New Data Confirms Endocrine Activity Index® as a Predictor of Benefit from Dose-Dense Chemotherapy

Data from the GEICAM/9906 trial, presented at the San Antonio Breast Cancer Symposium (SABCS) in December 2024, provides independent confirmation of the predictive value of the Endocrine Activity Index (EAI™).[1] In addition, results from a 12-year outcomes analysis from the CALGB 9741 trial that established EAI as a predictor of benefit from dose-dense chemotherapy in hormone receptor-positive breast cancer was published in the Journal of Clinical Oncology in early January 2025.[2]

Houston, TX, March 5, 2025 – Delphi Diagnostics, Inc. announces two important pieces of evidence to support the Endocrine Activity Index as a predictor of benefit from Dose-Intense Taxane-based Chemotherapy in patients with stage II-III HR+ breast cancer. First is the publication in the *Journal of Clinical Oncology (JCO)* of the 12-year outcome data from the CALGB9741 trial, which showed that EAI identified patients with ER+ breast cancer who benefited from dose-dense chemotherapy. The study entitled "Adjuvant Dose-Dense Chemotherapy in Hormone Receptor-Positive Breast Cancer" was published on January 2, 2025, by lead author Otto Metzger MD, from the Dana Farber Cancer Center.

This JCO manuscript reports results from a retrospective analysis of 613 patients from the prospectively enrolled CALGB9741 trial. Among patients with ER+ node-positive disease, EAI added both predictive and prognostic information. In this analysis of the 12-year follow-up data, an EAI of <0.75 was associated with superior disease-free survival (DFS) and overall survival (OS) in patients who received a dose-dense chemotherapy regimen. Tumor burden, molecular subtype, or menopausal status were not associated with dose-intense therapy benefit.

The second study, presented by Dr. Miguel Martin as an abstract and during a Poster Spotlight Session at SABCS 2024, confirmed that EAI predicted benefit from dose-dense paclitaxel-based chemotherapy with the pre-established cutoff from the CALGB9741 study. Patients with an EAI of <0.75 had higher disease-free survival (DFS) at 10 years when using dose-intense weekly paclitaxel compared those without paclitaxel. This prospective/retrospective study included 567 patients, and results were not affected by menopausal status.

"Data from these two studies support the ability of the Endocrine Activity Index to identify breast cancer patients who may derive more benefit from paclitaxel-based dose-intense chemotherapy and provide healthcare providers with important information to guide treatment decisions," said Winz Casagrande, Chief Executive Officer of Delphi Diagnostics.

"We are pleased that the predictive value of EAI has now been confirmed by a second study. Together, these two studies provide strong evidence for the predictive use of EAI in a clinical

setting," said Delphi Diagnostics Chief Medical Officer, Dr. Federico A. Monzon. "These findings suggest that physicians could consider the use of this test to identify patients who are more likely to benefit from a dose-intense adjuvant chemotherapy regimen."

In the manuscript, Metzger et al. state that: "Our findings…challenge the long-held paradigm that more intense chemotherapy regimens should be selected based solely on tumor burden and proliferation driven metrics, challenge more recent inferences that postmenopausal women would not benefit, and provide new insight into the influence of endocrine activity within breast cancer cells on the rationale for dose intensity of adjuvant chemotherapy."

*The Endocrine Activity Index (EAI) is known in scientific publications as the Sensitivity to Endocrine Therapy (SET) Test.

1. *https://sabcs.org/Portals/0/Documents/Formatted_Abstracts%2011-27%20Without%20Embargoed.pdf?ver=vMTqAQGg9YU-Obb3YfuaqQ%3d%3d* (search for abstract SESS-1603)
*2. Otto Metzger Filho et al., Adjuvant Dose-Dense Chemotherapy in Hormone Receptor–Positive Breast Cancer. JCO **0**, JCO-24-01875 DOI:10.1200/JCO-24-01875*

About EAI
Delphi Diagnostics' Endocrine Activity Index® (EAI™) test can provide actionable information for prognosis and prediction of dose-intense taxane-based chemotherapy benefit in stage II-III, HR+ HER2- breast cancer. The EAI measures endocrine activity in a breast tumor and for prognostic use, the Index Score is adjusted for baseline prognosis using molecular subtype genes (RNA4) and clinical factors such as tumor size and regional lymph node involvement. The EAI test has been shown in various studies to be a consistent prognostic indicator for long-term outcomes in stage II-III breast cancer patients, to be independent of other prognostic tests, as well as to be predictive for response to dose-dense chemotherapy.

About Delphi Diagnostics
Delphi Diagnostics Inc. is a Texas-based company focused on advancing clinically valid tests for the prognosis and prediction of breast cancer treatment. Delphi Diagnostics, Inc. holds an exclusive license from The University of Texas MD Anderson Cancer Center in Houston, TX to commercialize the Endocrine Activity Index, a technology that was developed by the laboratory of Dr. W. Fraser Symmans**. The Endocrine Activity Index (EAI) test measures endocrine activity in stage II-III, HR+HER2- breast cancer. Delphi's vision is to make the EAI test available to breast cancer patients and open new pathways for personalized breast cancer treatment. To learn more, visit www.delphi-diagnostics.com.

**Dr. Symmans has a personal financial relationship with Delphi that has been identified as a conflict of interest with this research and is managed by MD Anderson's Conflict of Interest Committee.

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