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Imatinib in combination with hydroxyurea versus hydroxyurea alone as oral therapy in patients with progressive pretreated glioblastoma resistant to standard dose temozolomide.

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A randomized, multicenter, open-label, phase 3 study of patients with progressive, recurrent glioblastoma multiforme (GBM) for whom front-line therapy had failed was conducted. This study was designed to determine whether combination therapy with imatinib and hydroxyurea (HU) has superior antitumor activity compared with HU monotherapy in the treatment of recurrent GBM. The target population consisted of patients with confirmed recurrent GBM and an Eastern Cooperative Oncology Group performance status of 0-2 who had completed previous treatment comprising surgical resection, irradiation therapy, and first-line chemotherapy (preferably temozolomide (TMZ) containing regimen) and who have progressed despite treatment. If first-line chemotherapy did not contain TMZ, a second completed chemotherapy was acceptable. The primary efficacy parameter was progression-free survival (PFS). The primary comparison of combination therapy versus monotherapy for PFS was not significant (adjusted P = 0.56). The hazard ratio (HR) (adjusted HR = 0.93) was not clinically relevant. The median PFS for the combination arm was low at 6 weeks and similar to the median PFS in the monotherapy arm (6 weeks). The 6-month PFS for the two treatment groups was very similar (5% in the combination arm vs. 7% in the monotherapy arm). No clinically meaningful differences were found between the two treatment arms, and the primary study end point was not met. Among the patients receiving imatinib, no adverse events were reported that were either previously unknown or unexpected as a consequence of the disease.

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