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Authors
Zadeh, G
Walbert, T
Perry, J
et al.

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Toca 5: Toca 511 combined with Toca FC versus standard of care in patients undergoing planned resection for recurrent glioblastoma or anaplastic astrocytoma

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Zadeh G, Walbert T, Perry J, Zhu J, Salacz M, Bota D, Kim L, Iwamoto F, Petrecca K, Sully S, Montellano T, Kheoh T, Das A, Cloughesy TF. tmontellano@tocagen.com

ABSTRACT

Toca 511 (vocimagene amiretrorepvec) is an investigational, conditionally lytic, retroviral replicating vector (RRV). RRVs selectively infect cancer cells due to innate and adaptive immune response defects in cancers that allow virus replication, and the requirement for cell division for virus integration into the genome. Toca 511 spreads through tumors, stably delivering an optimized yeast cytosine deaminase gene that converts the prodrug Toca FC (investigational, extended-release 5-FC) into 5-FU within the tumor microenvironment. 5-FU kills infected dividing cancer cells and surrounding tumor, myeloid derived suppressor cells, and tumor associated macrophages, resulting in long-term tumor immunity in preclinical models. Data from a Phase 1 resection trial showed six durable CRs and extended mOS compared to historical controls. The FDA granted Breakthrough Therapy Designation for Toca 511 & Toca FC in the treatment of patients with rHGG. Toca 5 is an international, randomized, open-label Phase 3 trial (NCT02414165) of Toca 511 & Toca FC versus SOC in patients undergoing resection for first or second recurrence of rHGG. Patients will be stratified by IDH1 status, KPS, and geographicregion. Primary endpoint is OS, and secondary endpoints are durable response rate, durable clinical benefit rate, duration of durable response, and 12-month survival rate. Key inclusion criteria are histologically proven GBM or AA, tumor size ≥1cm and ≤5cm, and KPS ≥70. Immune monitoring and molecular profiling will be performed. Approximately 380 patients will be randomized. An IDMC is commissioned to review the safety and efficacy data which includes 2 interim analyses. Enrollment is ongoing. 11

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