Title

PC3 - 151 Toca 5: A Phase 2/3 Randomized, Open-Label Study of Toca 511, a Retroviral Replicating Vector, Combined with Toca FC versus Standard of Care in Patients Undergoing Planned Resection for Recurrent Glioblastoma (GBM) or Anaplastic Astrocytoma...

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PC3 - 151 Toca 5: A Phase 2/3 Randomized, Open-Label Study of Toca 511, a Retroviral Replicating Vector, Combined with Toca FC versus Standard of Care in Patients Undergoing Planned Resection for Recurrent Glioblastoma (GBM) or Anaplastic Astrocytoma (AA) (NCT02414165)

18th Biennial Canadian Neuro-Oncology Meeting, Banff Alberta, May 10-12, 2018

Zadeh G, Bota D, Cachia D, Landolfi J, Schiff D, Vogelbaum MA, Walbert T, Tran D, Chu A, Das A, Jolly DJ, Ibañez CE, Ostertag D, Sully S, Cloughesy TF.

ABSTRACT

Recurrent GBM and AA have a dismal prognosis and a high unmet need for effective therapies. Toca 511 (vocimagene amiretrorepvec) is an investigational retroviral replicating vector that encodes the transgene cytosine deaminase (CD). Toca 511 selectively infects, persists and spreads in tumor. Subsequent oral administration of 5-fluorocytosine (Toca FC) produces 5-fluorouracil (5-FU) by CD within infected cells. 5-FU kills cancer cells and myeloid derived suppressor cells, inducing robust antitumor immune responses in animal models. Clinical data from phase 1 trials are consistent with this mechanism of action, and show extended survival compared to historical controls. Toca 5 is a multicenter, randomized, open-label Phase 2/3 trial of Toca 511 and Toca FC versus standard of care administered to patients undergoing resection for first or second recurrence of GBM or AA. Phase 2 will enroll 170 patients. Primary endpoint is overall survival (OS). Key secondary endpoints are safety, objective response rate, clinical benefit rate, progression-free survival, and landmark OS. Key inclusion criteria are age 18-75 years, histologically proven GBM or AA, measurable disease preoperatively of less than 5cm, candidate for equal or greater 80% resection of enhancing tumor based on pre-operative evaluation, and KPS equal or greater to 70. Assays for immune monitoring will be performed and molecular profiling of resected tumor samples will be correlated efficacy.

Type

Poster Viewing Sessions

Information

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