

# Subgroup and quality of life analyses of the phase III clinical trial of NovoTTF-100A versus best standard chemotherapy for recurrent glioblastoma

Zvi Ram<sup>1</sup>, Philip H. Gutin<sup>2</sup> and Roger Stupp<sup>3</sup> on behalf of the EF-11 clinical trial investigators

<sup>1</sup> TASMC Tel Aviv, Israel; <sup>2</sup> MSKCC New York, NY; <sup>3</sup> CHUV Lausanne, Switzerland

## Background:

NovoTTF is a portable device delivering low intensity, intermediate frequency, electric fields using noninvasive, disposable scalp electrodes. These fields physically interfere with cell division. Preliminary studies in recurrent and newly diagnosed GBM have shown promising results. A phase III study in recurrent GBM has recently been concluded.

## Methods:

Adults (KPS $\geq$ 70%) with recurrent GBM (any recurrence) were randomized (stratified by surgery and center) to either NovoTTF administered continuously (20-24h/day, 7 days/week), or the best available chemotherapy (best physician choice - BPC). Primary endpoint was overall survival (OS). PFS6, 1-year survival, and QOL were secondary endpoints.

## Results:

237 pts were randomized (28 centers in USA & Europe) to either NovoTTF alone (120 pts) or BPC (117 pts). Patient characteristics were balanced, median age was 54 years (range 23-80), median KPS 80% (50-100). One quarter had surgery for recurrence and over half of the patients were at their second or more recurrence. A survival advantage for the device group was seen (median OS 7.8m vs. 6.1m; n=185; p=0.01). Moreover, subgroup analysis in patients with better prognostic baseline characteristics (KPS $\geq$ 80%, age $\leq$ 60, 1<sup>st</sup>-3<sup>rd</sup> recurrence) demonstrated a robust survival benefit for NovoTTF patients compared to matched BPC patients (median OS 8.8m vs. 6.6m; n=110; p<0.01). In this group, 1-year survival was 35% vs. 20% and PFS6 was 25.6% vs. 7.7%. Interestingly, in patients who failed Bevacizumab prior to the trial, OS was also significantly extended by NovoTTF (4.4m vs. 3.1m; n=23 vs. n=21; p<0.02). Quality of life (QOL) was equivalent or superior in patients treated with NovoTTF.

## Conclusions:

NovoTTF, a non-invasive, novel cancer treatment modality shows significant therapeutic efficacy with improved quality of life. The impact of NovoTTF was more pronounced when patients with better baseline prognostic factors were treated. A large scale phase III clinical trial in newly diagnosed GBM is currently being conducted.