CytoLuminator Research
4th generation Photodynamic Therapy

RE: Experimental protocol for photodynamic treatment of MS.

Tuesday, 9 September 2008

Attention: Professor (name with held)

We are of course encouraged by your expression of interest in what we are doing. I am aware of some of your work and some of the comments you have made. Of particular interest of course is your work leading to the Eureka prize and also your comment to ABC regarding the latitude gradient.

There is an alternative explanation for that phenomena which has a basis in the observed remission of autoimmune disorders which we could discuss if you are interested.

Since you have an outstanding reputation and experience in clinical trials, we would appreciate your advice, endorsement and /or involvement.

I am including the basic information of what we have done below.

Patient MRI's and other medical data are currently being accumulated and should be available shortly.

Patient information; DOB 13th Jan. 1965 was diagnosed with MS based on symptoms which were verified by an MRI scan in April of 1999. In 2006 she was still ambulatory and fit enough to make a motorcycle trip from Cowra to Darwin.

In spite of best attempts to maintain an allergen free life style her condition degraded gradually until she decided it was time for a wheelchair in late 2007. She asked to take part in an experimental treatment with PDT to see if it was possible to have significant improvement in her symptoms.

Arrangements were made to treat this person experimentally with PDT under the Special Access Scheme with a doctor providing the administration of the sensitizer and supervising the laser stimulation of the sensitizer.

I met Jo in the middle of January of 2008 to instruct the doctor in the protocol which had been set up by myself based on scanty information regarding modulation of autoimmune dysfunction. At that time her condition had degraded significantly and it was immediately apparent why she was looking at wheelchairs.

She was only able to take 5-6 steps without assistance or leaning on something. She had lost control of one eye the previous day and it was turned outward. If you spoke to her when she was facing away it took a long time, on the order of 5 seconds, for her to rotate her head toward you and acknowledge what you were saying.

It had been discussed previously, but we covered again the entirely experimental nature of the treatment. Jo was once again informed that this had apparently been done with some success, but it was not an approved procedure and there was precious little evidence to support the claim that it was possible, and there was no information at all on what percentage of people could benefit from it, how long it took to detect a positive response, how much if any symptom remission could be expected or how long it would last.

She was informed that we had done a treatment of advanced Scleroderma which had caused a complete remission of all symptoms within a few days and there was no sign of the disease returning one year later, but there was nothing to indicate we would have the same success with MS.

PROTOCOL: At that time there was very little information to support the procedure even in theory let alone in practice, but we had some operational parameters regarding dosage of light and sensitizer, subsequent sensitization of the skin and how long Jo needed to be kept from direct sun.

There are competing theories regarding modulation of autoimmune disorders by PDT, with some researchers focusing on direct kills of select leukocytes, others preferring to analyse in terms of selective stimulation of APC's, most commonly focusing on Dendritic cells, and yet others adhering to the belief that there is selective destruction of cytotoxic T cells based either on their clusters of differentiation of possibly even selectively based on their activation at the time of treatment.

Depending on which theory one adheres to there would be logical protocol changes, for example if the target was dendritic cells and one wanted to avoid direct damage to the

T cells, macrophages etc then a longer period of time to allow clearance of sensitizer from the blood while localization in the skin increased would be appropriate. There is also the question of what sensitizer is optimal, and we believed that previous research had been done with less than optimal sensitizers.

A protocol was developed and initial tests were done in vitro to validate the safety of the procedure. At this time we must regard the protocol details as confidential as disclosure without confidentiality agreements might endanger our patent rights, but we are more than happy to disclose it in detail given that it is agreed that the disclosure is to be regarded as confidential. We would be pleased if you would like to review the protocol details.

There was no adverse reaction to the administration of sensitizer or laser detectable at the time of treatment. Jo was kept under observation for one hour after treatment and then released. Patient had previously been advised that a period of avoidance of direct sun was mandatory and instructed on how to determine when it was safe to be exposed to the sun.

A minimum period of one week of avoiding direct sunlight was recommended and it was agreed that patient would be visited in her home within 10 days for measurement of the level of sensitizer in her body to determine whether she was sun safe.

Blood sample was drawn at the hospital for evaluation, but analysis of pertinent immune factors was not available to the level desired.

