Abstract

Objectives

Primary

Efficacy of aldoxorubicin compared to topotecan in subjects with extensive-stage SCLC who have relapsed or were refractory to prior chemotherapy, as measured by PFS.

Secondary

OS, disease control rate, and tumor response.

Safety, cardiac function.

Key Eligibility Criteria

Inclusion

1. Age ≥ 18 years male or female.

2. Prior treatment with topotecan.

3. Palliative surgery and/or radiation treatment < 21 days prior to date of randomization.

4. Exposure to any investigational agent within 30 days of randomization.

5. Exposure to any systemic chemotherapy within 21 days of date of randomization.

6. Measurable tumor lesions according to RECIST 1.1 criteria.

7. Laboratory values: Screening serum creatinine >1.5 x ULN, ALT >3 x ULN or AST >3 x ULN, bilirubin >2 x ULN, hemoglobin <9 g/dL, albumin <2 gm/dL.

Exclusion

1. Prior exposure to >375 mg/m² prior doxorubicin.

2. Prior treatment with doxorubicin or liposomal doxorubicin.

3. Palliative surgery and/or radiation treatment < 21 days prior to date of randomization.

4. Exposure to any investigational agent within 30 days of randomization.

5. Exposure to any systemic chemotherapy within 21 days of date of randomization.

6. Active (symptomatic) CNS metastases.

7. Laboratory values: Screening serum creatinine >1.5 x ULN, ALT >3 x ULN or AST >3 x ULN, bilirubin >2 x ULN, hemoglobin <9 g/dL, albumin <2 gm/dL.

8. Serious mucocutaneous dysfunction defined by ECHO as absolute UFE below the institution’s lower limit of predicted normal.

Study Design

Approximately 132 subjects randomized 1:1 to receive either aldoxorubicin or topotecan.

Aldoxorubicin treatment at a dose of 230 mg/m² (doxorubicin equivalents of 170 mg/m²) will be administered as a 30 minute IV infusion on Day 1, every 21 days, for a maximum of 24 doses. Patients with a 6 month or greater partial response will continue to receive therapy until disease progression is observed, subject withdrawal, or unacceptable toxicity occurs.

Cardiac function (ECHO) for subjects receiving aldoxorubicin.

Tumor response screening every 6 weeks from Cycle 1-Day 1 through week 33, and then every 12 weeks until disease progression using the RECIST 1.1 criteria.

PFS determined by both Blinded Independent Radiology Review (primary) and investigator assessment (secondary).

Subjects stratified according to their initial ECOG PS (0-1 vs 2) and whether they had progressed in less than or greater than 90 days after their initial chemotherapy.

References


