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## Phase I clinical study of the new amino acid-linked nitrosourea, S 10036, administered on a weekly schedule.

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### Abstract

Diethyl-1-[3-(2-chloroethyl)-3-nitrosoureido]ethylphosphonate (S 10036) is a new nitrosourea that has been evaluated in a clinical trial because of its activity in the National Cancer Institute panel screen and its rational chemical approach. A Phase I study was conducted in 22 evaluable patients with advanced cancers. The drug was given as a slow i.v. infusion over a period of 60 min on days 1, 8, 15, and 22 followed by a 4-week rest period. The dose levels ranged from 25 to 200 mg/m<sup>2</sup>/week for 4 consecutive weeks using a modified Fibonacci scheme. Thrombocytopenia was the only acute dose-limiting toxicity and started at a dose of 100 mg/m<sup>2</sup>/week and above. Hematological toxicity was delayed, cumulative, and dose related. Nausea and vomiting were moderate to severe and dose related. Three responses (one complete and two partials) have been noted. Phase II studies of S 10036 are planned at a dose of 100 mg/m<sup>2</sup>/week for 4 consecutive weeks ("induction therapy") for patients without prior therapy and 100 mg/m<sup>2</sup>/week for 3 consecutive weeks for those with prior chemotherapy or radiotherapy. Because of the cumulative toxicity, the recommended dose for the second cycle of S 10036 chemotherapy ("maintenance therapy") is 100 mg/m<sup>2</sup>/week every 3 weeks.

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