DATE: 20th April 2020

MEMO RE: **Update on ERC Company Progress in past 12 months**

INTRODUCTION:

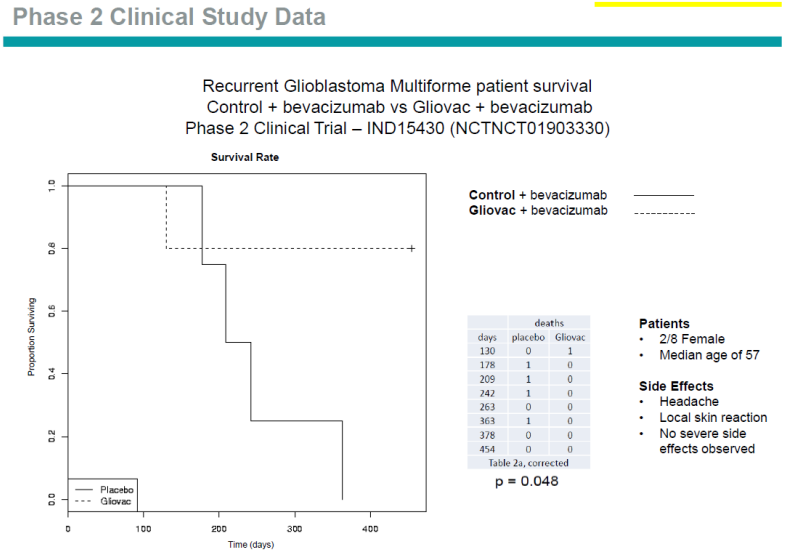
ERC has made significant progress over the past 12 months in moving our experimental vaccine Gliovac (also known as ERC1671) towards commercialization. Major progress has been made in several areas:

1. **Clinical Trial - FDA (IND-15430)**

Daniela Bota, MD, Ph.D., Director, Neuro-oncology Program, UC Irvine Medical Center Orange, CA, 92868, received approval from the FDA on the 17th April 2013 for an investigator sponsored, 84 patients, double-blind, placebo controlled clinical trial of ERC-1671.

By the early 2017, Dr. Bota noticed that some patients participating in the trial experienced stable disease for an unusually long period, which is normally not seen in recurrent refractory glioblastoma. As a result, a decision was made to unblind the first 9 patients who had completed the study.

The unblinding demonstrated a surprisingly promising separate distribution between patients receiving placebo and those receiving Gliovac (ERC1671). While the numbers are very small (5 placebo controls and 4 patients), the results were highly promising (see graphical representation below).



2. **<u>Treatment of Patients Under the U.S. Right-to-Try law (RTT)</u>**

   a. The first patient in the U.S. to be treated under RTT law was a patient with grade IV recurrent glioblastoma (GBM) who requested treatment with ERC1671 (Gliovac) at UC Irvine in December 2018.

   b. Treatment of this patient received quite a bit of press for ERC.

   c. Since this initial patient, ERC has provided ERC1671 to five patients with grade IV GBM. Patients have been treated in New York, New Jersey and California. All patients are still alive and have stable disease or have gone into remission. This is an astonishing result where 100% of patients have responded to our treatment. NO OTHER TREATMENT HAS EVER STOPPED GRADE IV GBM.

   d. Some RTT patients have been able to pay for some of the treatment to offset ERC's significant costs. Thus, RTT is generating many new patients and a steady stream of revenue for the company.

3. **<u>Reimbursement by Insurance:</u>**

   a. **<u>Aetna Insurance:</u>** ERC met with the Aetna Insurance company in Boston on 13th September 2019 and made a strong case for Aetna to reimburse RTT treatment of their clients who receive ERC1671. Aetna is currently considering our proposal.

   b. **<u>US Veterans Administration (VA):</u>** ERC had a meeting in Washington DC at the headquarters of the VA and made a strong case that they reimburse treatment of veterans who receive ERC1671 under RTT. The VA was receptive to ERC's arguments

and have tentatively agreed to a pilot project of up to $5 million to treat up to 10 veterans.

c. **Centers For Medicare & Medicaid Services:** ERC has a meeting October 10 in Washington DC at the headquarters of Medicare after invitation to reimburse the Medicare patients who will receive Gliovac ERC1671.

