Randomized phase II study of weekly irinotecan/carboplatin with or without cetuximab in patients with metastatic breast cancer

O'Shaughnessy J1,2,3, Weckstein DJ4, Vukelja SJ1,5, McIntyre K1,5, Kerek L1,6, Holmes FA1,7, Asmar L1, Blum JL1,2
1US Oncology Research, Inc., Houston, TX; 2Baylor-Charles A. Sammons Cancer Center, Dallas, TX; 3Texas Oncology, P.A. – Dallas Presbyterian, Dallas, TX; 4New Hampshire Oncology-Hematology, Hooksett, NH; 5Tyler Cancer Center, Tyler, TX; 6The Breast Care Center of North Texas, Bedford, TX; 7Texas Oncology, P.A., Houston, TX

Abstract

Background: Irinotecan and carboplatin (ICb) is a synergistic antitumor combination in several cancers. Weekly irinotecan is active in metastatic breast cancer (MBC) and has proven activity in combination with cetuximab in colorectal cancer. The primary objective of this study was to determine the objective response rates produced by irinotecan and carboplatin chemotherapy ± cetuximab; secondary objectives were progression-free survival (PFS), overall survival, and safety.

Objectives

PRIMARily Objective: Objective response rates with irinotecan and carboplatin (ICb) ± cetuximab (E)

SECONDARY Objectives: • Progression-free survival (PFS) with ICb ± E • Overall survival (OS) with ICb ± E • Toxicities with ICb ± E

Key Eligibility

• Metastatic breast cancer measurable by RECIST
• HER2 positive (HER2+), patients must have progressed on trastuzumab

Medications

• Irinotecan (I) 100 mg/m², D1, 8 q 21d
• Carboplatin (Cb) AUC = 2.5, D1, 8 q 21d
• Cetuximab (E)

Patient Characteristics

In patients with measurable disease, were randomized to either Arm 1 (ICb) or Arm 2 (ICb+E). Of 20 pts who crossed over on Arm 1 at PD to receive single-agent cetuximab, 1 patient had a PR.

Toxicities

• Nausea - 2
• Vomiting - 2
• Diarrhea - 4
• Alopecia - 1
• Anaphylaxis - 1

Conclusions

Irinotecan and carboplatin is an active regimen for both HR+ and triple negative breast cancer. Weekly irinotecan is active in MBC and has proven activity in combination with cetuximab in colorectal cancer. The primary objective of this study was to determine the objective response rates produced by irinotecan and carboplatin chemotherapy ± cetuximab; secondary objectives were progression-free survival (PFS), overall survival, and safety.

References: