Etirinotecan Pegol Target-Specific Pharmacodynamic Biomarkers in Circulating Tumor Cells from Patients with Metastatic Breast Cancer in the Phase 3 BEACON Study

Edith A. Perez,a Katie Caygill,b Alison L. Hannah,c Javier Cortes,d Ahmad Awada,e Joyce O’Shaughnessy,f Christopher Twelves,g Hope S. Rugo,h Seock-Ah Im,i Darren W. Davis,j Ute Hoch,b

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ABSTRACTS 2014, Poster Number: P9-1305. Style and Time: Thursday, December 11, 6:00 PM - 7:30 PM. Location: Hall A-B.

INTRODUCTION

Etirinotecan pegol (NKT-102) is a long-acting topoisomerase 1 inhibitor designed for prolonged tumor cell exposure.

In patients, etirinotecan pegol leads to greatly prolonged plasma SN38 exposure compared to irinotecan (elimination halftime 30 days compared to 2 days), per maximal SKBR3 concentrations are at least 5- to 10-times was.

In a Phase 3 trial, patients with metastatic breast cancer whose disease failed prior taxane-based treatment, etirinotecan pegol administered q14d or q21d (35 per treatment regimen) demonstrated objective response rate (ORR) of 32% with both schedules showing similar overall response rate (ORR). See Table 1.

METHODS

In a Phase 2 trial in patients with metastatic breast cancer whose disease had failed prior taxane-based treatment, etirinotecan pegol leads to greatly prolonged plasma SN38 exposure compared to irinotecan (elimination halftime 30 days compared to 2 days), per maximal SKBR3 concentrations are at least 5- to 10-times was.

In a Phase 3 trial, patients with metastatic breast cancer whose disease failed prior taxane-based treatment, etirinotecan pegol administered q14d or q21d (35 per treatment regimen) demonstrated objective response rate (ORR) of 32% with both schedules showing similar overall response rate (ORR). See Table 1.

BIOMARKER SELECTION

Relevance of etirinotecan pegol target-specific PD biomarkers and grouping of staining panels

RESULTS

Top1+, Rad51+, ABCG2+, Ki67+ biomarkers are highly expressed in circulating tumor cells (CTCs) from patients with metastatic breast cancer in the Phase 3 BEACON Study.

BEACON CTC SAMPLE FLOW

CTCs detected in 97% of patients with high median number of CTCs

CONCLUSIONS

• Blood sample collection for CTC analysis was successfully incorporated into the BEACON study with 80% patient participation.

• Blood samples were successfully processed with a low technical failure rate of 2%.

• CTC detection rate using ApoBend was high (97% of patient; median # of CTCs: 472 CTC/mL, 5 mL sample).

• Clinical benefit rate: 32% with etirinotecan pegol treatment compared to the physician's choice (TPC) in patients with locally recurrent or metastatic breast cancer.

• Pharmacoeconomic implications using healthcare utilization measures.