4. Regulatory Progress

a. US Food and Drug Administration (FDA)

As a result of this promising data, ERC and Dr. Bota's clinical team plans a meeting with the FDA Center for Biologics Evaluation and Research (CBER) to discuss the potential for Fast Track and Breakthrough Therapy designation of the Gliovac program. In general, the FDA team has been receptive to the concept.

ERC is preparing a commercialization request for its product and will submit it to the FDA in April 2020.

b. European Medicines Agency (EMA)

The EMA's Committee for Medicinal Products for Human Use (CHMP) agreed to consider Gliovac for Conditional Marketing Authorization and ERC has had two meetings with the EMA's CHMP, on 9th February 2018 and on 9th July 2018 to further our applications for such authorization. If ERC's application for conditional approval is successful, we will be able to proceed with commercialization Gliovac within the EU and state insurance will be obligated to reimburse the cost of treatment.

c. UK Medicines and Healthcare Products Regulatory Agency (MHRA)

ERC has been approved to apply for a Promising Innovative Medicine (PIM) designation in the UK and the ERC team submitted its application and was invited for a meeting with the MHRA on 29th July 2018. The meeting went very well and we will be submitting additional information to the UK authorities for PIM designation. If successful, this will allow ERC to market Gliovac in the UK, in the next 12 months.
In this context, a commercialization request has been submitted to the UK authorities at the end of January 2020.

5. Expanding the Clinical Trial:

Dana Farber Cancer Institute (DFCI) in Boston, a Harvard University hospital, has joined the ERC clinical trial as additional site. The Dana Farber IRB and SRB of Dana Farber have both endorsed the commencement of the trial. The first patients should be recruited by November 2019. DFCI is the largest brain cancer referral center in the United States. Once DFCI begins recruiting patients next month, we are confident that we will be able to complete the clinical trial in 12

months and begin the process of full commercialization.

6. **Compassionate Use**

The company has continued to make ERC-1671 available for compassionate use around the world. By the end of 2019, more than 28 patients with recurrent, terminal (stage IV) GBM had been treated with ERC-1671 in Belgium, Germany, Colombia, South Africa and Australia.

7. **Manufacturing**

ERC's facility in Schaijk, The Netherlands, was inspected by the Dutch Health Authorities and was issued a new GMP certificate dated 26th July 2018 authorizing ERC-NL to continue to produce Gliovac for human use.

8. **Scientific**

ERC's academic collaborators continue to receive great attention. Prof. Daniela Bota, ERC's principal investigator in the Gliovac clinical trial in the US, has been invited to present our latest findings at the Society for Neuro-oncology (SNO) meeting in Phoenix Arizona in November 2019. Furthermore, our extraordinary clinical responses of the five RTT patients are being summarized in a publication soon to be submitted to a tier 1 neuro-oncology journal.

9. **US Expansion**

ERC has opened a second US office at 745 Fifth Avenue, Suite 500, New York. ERC now has an office on the West coast in Pasadena and on the East coast in New York which will allow the company to manage the expansion of its clinical trial and the escalating demand for RTT treatment across the US.

10. **Commercialization**

a. Commercialization request in **UK** : file submitted to the EMEA in January 2020.
b. Preparation of the commercialization request to the FDA, in the **USA**, in progress.

11. **COVID-19**

ERC has filed a patent against SARS-CoV-2 virus (Covid-19) for the **COVIDVAC** vaccine.

CONCLUSION:

ERC has made significant progress over the past 12 months and our success continues to aggressively accelerate the development of ERC1671 (Gliovac) on commercial, scientific and regulatory fronts. With the inclusion of DFCI in Boston in our clinical trial, we will be at the forefront clinical development at one of the world's leading cancer centers and will be well on the way to commercial success in the next 12 to 18 months.