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An I.V. formulation of human granulocyte colony-stimulating factor (G-CSF) in patients with small-cell lung cancer. The safety and pharmacokinetic profile of an intravenous (I.V.) formulation of granulocyte colony-stimulating factor (G-CSF) was evaluated in patients with small-cell lung cancer. G-CSF, in the form of a solution containing 5 microg/ml of G-CSF, was administered daily by I.V. infusion (5 microg/ml; n = 20) to patients with small-cell lung cancer. The safety and tolerability profile of G-CSF was comparable to that previously reported for subcutaneous (S.C.) G-CSF. No patients developed either local or systemic hypersensitivity reactions to G-CSF. Of the 19 evaluable patients, three (15%) achieved stable disease. Two patients (10%) had prolonged survival. The peak serum G-CSF concentrations in the majority of patients (81%) were greater than the concentration reported to increase granulocyte counts in patients given S.C. G-CSF. Peak serum G-CSF concentrations exceeded the concentration that induced maximum granulocyte stimulation in most of the patients. I.V. administration of G-CSF



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