AT-15. A PHASE II STUDY OF ANTINEOPLASTONS A10 AND AS2-1 IN PATIENTS WITH BRAINSTEM GLIOMAS FINAL REPORT (PROTOCOL BT-11)

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PURPOSE: To evaluate the efficacy and safety of antineoplastons A10 and AS2-1 (ANP) in patients with brainstem glioma (BSG). METHODS: In the intent to treat (ITT) population forty patients (median age 11.2 years) were enrolled, and all were included in safety analysis, but only 39 patients were evaluated for efficacy. ANP was administered intravenously daily. Efficacy analyses were conducted in all BSG patients and in two subgroups: recurrent pediatric diffuse intrinsic pontine glioma (RPDIPG) and non-DIPG (NDIPG). RESULTS: In BSG, complete responses (CR) were observed in 13% of patients, partial responses (PR) 10%, and stable disease (SD) 20.5%. Overall survival (OS) at 1, 2, 5, 10 and 15 years was 38.5%, 28%, 23%, 20%, and 17% correspondingly. Six patients are presently alive 7.6 years to over 18 years. In the RPDIPG group, CR was 6%, PR 23.5%, and SD 17.5%. One year OS was 29%, 2 years 12%, and 5, 10, and 15 years 6%. In the NDIPG group, there were 36% CR and 27% SD. OS at 1, 2, 5, 10, and 15 years was 82%, 73%, 73%, 62%, and 50% correspondingly. Grade 3 and higher sodium and potassium abnormalities occurred in 15%, fatigue and somnolence in 12.5%, skin allergy and urinary incontinence occurred in 2.5% (all toxicities in ITT). No chronic adverse events occurred. Responding patients experienced improved quality of life. CONCLUSION: The results suggest that ANP shows efficacy and acceptable tolerability profile in patients with BSG, RPDIPG, and NDIPG.