LATE BREAKING ABSTRACT

The 19th Annual Scientific Meeting and Education Day of the Society for Neuro-Oncology
Presented: Saturday, November 15, 2014 · Miami, Florida

Abstract Number NT-40

##########

Interim Analysis of the EF-14 Trial: A Prospective, Multi-center Trial of NovoTTF-100A Together With Temozolomide Compared to Temozolomide Alone in Patients with Newly Diagnosed GBM

Roger Stupp, Eric Wong, Charles Scott, Sophie Taillibert, Andrew Kanner, Santosh Kesari and Zvi Ram on behalf of the EF-14 Trial investigators

BACKGROUND: Tumor Treating Fields (TTFields) are an anti-mitotic, physical treatment modality that acts in metaphase, anaphase and telophase. The NovoTTF-100A System (NovoTTF), a home-use medical device that delivers TTFields to the brain, is an established monotherapy for recurrent glioblastoma (GBM).

METHODS: We conducted an international, multicenter, prospective, randomized phase III trial in newly diagnosed GBM patients. After completion of radiotherapy (RT) with concomitant temozolomide (TMZ), patients were randomized (2:1) to adjuvant TMZ with NovoTTF or adjuvant TMZ alone. The primary endpoint was progression-free survival (PFS), with overall survival (OS) an important secondary endpoint. Here we report on a pre-specified interim analysis of the first 315 patients randomized, after a minimum follow-up of 18 months (range 18-60 months).

RESULTS: (intent-to-treat): 210 pts were randomized to NovoTTF/TMZ and 105 to TMZ alone. Patient characteristics were balanced: median age 57 and 58 years, tumor resection in 89 and 90%, KPS 90%, for the NovoTTF and the control arms, respectively. *MGMT* promoter methylation status was assessable centrally in 60% of patients; of these 39% and 41% were methylated. Adverse events (AE) were comparable between treatment arms. The most common device-related AE was skin irritation in 45% of patients (all grades, severe 2%). Severe seizures were observed at a frequency of 7% in both arms. Median PFS was 7.1 months [mo] (95% confidence interval [CI] 5.9-8.2) and 4.0 mo (CI 3.0-4.3; Hazard ratio 0.63, p=0.001), OS was 19.6 mo (CI 16.5.-24.1) and 16.6 mo (CI 13.5-19.1) (HR 0.75, p=0.034), both favoring NovoTTF. This translates into a 24-mo survival rate of 43% (CI 36-50%) and 29% (CI 21-39%) for the NovoTFF/TMZ and the TMZ alone arm, respectively.

CONCLUSIONS: The trial met its primary and main secondary endpoints, and was closed to accrual after this interim analysis. Adjuvant TMZ chemotherapy and NovoTTF provides a clinically and statistically significant improvement in progression-free and overall survival, and should become the new standard of care against GBM.