

25 mg IV over 30 minutes weekly with 8 planned weeks of therapy (2 cycles) in pts with relapsed/refractory diffuse large B-cell lymphoma (DLCL), follicular lymphoma (FL), small lymphocytic lymphoma/chronic lymphocytic leukemia (SLL/CLL) and other indolent B-NHL.

Results

82 pts with a median age of 62 yrs (range, 30-88 yrs) enrolled; 4 pts refused treatment and 4 pts are too early for eval. Pts had median 2 prior regimens (range, 1-7), and all but 9 had prior rituximab. Of 74 pts, 56 received > 2 cycles of

temsirolimus; 18 pts received < 2 cycles due to rapid PD (n=6) or toxicity (n=12). ORR in pts completing > 2 cycles of temsirolimus is 46% (26/56). ORR in pts receiving at least one dose of temsirolimus is 35% (26/74) with 25 pts maintaining SD. Response by histology is in Table 1. Median PFS of all pts is 123d, with 60% 100-day PFS. Median PFS of pts completing > 2 cycles is 156d, with 79% 100-day PFS. Median PFS of pts with PR/CR is 215d, with 96% 100-day PFS. Median DR of pts with PR/CR is 116d. Most non-hematologic toxicities were grade 1/2 (stomatitis, rash, and metabolic

deregulation) but 12 pts were removed from study due to pneumonitis (n=5), pneumonia/stomatitis (n=2), infection (n=2), or cytopenias (n=3).

Conclusion

The ability of temsirolimus, a presumably cytostatic compound, to induce a 46% ORR (35% ITT ORR) suggests an activity signal that should be pursued further. The heterogeneity of response implies that there is a subset of pts more likely to benefit from MTI; identifying this population will be key to future development of MTI in NHL. ★

CAPECITABINE IN ADVANCED BREAST CANCER: PREDICTIVE FACTORS FOR RESPONSE.

[1126]

Abstract No: 1126

Citation: J Clin Oncol 26: 2008 (May 20 suppl; abstr 1126)

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Background

Capecitabine is increasingly used in the treatment of metastatic breast cancer (MBC). We evaluated the use of capecitabine therapy (XT) in MBC at our centre, to determine factors that might predict response.

Methods

We reviewed the records of patients (pts) with MBC who received XT, from February 05 to March 06. The duration of XT, whether use was continuous or intermittent, the line of use and concurrent treatments were evaluated. Response to XT was correlated to potential predictive factors including age, tumour grade, estrogen receptor (ER) status and HER2 expression. Time to

progression (TTP) and overall survival (OS) after XT were calculated.

Results

Seventy-two women received XT with a median age at initiation of 57 years. At diagnosis, 44% had grade 3 tumors. ER was positive in 61% and HER2 over-expressed in 33%. Adjuvant chemotherapy was given to 61% and adjuvant hormones to 54%. Median time to first relapse was 29 months (mths). XT was used commonly as 2nd- (26.4%) or 3rd-line (30.6%) treatment after relapse. XT was continuous in 83% and intermittent in 17%. Median number of XT cycles was 4 (range: 1-37). An objective response was noted in 23% and the overall clinical benefit rate was 43%

(partial/good responses plus stable disease). The only positive correlation to predict response was ER positivity (p = 0.04). Common significant toxicity included grade 2, palmo-plantar erythema (22%) and fatigue (15%). In 22% a dose modification or delay was necessary. XT was stopped in 5 pts due to toxicity. Median OS after XT was 12 mths (95% CI 6.87-17.13) and median TTP on XT 3 mths (95% CI 2.07-3.93).

Conclusion

XT remains an important palliative treatment option for patients with MBC. Patients with ER positive tumours respond better to XT. We did not identify any other factor that predicted response to XT. ★