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A Multicenter Phase II Trial Evaluating Safety and Efficacy of Activity Escalation with ^{177}Lu-DOTA-TATE in Patients with Disseminated Neuroendocrine Tumors, Based on Detailed Dosimetry and Patient Selection

Anna Sundlov[1]; Johanna Svensson[2]; Katarina Sjögreen Gleisner[1], Peter Bernhardt[2]; Cecilia Hindorf[1]; Michael Garkavij[1]; Bo Wängberg[2]; Tomas Ohlsson[1]; Eva Forssell-Aronsson[2]; and Jan Tennvall[1]

[1]Depts of Oncology and Radiophysics, Lund University and Skane University Hospital, Lund, Sweden
[2]Depts of Oncology, Radiophysics and Surgery, Sahlgrenska University Hospital, Gothenburg, Sweden

Background: There is a rapidly growing body of evidence indicating that peptide receptor radiotherapy (PRRT) is a safe and effective treatment for neuroendocrine tumors, ^{177}Lu-DOTA-TATE being the most commonly used radiopharmaceutical. The bone marrow and the kidneys are the dose limiting organs. The limits in terms of absorbed dose are not well established. In this trial we aim to investigate whether detailed individual dosimetry and patient selection can make it possible to give a higher number of ^{177}Lu-DOTA-TATE treatments and whether this in turn translates into better tumor response without an elevated rate of toxicity.

Methods: Adult patients with progressive metastatic neuroendocrine tumors, grade 1-2, with a high uptake on somatostatin receptor scintigraphy, are included in this trial. They are treated with 7.4 GBq ^{177}Lu-DOTA-TATE with 10 week intervals. Detailed 3D-dosimetry is performed in all patients after each treatment. The absorbed kidney dose, clinical toxicity and periodic RECIST-evaluations guide the total number of treatments given. The limit for the first stage of treatment is an absorbed kidney dose of 27 Gy. Patients without risk factors for bone marrow and/or kidney toxicity that have tolerated stage 1 treatment well, and not progressed further, continue treatments up to an absorbed dose of 40 Gy.

Results: The trial's background, patient population, design, dosimetric methods, etc will be presented together with initial data from the first 40 patients included. We have already observed that by conducting detailed dosimetry the variations in the number of treatment cycles that can be administered within the predetermined dose limits varies widely from one patient to another.

Conclusions: Individualized treatment planning, as described above, permits us to determine the optimal number of treatments for each patient which can be expected to translate into an improved overall outcome in terms of the relationship between treatment efficacy and toxicity.