

June 30, 2007

Carcinoid Cancer Foundation
And the Carcinoid Cancer Community

To all who have made this project possible

PROGRESS REPORT

I am writing to bring you up to date on the status of the several PET imaging of neuro-endocrine tumor projects underway at the CBIC, a research imaging facility of the Weill College of Medicine of Cornell University.

Our group has performed studies on almost 30 patients using the C-11 5HTP tracer described some time ago by the group in Uppsala, Sweden. These findings will be reported next week at the Annual Scientific meeting of the Society of Nuclear Medicine in Washington, DC. The synthesis was developed with an earlier grant from the Foundation and the carcinoid community. The initial imaging studies were supplemented by additional funding from the Foundation. We thank the Foundation for this support.

Since January, 2007, we have initiated a revised protocol based on observations made on the initial 20 studies. These studies have been performed without a grant but our nuclear medicine department has on several occasions received voluntary contributions from individuals choosing to support this effort. These funds have enabled us to continue this phase of our studies.

We are eager to begin a protocol to evaluate the utility of Gallium-68 peptide. The chemistry has been worked out, again with a grant from the Foundation which made it possible to purchase our initial Germanium-68 / Gallium-68 generator. This material has the potential of being more widely accessible than Carbon-11.

It is important to note that the relative merit of PET labeled somatostatin receptor ligands [the peptides] and PET substrates such as F-18 FDOPA or C-11 HTP has never been established. We are eager to move into that area so as to determine which study or studies are best and in which circumstances. It is premature to conclude that the “universal” or “best” tracer has been identified by any of the groups involved in these studies.

Concerned individuals should note that the publications to date report investigations in patients with known neuroendocrine tumors whereas many of the patients studied by our

group have symptoms, concerns and suspicions. It is a far different question to evaluate and compare images in patients with proven tumors from detecting tumors that are suspected but not proven. In many patients, elevated neuroendocrine tumor markers have not been consistently demonstrated.

Over the years, working with patients with neuroendocrine tumors, I have come to appreciate the medical and personal difficulties many experience. My group and I are eager to contribute to their relief. It is necessary, however, both from a scientific as well as from a regulatory perspective to proceed in a well defined manner.

Despite the many publications and the superior cosmetic quality of PET images in general, I have found that many patients have undergone sub-optimal In-111 octreotide studies prior to seeking PET imaging to guide clinical decisions. Patients and concerned family members would do well to query their local imaging facility as to the technique to be used with IN-111 octreotide. Although it has not yet been confirmed that the technique known as SPECT/CT is required, I believe this to be the case. In addition to optimizing image acquisition, display also is of great importance. Computer display manipulation is of utmost importance to “detect or exclude tumor”.

This summer, we plan to complete the registration of these ideas with the FDA as well as to prepare a Grant application for the NCI with the hope that we can proceed with a comparison of PET peptide ligand vs substrate and SPECT for the detection of neuroendocrine tumors.

In closing, let me repeat that our group is appreciative of the support we have received from the Foundation and the carcinoid community in the past. Despite our determination to seek government agency support for a more sustained effort, any level of continuing support is appreciated and will be put to good use.

Cordially,

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