/m², brain metastases, visceral crisis, prior radiation to only evaluable lesion, severe comorbidity or other malignancies and > 1

Continued on Page 31

Clinical Benefit and Survival Endpoints from a Phase III Trial Comparing Decitabine (DAC) vs. Supportive Care (SC)

In Patients with Advanced Myelodysplastic Syndromes (MDS) [6543]

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Background: MDS is a blood disorder characterized by dysplasias of hematopoietic cells resulting in cytopenias and progression to acute myelogenous leukemia (AML). There is only one approved therapy for MDS. Decitabine (Dacogen™) is a cytosine analog that reverses aberrant DNA methylation leading to re-expression of silenced tumor

suppressor genes. Results of adjudicated data (responses independently judged by a blinded reviewer) are presented for the first time.

Methods: We report a phase III, randomized, open-label trial of DAC vs SC in MDS patients (pts) with International

Prognostic Scoring System (IPSS) Intermediate (Int)-1 (31%), Int-2 (44%), and high-risk disease (26%). Secondary MDS (14%)/previously treated (27%) pts were included. Co-primary endpoints were response rate (CR + PR) and Time to AML or Death (TTAML/D).

Continued on Page 31