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ABSTRACTS – ORAL PAPERS

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Activity of cediranib, a highly potent and selective VEGF signaling inhibitor, in alveolar soft part sarcoma

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Background

Alveolar soft part sarcoma (ASPS) is a rare entity making up <1% of soft tissue sarcomas (STS). It is typically indolent but with a high incidence of metastatic disease, usually to lungs, but also to sites such as the brain. Response to conventional chemotherapy is poor (overall response rates are approximately 7% [Reichardt P et al. Eur J Cancer 2003;39:1511–1516]). This is a preliminary report of the activity of cediranib, a highly potent and selective VEGF signaling inhibitor, in this disease.

Methods

Efficacy and tolerability data were collected for seven patients with ASPS. One patient was treated in a Phase II randomized trial of cediranib ± prophylactic antihypertensive therapy and six were treated in a Phase II study in patients with imatinib-refractory gastrointestinal stromal tumors or other STS. Cediranib was administered orally, once daily at an initial dose of 45 mg. Response was assessed using RECIST (Response Evaluation Criteria in Solid Tumors).

Results

Median age at diagnosis was 39 years (range: 26–49). All patients had pulmonary metastases and two had additional sites of disease (brain, bone, intra-abdominal) at study entry. Adverse events were generally CTC grade 1–2 and manageable. The most common adverse events were fatigue (n=6), diarrhea (n=5), stomatitis (n=4), headache (n=3) and hypertension (n=3). Four patients had a best response of partial response, two patients had a confirmed reduction in maximum tumor diameter of ≥10% and <30% and one patient experienced stable disease. As of November 2008, three patients remain on treatment with a median (range) time on study of 61 weeks (49–74). Time to progression and progression-free survival will be calculated and available at the time of presentation.

Conclusions

These data demonstrate the promising preliminary activity and safety of chronic administration of cediranib in this disease. Further investigation is warranted, particularly as there is no effective systemic treatment for patients with advanced ASPS.