

high dose indium-111 pentetreotide (octreotide) therapy

In somatostatin receptor expressing neuroendocrine neoplasm

October 2005

It is with great pleasure to inform you that our Investigational New Drug (IND) Application for “**High Dose Indium-111 Pentetreotide (Octreotide) Therapy in Somatostatin Receptor Expressing Neuroendocrine Neoplasms.**” has been approved by FDA. RITA Foundation in collaboration with Excel Diagnostic Imaging Clinics in Houston will provide this therapy to patients with metastatic Carcinoid.

Following is the inclusion and exclusion criteria copied from the protocol for your information:

Criteria for Patient Selection

Inclusion Criteria

1. Patients with biopsy proven malignancies which express the somatostatin receptor as demonstrated by significant uptake of Indium-111 pentetreotide during a diagnostic scan. If possible, tumor tissue should be submitted for somatostatin receptor assay.
 2. Patients must have received first line standard chemotherapy and/or radiation therapy for neuroendocrine malignancy in the past and failed the therapy.
- Patients must have evidence of residual multifocal active tumor.
3. All patients must sign an informed consent indicating the awareness of the investigational nature of the studies involved.
 4. All patients must have a Karnofski performance status of at least 60%.
 5. Patients must be greater than 18 years of age.
 6. Patients must have measurable and/or followable disease based on either clinical or radiologic exam.
 7. Sensitivity to Indium-111 pentetreotide or any of its components is an absolute contraindication to participation in this trial.
 8. An absolute contraindication is pregnancy as evidenced by the clinical condition, a positive pregnancy test (B-HCG or pelvic ultrasound).
 9. If patients have received prior radionuclide therapy of the same product, there must be documented response to that therapy and/or residual active stable disease.

Exclusion Criteria

1. Karnofski performance status of 50% or less.
2. Patients who are unable to give informed consent.

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3. Patients under 18 years of age. There will be no upper age discrimination.
4. Patients who are pregnant or those potentially pregnant subjects not willing to practice effective contraceptive techniques during the study period.
5. Patients with renal insufficiency as defined by a calculated creatinine clearance (based on age, weight and serum creatinine) of 39.9 ml/min or less.

We have been authorized by FDA to administer up to 500 mCi of Indium-111 Octreotide to the eligible patients. This treatment may be administered in an outpatient settings to qualified patients. The above dose can be administered safely to the patients. No significant renal or liver toxicity has been reported in the literature regarding this therapy. Hematological toxicity are typically seen 4 to 6 weeks after therapy and are commonly transient. are only allowed . Multiple dose administration protocol has been approved by FDA. Insurance approval has been accepted by some carriers. Medicare approval is pending.

We are extremely excited for having this therapeutic option available to the patients with Octreotide avid neuroendocrine malignancies in Houston. As you probably know, the only other place offering this therapy is at the Professor Krenning's clinic in Netherlands.

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Special Note: Ms. Cork's assistant is Daisy. Please email first for a prompt response as there is much information that needs to be gone over and email proves to be the most effective way of sharing the information. For follow-up telephone calls dial (713) 781-6200 and ask the operator for Susan or Daisy.

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