Patient returned home the following day, travelling in the evening to avoid excessive light exposure.

Ten days later patient was visited in home for follow up. The differences were striking in that she met me at the door, free standing and stable and chatted amiably, responding rapidly to visual and verbal stimuli. Her eye was back under control

and she stated she had regained control of her eye about 3 days after treatment.

She walked me into the house and suggested we sit at the table for a cup of tea. She was at all times stable and well controlled in her movement, speech and apparent cerebration.

When addressed while facing away the time for her to rotate her head and respond was completely normal, there was no hesitation. Gesticulation was rapid and precise. During the visit she walked throughout the house unassisted without leaning on anything, but she tired of standing after about 45 minutes and decided to sit and rest for about ten minutes, after which she led me around the house.

At one time walking down a long narrow hall she reached out and touched the wall with her fingertips three times. I asked her if that was for stabilization and she said no, it was unconscious rote behaviour because she had in the past needed to lean on the wall as she went down that hall.

She was checked for sensitizer level and it was found that it had dropped in about the expected amount, and she was advised to use caution over the next few weeks on her level of sun exposure. She was instructed to expose a small patch of skin to direct sun for a few minutes and wait a short while to see if there were signs of erythema, and if there were none it was reasonable to assume that she was safe for whole body exposure for at least the duration of time which she had tested herself for.

In follow up phone calls she stated that she had gradually returned to sun exposure starting with hanging out the clothes and increasing her exposure daily. After a few weeks she said that she had an unusual glowing tan which people remarked on, but there was no outward sign of sun damage.

As the change was so very remarkable I asked her husband several questions in private to determine if this could

possibly be within the range of normal variation in her condition. I asked whether her condition at the time I first met her was below normal due to stress of travel or other factors and he said no, at the time I saw her she was in the same condition she had been for months except loss of control of her eye which had occurred just before we met.

I asked if she normally had substantial variations ofcondition which might encompass the present changes and he said absolutely not, she had never been in this condition since they had met five years earlier, but they weren't talking about it much as they didn't want to get their hopes up in case it was a temporary improvement.

A few months later she saw her neurologist and explained that she had lost control of her eye but it had returned to normal a week later. He evaluated her and ordered an MRI because he said the changes were inexplicable.

We stayed in touch on a monthly basis and were always told that there was nothing but constant improvement.

On the seventh of July we received the following message from Peter, Jo's partner.

We think the immune sufferers (MS) would be a good trial for Terry's PDT
to get some serious momentum. We had a visit with Jo's neurologist today
and after hearing Jo's condition Dec/Jan.. wheel chair eye etc.. he
started telling us about new generation drugs coming online yak yak...
then he checked Jo's MRI scans (head) and was amazed that the signs of
flaring were minimal.

He expected to see bright flaring and black holes which are normally highly evident for 4-6 months following such a

major episode and there was basically nothing. He then started to listen to us about diet, lifestyle and pdt.

When we explained that your system was switching the T2 T3 into correct balance/mode he became very interested as it was doing what they try to achieve with drugs.

He felt you should contact MS/immune research groups and get some serious trials happening. After doing lots of function tests on Jo he simply said "go home and continue what you do, I've got no better alternative.." when we can get the written report that will be sent to Jo's GP we will see if we can organise a local group to trial PDT.

In the first week of September 2008 several contacts have been made during which her partner, Peter, repeatedly stated she is in better condition than he is in most aspects, she now takes over computer work because she says he is too slow and has no signs of any form of debilitation. On the sixth I spoke with her and remarked she sounded tired and she said she had gotten up about 5 am to go to Canberra to markets and had spent the whole day on her feet, then travelled home and it was about 9 pm, so being tired was to be expected.

She has her most recent MRI on film which is being sent to me to be digitized, a request has been sent for a duplicate of her 1999 MRI in digital format. She is requesting copies of all pertinent medical records and these can be made available for analysis.

We are aware that this is a one-time event, but given that it was performed in a manner consistent with a procedure expected to produce this response and the response was as predicted we feel it at the very least is an initial indicator of a possibility that the result may be, most likely is, repeatable and therefore is deserving of further investigation.

Best regards