SM-03. A RANDOMIZED, PLACEBO-CONTROLLED PILOT TRIAL OF ARMODAFINIL FOR FATIGUE IN PATIENTS WITH GLIOMAS UNDERGOING RADIOTHERAPY

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BACKGROUND: Fatigue is a common symptom among glioma patients and affects quality of life. Armodafinil, a wakefulness-promoting medication, benefits patients with fatigue of various causes. This study evaluates the effects of armodafinil on fatigue in glioma patients undergoing radiation therapy (RT). METHODS: Eligibility criteria included age ≥ 18; KPS ≥ 60; grade 2-4 glioma undergoing RT to a total dose of 50-60 Gy with or without chemotherapy. Patients were randomized 1:1 to armodafinil or placebo. Fatigue assessments were made at baseline, Day 22, Day 43, and Day 56 with the FACIT-F Fatigue Scale, FACT-G, Brief Fatigue Inventory (BFI), and Cancer Fatigue Scale (CFS). The primary aim was to detect a difference in the 42-day change in FACIT-F fatigue subscale scores between the two groups using a 2-sample Wilcoxon statistic. Secondary outcomes include a 42-day change in FACT-G, CFS, and BFI. RESULTS: In the armodafinil arm, median age was 56 (25-79), median KPS was 90 (70-100), 58.5% with grade 4 glioma, 34.2% with grade 3 glioma, 2.4% with grade 2 glioma. In the placebo arm, median age was 54 (19-78), median KPS was 90 (70-100), 47.8% with grade 4 glioma, 30.8% with grade 3 glioma, 10.3% with grade 2 glioma. The median 42-day change in the FACIT-F fatigue subscale scores in the armodafinil arm was 1 (range -40 to 26) and in the placebo arm was -5.50 (range -65 to 28) with Wilcoxon p-value of 0.14. Toxicity was rare and similar between arms. CONCLUSIONS: Treatment with armodafinil is well tolerated in glioma patients undergoing RT. Preliminary results do not demonstrate statistically significant reduction in fatigue between groups. Updated results will be presented.