

September 24, 2007

Dear Friends,

Thank you for your continuing support and your patience. We have been working very hard to fulfill our commitments and promises in this challenging project.

Before a drug like DCA is considered safe and effective, many more trials, involving several centers around the world need to be completed and the results need to be scrutinized. Therefore it may take years and many millions of dollars before efficacy of DCA is established. We also need to emphasize that even with the support of pharmaceutical companies, it usually takes 3 years from the time that a drug is shown to be promising in animals to the point that it is first tried on a human being.

Lastly, we would like to let you know that before a trial can be initiated, it first has to obtain approval for the institutional human ethics committees; these committees include physicians, scientists and community representatives that make sure that the clinical trial will respect and protect the enrolled patients according to international standards. Thereafter, the study has to be approved by Health Canada, an agency of the Federal Government, that also applies very strict criteria in order to ensure that patients are protected, that there is scientific rationale for the conduction of the trial and that the physicians and hospitals involved are well-trained and equipped to conduct such a trial. These applications are quite complex and require the work of many team members.

We are very proud of the progress that we have made over the last few months, without the support from the pharmaceutical industry, and would like to share the following developments with you:

1. Our fundraising continues to expand and we are proud to announce that **we have now raised more than \$800,000**. We have set a target of \$1.5 million to complete a set of 2 pilot trials. At this point we are comfortable that we can complete at least one trial, as we continue our fundraising efforts.

2. We have also developed 2 clinical trial protocols using DCA in patients with cancer as a starting point.

2.1. The first clinical trial is a “phase I” trial; this means that the doctors try to slowly increase the dose of the drug in patients with a variety of cancers, in order to first identify the maximal dose tolerated, i.e. the dose that can be hopefully effective without any significant adverse effects. These “phase I” trials are slow to conduct and involve a relatively small number of patients, but their significance for subsequent work is very important. This trial will be conducted mostly at the Cross Cancer Institute in Edmonton. We have already secured the approval from the human ethics committees from the Cross Cancer Institute and the University of Alberta Hospitals. We have applied to Health Canada and we are waiting for the results. After we receive the response from Health Canada, we will let you know of the relevant details and the key team members that will be conducting the trial.

2.2. The second trial is a “phase II” trial; this means that a specific dose of the drug is given to a specific group of patients with advanced cancer, in an effort to determine both whether the drug is safe and whether it is effective. In this trial we will administer oral DCA in patients with malignant brain tumors (anaplastic astrocytomas and glioblastomas), specifically patients with newly diagnosed tumors and patients that have failed previously standard therapies, including surgery, radiation therapy and chemotherapy. This trial will be conducted in one center (the University of Alberta Hospital) and will be based in the Division of Neurosurgery.

We are excited to report that we have secured all the required approvals, from both our local ethics committee and Health Canada. We have secured the funds and the drug and we are now working on recruiting patients into the trial. This is a remarkable achievement considering that our work on animals was published only 8 months ago. We will update this site with more details and contact numbers of the key team members conducting this trial in the immediate future. This initial trial is relatively small (enrollment- up to 50 patients in the next 18 months). As is always the case with all single-center studies, the patients have to originate from the Edmonton area and be available for scheduled assessments for the duration of the trial (i.e. for at least 6 months). Unfortunately, patients from remote provinces or other countries might not be able to participate in this initial trial as we do not have the ability to fund the cost of living expenses and the costs of tests for patients from out of Canada, although arrangements may be possible for patients from other Canadian provinces. We are exploring all possibilities and will report on this in our future communications on this site.

Our next update on this site will be in approximately 2 weeks. The dedicated line for information on these trials is: 492-2604.

We need to be both optimistic and cautious at the same time. We are pleased that we are able to move ahead with these initial trials. Many more trials, involving several centers around the world need to be completed. We consider this to be the first step of many....

On behalf of our team, thank you from the bottom of our hearts!

Evangelos D. Michelakis, MD