DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

May 6, 2020

Announcement of Availability to Investigators of Lutathera® (815530)

For Clinical and Nonclinical Study Proposals

The Cancer Therapy Evaluation Program (CTEP) is accepting Letters of Intent (LOIs) to conduct clinical studies using Lutathera®, a radiolabeled somatostatin analog, which is being developed by CTEP as an anticancer agent in collaboration with Advanced Accelerator Applications (AAA) - Novartis Pharmaceutical Company. CTEP will also consider requests to supply Lutathera® for nonclinical studies. All clinical and nonclinical researchers possessing an interest in working with the agent are welcome to apply. Proposals for clinical trials should be supported by a strong rationale and robust preclinical data (see "Components of a Competitive Letter of Intent" at http://ctep.cancer.gov/protocolDevelopment/lois_concepts.htm). ***All proposals approved by CTEP will be sent to the industry collaborator for a commitment to supply drug for the study.***

Lutathera®, lutetium-177 (^{177}Lu)-dotatate, is a beta-emitting radionuclide that can deliver a tumoricidal radiation dose to tissues overexpressing somatostatin-receptors (SSTRs). The antitumor activity of somatostatin occurs directly via cell cycle arrest and/or apoptosis downstream from tumor SSTR activation, and indirectly via SSTR-induced inhibition of tumor angiogenesis and the production of factors that support tumor growth. ^{177}Lu induces cellular damage by formation of free radicals in SSTR-positive cells and in neighboring cells. In rat SSTR-positive tumor models, Lutathera® treatment resulted in complete ablation of implanted tumors (Erlion *et al*., 2000), while half of the SSTR-positive rats treated with Lutathera® lived a normal life span without tumor recurrence. On January 26, 2018, the FDA approved Lutathera® for the treatment of SSTR positive gastroenteropancreatic neuroendocrine tumor (GEP-NETS) in adults, based on the results of two clinical studies: the NETTER-1 study (NCT01578239) and the Erasmus Medical Center study (MEC 127.545/1993/84); Lutathera® showed beneficial effects on neuroendocrine tumors (NETs) including significantly increasing survival and low radiobiological toxicity.

Obtaining Forms and Contact Information

For clinical study proposals, the LOI Submission Form may be downloaded from the CTEP website at http://ctep.cancer.gov/protocolDevelopment/lois_concepts.htm.

If you are interested in obtaining the agent for nonclinical studies, whether alone or in association with a proposed clinical study, please complete the DCTD Nonclinical Request Form, which may be downloaded from the CTEP website at http://ctep.cancer.gov/industryCollaborations2/agreements_agents.htm.

Further instructions for completing and submitting the forms may be found within the respective documents.

Questions may be addressed to Charles Kunos, M.D. Ph.D., Medical Officer, Investigational Drug Branch, CTEP, DCTD, NCI (phone: 240-276-6939; FAX: 240-276-7894; e-mail: charles.kunos@nih.gov).

A complete list of agents available for distribution by CTEP may also be found on the CTEP website at http://ctep.cancer.gov/industryCollaborations2/agreements_agents.htm.