

# Information Regarding Clinical Trial

<b>Title</b>	A Randomized, Multicenter, Phase 2 Study of DSP-7888 Dosing Emulsion in Combination with Bevacizumab versus Bevacizumab Alone in Patients with Recurrent or Progressive Glioblastoma <u>following</u> Initial Therapy
<b>Protocol Number</b>	BBI-DSP7888-201G
<b>Sponsor</b>	Boston Biomedical
<b>Investigator</b>	J. Thaddeus Beck, MD 3232 N. North Hills Blvd. Fayetteville, AR 72703
<b>Study Related Phone Numbers</b>	479-587-1700 (24 hours)
<b>Key Points for Study</b>	<ul style="list-style-type: none"> <li>-Prescreen ICF for <u>required</u> HLA typing to determine eligibility. (This central lab test can be done prior to Screening <u>after</u> obtaining prescreening ICF signature. Results take about 10 days to come back.</li> <li>*Might be a good idea to perform while pt is still receiving chemoradiation)</li> <li>-Radiographic evidence of progression following <u>first</u> recurrence or progression from primary therapy consisting of surgery and chemoradiation</li> <li>-Karnofsky Performance Status (KPS) score of <math>\geq 60</math></li> <li>-Must be at least 12 weeks from completion of prior RT in order to discriminate pseudo-progression from progression</li> <li>-<u>NO</u> evidence of leptomeningeal spread of tumor OR any hx, presence, or suspicion of metastatic disease extracranially</li> <li>-If pt on dexamethasone, dose may not exceed 4mg/day</li> <li>-<u>NO</u> active autoimmune diseases within 2 years of study enrollment</li> <li>- QTcF must be less than 480 msec</li> <li>- LVEF greater than 40%</li> </ul>