Presentations

GS3-01. Gnant M,Steger G, Greil R, Fitzal F, et al. A prospective randomized multi-center phase-III trial of additional 2 versus additional 5 years of Anastrozole after initial 5 years of adjuvant endocrine therapy - results from 3,484 postmenopausal women in the ABCSG-16 trial.

The authrs conclude that:

After 5 years of adjuvant endocrine therapy (Tamoxifen or AI or Sequence), 2 additional years of Anastrozole are sufficient for extended adjuvant therapy – a further extension to 5 additional years did not yield additional outcome benefit but added toxicity. See the webcast from the press conference

GS3-02. Krop IE, Hillman D, Polley M-Y, Tanioka M, et al. Invasive disease-free survival and gene expression signatures in CALGB (Alliance) 40601, a randomized phase III neoadjuvant trial of dual HER2-targeting with lapatinib added to chemotherapy plus trastuzumab.

The authrs conclude that:

Dual HER2-targeting with lapatinib added to 16 weeks of TH produced significantly longer IDFS than TH alone, despite modest effects on pCR. Similar to pts with HER2-negative disease, pts with luminal A had better IDFS than those with other molecular subtypes. Immune activation as measured by RNA-based signature independently predicted both pCR and IDFS.

GS3-03. Coombes RC, Tovey H, Kilburn L, Mansi J, et al. A phase III multicentre double blind randomised trial of celecoxib versus placebo in primary breast cancer patients (REACT - Randomised EuropeAn Celecoxib Trial).

The authrs conclude that:

There is no benefit of celecoxib in the ITT population. Further exploratory studies focussing on the ER+ subpopulation are ongoing. Celecoxib treatment is not associated with significant toxicity when compared to placebo in this population of BC patients.

GS3-04. Joensuu H, Fraser J, Wildiers H, Huovinen R, et al. A randomized phase III study of adjuvant trastuzumab for a duration of 9 weeks versus 1 year, combined with adjuvant taxane-anthracycline chemotherapy, for early HER2-positive breast cancer (the SOLD study). See the webcast from the press conference

GS3-05. Schneeweiss A, Jackisch C, Schmatloch S, Aktas B, et al.[**nbsp**]Survival analysis of the prospectively randomized phase III GeparSepto trial comparing neoadjuvant chemotherapy with weekly nab-paclitaxel with solvent-based paclitaxel followed by anthracycline-cyclosphosphamide for patients with early breast cancer - GBG69.

The authrs conclude that:

Neoadjuvant GeparSepto study demonstrated a significantly higher pCR rate when patients received nP instead of P as part of an anthracycline/taxane based sequential chemotherapy. The expected long-term results will help to assess the overall benefit of nP in BC and the surrogate value of pCR for survival endpoints.

GS3-06. Rugo HS, Barry WT, Moreno-Aspitia A, Lyss A, et al Long-term follow-up of CALGB 40502/NCCTG N063H (Alliance): A randomized phase III trial of weekly paclitaxel (P) compared to weekly nanoparticle albumin bound nab-Paclitaxel (NP) or ixabepilone (IX) +/- bevacizumab as first-line therapy for locally recurrent or metastatic breast cancer (MBC).

The authrs conclude that:

In patients with chemotherapy-naive MBC, Ix was inferior to P for PFS, and P was better tolerated than either NP or Ix. In this retrospective subset analysis, Ix and NP were inferior to P in HR+ disease, with a suggestion of improved PFS and OS with NP in patients with TNBC. Further investigation is required to explain and validate the subtype specificity seen in this exploratory analysis.

GS3-07. Stover DG, Parsons HA, Ha G, Freeman S, et al. Genome-wide copy number analysis of chemotherapy-resistant metastatic triple-negative breast cancer from cell-free DNA.

The authrs conclude that:

Here, we present the first large-scale genomic characterization of metastatic TNBC to our knowledge, derived exclusively from cfDNA. 'Tumor fraction' of cfDNA is an independent prognostic marker in mTNBC. Primary and metastatic TNBC have remarkably similar copy number profiles yet we identify alterations enriched and prognostic in mTNBC. Collectively, these data have potential implications in the understanding of metastasis, therapeutic resistance, and novel therapeutic targets.

GS3-08. Yee D, DeMichele A, Isaacs C, Symmans F, et al. Pathological complete response predicts event-free and distant disease-free survival in the I-SPY2 TRIAL.

The authrs conclude that:

The first long-term efficacy results from the I-SPY2 TRIAL demonstrate that achieving pCR is a very strong surrogate endpoint for improved EFS and DDFS in a high-risk population, across all treatment arms,

regardless of subtype. I-SPY2 shows substantially lower estimated EFS hazards for patients achieving pCR, compared to the 5 yr EFS hazard ratio for pCR vs not in Cortazar (hazard ratio 0.49), demonstrating important differences between a metaanalysis compared to a platform trial with uniform high-risk eligibility, standardized pathology assessment, and multiple targeted therapies.
Our data support the use of pCR as a primary endpoint for accelerated approval of new drugs if EFS is evaluated in the same population. Based on these findings, the I-SPY2 TRIAL will test whether therapy can be deescalated or escalated for individual patients with the goal of achieving pCR for all.