ERC Announces Interim Results from Phase 2 Trial of Immunotherapy ERC1671 in Recurrent Glioblastoma Patients

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ISNES, Belgium--(ERC Belgium, a clinical-stage biopharmaceutical company developing immunotherapies for the treatment of cancer, has announced promising interim results in the phase 2 clinical trial for ERC1671 (also known as Gliovac or SITOIGANAP) under FDA IND 15430 at the University of California, Irvine Medical Center in Orange, California.

“Prior to this study of ERC1671 immunotherapy for recurrent GBM, it was almost unknown for such patients to experience recovery. We are excited to accelerate recruitment and complete this study.”

The trial, “ERC1671/GM CSF/Cyclophosphamide+Bevacizumab vs Placebo,” is a double-blind, placebo-controlled study of 84 patients with recurrent GBM. Interim unblinding and analysis of the first 10 patients from the study demonstrated the following results in patients treated with ERC1671:

- 6-month overall survival (OS) rate of 100%;
- 12-month OS rate of 40%;
- Median OS is 46 weeks (10.5 months)

Historic controls have 6-month OS rate of 33% and median OS of 23 weeks (5.3 months). This dataset reveals a striking improvement over current clinical practice and the results demonstrate a highly significant (log rank test, $p < 0.0001$) increase in the OS of patients when treated with ERC1671.

Approximately 10% of the patients receiving ERC1671 experienced total recovery and survived longer than 3 years when treated following GBM recurrence and after receiving standard of care treatment. In contrast, no spontaneous remissions were observed in the control group and all patients experienced tumor progression.

Furthermore, a subgroup of patients who had failed treatment with bevacizumab (Avastin) benefited disproportionately with an apparent doubling of survival compared to historical controls.

Principal investigator of the clinical trial, Daniela Bota, MD, PhD, commented, “Prior to this study of ERC1671 immunotherapy for recurrent GBM, it was almost unknown for such patients to experience recovery. We are excited to accelerate recruitment and complete this study.” Dr. Bota is Vice Dean for Clinical Research, Medical Director, UCI Center for Clinical Research; Director, UCI Alpha Stem Cell Clinic; Medical Director, UCI Health Comprehensive Brain Tumor Program.

Apostolos Stathopoulos, MD, PhD, President and CEO of ERC Worldwide commented, “We are encouraged by such strong results for ERC1671 in Dr. Bota’s study and pleased to see a high number of patients going into remission. We believe that ERC1671 is finally leading the way for immunotherapy to treat intractable cancers like recurrent GBM that currently do not have alternative therapeutic options.”

About ERC1671

ERC1671 (Gliovac or SITOIGANAP) is an advanced immunotherapy based on freshly extracted tumor cells and lysates that stimulates the patient's immune system to recognize and reject cancer cells. The immunotherapy contains a combination of autologous tumor cells, and allogeneic tumor cells, generated from the glioma tumor tissues of three different donor cancer patients, and the lysates of all of these cells. Upon injection, this mixture stimulates the patient's immune system to mount an immune response against the tumor cells, which may lead to their destruction.

ERC1671 is for patients suffering from a grade IV glioma (glioblastoma multiforme and gliosarcoma) when all other traditional treatments have failed. The response to SITOIGANAP is the same whether the MGMT promoter is methylated or unmethylated.

ERC1671 is currently in randomized, placebo-controlled Phase 2 clinical trials in the United States as part of combination treatment for glioblastoma multiforme and gliosarcoma.

About ERC Belgium

ERC-Belgium SA, is a clinical stage emerging Biopharmaceutical Company developing a safe, highly effective approach for the treatment of cancer, particularly cancers of the brain. ERC has built a network of leading neuro-oncologists in several countries in the world, among others in the US and Europe to propel its immunotherapies through clinical development and to market. ERC's regimen of therapeutic vaccines has shown early promise in patients suffering from recurrent Glioblastoma multiforme (GBM), the deadliest of brain cancers. We are very proud to provide the product for patients that are not eligible for the current clinical trials, under the RIGHT TO TRY law and other new programs established by different medical centers in the United States.

The company's therapeutic approach is also being applied to a developmental vaccine against COVID-19 and can be potentially applied to many other types of solid cancers. ERC Belgium is based in Isnes, Belgium with subsidiaries in the U.S.A., Netherlands, Canada, Australia and an international presence throughout country-specific agreements within Europe and Latin America. To learn more, please visit http://erc-immunotherapy.com.