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Session title: Keynote Lecture, Oral and Late Breaking Abstracts

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Abstract title: **LATE BREAKING ABSTRACT: Prospective WSG Phase III PlanB trial: Clinical outcome at 5 year follow up and impact of 21 Gene Recurrence Score result, central/local-pathological review of grade, ER, PR and Ki67 in HR+/HER2- high risk node-negative and –positive breast cancer**

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Background: The 21-gene Recurrence Score (RS) assay, nodal status, grade, and immunohistochemical markers are recommended for chemotherapy decision making in HR+/HER2- early breast cancer (EBC). The phase III PlanB trial, prospectively used RS to define a low-risk subset of patients with node negative disease with high risk traditional parameters and patients with node positive disease (HR+, HER2-) who could be treated with adjuvant endocrine therapy alone. We have previously reported the prospectively planned interim analysis at 3-years of clinical outcome and substantial discordance between central and local grade, Ki67 and RS. Here, we report for the first time 5-year outcome data from the trial.

Material and Methods: A central tumor bank was prospectively established within PlanB. Following an early amendment, HR+, pN0-1 patients with RS ≤ 11 were recommended to omit adjuvant chemotherapy (CT). Patients with RS of 12 or above were randomized to 6× TC vs. 4× EC- 4× Docetax chemotherapy. Primary endpoint of the study was disease free survival (DFS), defined as relapse (invasive and non-invasive), secondary malignancy death. Reported survival percentages were based on the Kaplan-Meier estimator. Univariate and multivariate Cox proportional hazard models for DF were performed.

Results: From 2009 to 2011, PlanB enrolled 3198 patients; median age of 56 years; 41.1% had node-positive and 32.5% grade 3 disease. In 348 patients (15.3%), CT was omitted based on RS ≤ 11. After 55 months median follow-up, 5-year DFS in patients with RS ≤ 11 and endocrine therapy alone was estimated as 94% vs. 94% (RS 12-25) and 84% (RS > 25) in CT-treated patients (p < 0.001). Nodal status, central and local grade, Ki-67, ER, PR, tumor size, and RS were univariate prognostic factors for DFS; only pN2-3, both central and local grade, tumor size >2 cm, and fractionally ranked R were independent multivariate factors.

Conclusions: WSG PlanB for the first time shows excellent 5-year DFS of 94% in a population of high risk node-negative and node-positive (pN1) early BC patients (HR+ HER2-) who omitted adjuvant CT based on RS ≤ 11. Together RS and classical clinical-pathological markers, despite of

substantial heterogeneity in their assessment, provided independent prognostic information. These 5 year outcome data from a prospective trial incorporating the RS support the incorporation of the assay in combination with nodal status, grade and tumor size for adjuvant treatment decisions in early HR+ HER2- BC.

Conflict of interest: Advisory Board: Genomic Health.

