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Phase II Study of Imatinib in Patients With Recurrent Gliomas of Various Histologies: A European Organisation for Research and Treatment of Cancer Brain Tumor Group Study

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Purpose: To evaluate the safety and the efficacy of imatinib in recurrent malignant gliomas.

Patients and Methods: This was a single-arm, phase II study. Eligible patients had recurrent glioma after prior radiotherapy with an enhancing lesion on magnetic resonance imaging. Three different histologic groups were studied: glioblastomas (GBM), pure/mixed (anaplastic) oligodendrogliomas (OD), and low-grade or anaplastic astrocytomas (A). Imatinib was started at a dose of 600 mg/d with dose escalation to 800 mg in case of no toxicity; during the trial this dose was increased to 800 mg/d with escalation to 1,000 mg/d. Trial design was one-stage Fleming; both an objective response and 6 months of progression-free survival (PFS) were considered a successful outcome to treatment.

Results: A total of 112 patients (51 patients with GBM, 25 patients with A, and 36 patients with OD) were enrolled. Imatinib was in general well tolerated. The median number of cycles was 2.0 (range, 1 to 43 cycles). Five patients had an objective partial response, including three patients with GBM; all had 6 months of PFS. The 6-month PFS rate was 16% (95% CI, 8.0% to 34.0%) in GBM, 4.0% (95% CI, 0.3% to 15.0%) in OD, and 9% (95% CI, 2.0% to 25.0%) in A. The exposure to imatinib was significantly lower in patients using enzyme-inducing antiepileptic drugs. The presence of

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ABCG2 point mutations were not correlated with pharmacokinetic findings. No somatic activating mutations of KIT or platelet-derived growth factor receptor-A or -B were found.

Conclusion: In the dose range of 600 to 1,000 mg/d, single-agent imatinib is well tolerated but has limited antitumor activity in patients with recurrent gliomas.

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