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## Phase II Trial of Lomustine Plus Temozolomide Chemotherapy in Addition to Radiotherapy in Newly Diagnosed Glioblastoma: UKT-03

**Ulrich Herrlinger, Johannes Rieger, Dorothee Koch, Simon Loeser, Britta Blaschke, Rolf-Dieter Kortmann, Joachim P. Steinbach, Thomas Hundsberger, Wolfgang Wick, Richard Meyermann, Ta-Chih Tan, Clemens Sommer, Michael Bamberg, Guido Reifenberger, Michael Weller**

From the Department of General Neurology, Hertie Institute for Clinical Brain Research; Departments of Radiation Oncology and Neuropathology, University of Tübingen, Tübingen; Departments of Neurosurgery and Neurology, University of Mainz, Mainz; Department of Neuropathology, University of Duesseldorf, Düsseldorf, Germany

Address reprint requests to Ulrich Herrlinger, MD, Clinical Neurooncology Unit, Department of Neurology, University of Bonn, Sigmund-Freud-Str 25, D-53105 Bonn, Germany; e-mail: [Ulrich.Herrlinger@ukb.uni-bonn.de](mailto:Ulrich.Herrlinger@ukb.uni-bonn.de)

**PURPOSE:** To evaluate toxicity and efficacy of the combination of lomustine, temozolomide (TMZ) and involved-field radiotherapy in patients with newly diagnosed glioblastoma (GBM).

**PATIENTS AND METHODS:** Thirty-one adult patients (median Karnofsky performance score 90; median age, 51 years) accrued in two centers received involved-field radiotherapy (60 Gy in 2-Gy fractions) and chemotherapy with lomustine 100 mg/m<sup>2</sup> (day 1) and TMZ 100 mg/m<sup>2</sup>/d (days 2 to 6) with individual dose adjustments according to hematologic toxicity.

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**RESULTS:** A median of five courses (range, one to six courses) were delivered. WHO grade 4 hematotoxicity was observed in five patients (16%) and one of these patients died as a result of septicemia. Nonhematologic toxicity included one patient with WHO grade 4 drug-induced hepatitis (leading to discontinuation of lomustine and TMZ) and one patient with WHO grade 2 lung fibrosis (leading to discontinuation of lomustine). The progression-free survival (PFS) rate at 6 months was 61.3%. The median PFS was 9 months (95% CI, 5.3 to 11.7 months), the median overall survival time (MST) was 22.6 months (95% CI, 12.5 to not assessable), the 2-year survival rate was 44.7%. O<sup>6</sup>-Methylguanine-DNA methyltransferase (*MGMT*) gene-promoter methylation in the tumor tissue was associated with longer PFS ( $P = .014$ , log-rank test) and MST ( $P = .037$ ).

**CONCLUSION:** The combination of lomustine, TMZ, and radiotherapy had acceptable toxicity and yielded promising survival data in patients with newly diagnosed GBM. *MGMT* gene-promoter methylation was a strong predictor of survival.

U.H. and J.R. contributed equally to this work.

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Authors' disclosures of potential conflicts of interest and author contributions are found at the end of this article.

