

## Improved progression-free survival for Lutathera over octreotide in patients with progressive metastatic midgut NETs

3 June 2016

Moffitt Cancer Center will present results of the phase 3 NETTER-1 study, showing clinically meaningful and significant results for Lutathera (<sup>77</sup>Lu-DOTA<sup>0</sup>-Tyr<sup>3</sup>-Octreotate) in patients with metastatic midgut neuroendocrine tumors (NETs). The <u>data</u> will be presented Monday, June 6, 2016 during the <u>American Society of Clinical Oncology Annual Meeting</u> in Chicago.

Somatostatin analogs, such as Octreotide LAR, are commonly used to treat NETs. They reduce hormone-related symptoms and stabilize the tumor. However, patients who develop advanced midgut NETs that progress after somatostatin analog therapy have few effective treatment options.

Lutathera is a radiolabeled (Lu-177) somatostatin analogue that functions similar to standard somatostatin analogs, but also delivers toxic radiation directly to the tumor. Lutathera has received orphan drug status from the European Medicines Agency and the U.S. Food and Drug Administration.

The NETTER-1 phase 3 trial compares Lutathera to Octreotide LAR in patients with inoperable midgut carcinoid tumors that progressed following Octreotide LAR and express the somatostatin receptor.

Results to date in 230 randomized patients show improved outcomes for patients treated with Lutathera over Octreotide LAR. Median progression-free survival (PFS) was not reached in the Lutathera arm and was 8.4 months in the Octreotide LAR arm (P

The safety profile of Lutathera was also favorable, with only 5% of <u>patients</u> experiencing a toxicity that led to a dose modification. Grade 3 or 4 adverse

events were low, with the most common being neutropenia (1%), thrombocytopenia (2%) and lymphopenia (9%)

Jonathan Strosberg, M.D., associate member of the Gastrointestinal Oncology Department at Moffitt, will present the study results on June 6 during the 8 a.m. gastrointestinal cancer oral abstract session in Hall B1 at McCormick Place.

Provided by H. Lee Moffitt Cancer Center & Research Institute



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