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First U.S. Prospective Evaluation of Performance of Cu-64 DOTATATE PET/CT in Somatostatin Expressing Neuroendocrine Tumors

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BACKGROUND: 68Ga-labeled Somatostatin (SST) analogues are highly sensitive and specific PET radiopharmaceuticals for imaging SST expressing neuroendocrine tumors (NET). However, their major shortcomings are short half-life of 68 minutes, dependency on Ga-68 generator, and hence availability only in limited geographical regions. Cu-64 DOTATATE addresses all these shortcomings with half-life of 12.6 hours, cyclotron production, centralized high scale manufacturing and distribution throughout the country. Objective: The study aim was to prospectively evaluate the safety and diagnostic performance of 64Cu-DOTATATE PET/CT in detection of SST expressing NET

METHODS: All subjects received 4.0 ± 10% mCi of 64Cu-DOTATATE and PET/CT imaging was performed 60 ± 15 minutes after injection. PET/CT images were read by three independent nuclear medicine physicians blinded to clinical information. Separately, Independent oncologist determined disease or no disease as well as local or metastatic status of the subject, from all available Standard of Truth (SOT) pathology, clinical, and conventional imaging studies. A total of 63 subjects were considered for statistical analysis.

RESULTS: All the images were of high quality. The majority of readers had a sensitivity of 91% and specificity of 97%. 3 patients had their tumors surgically resected with no residual disease by any SOT but mistakenly were called "disease" by one of the oncologists. Correcting for this, the sensitivity, specificity,

PPV, NPV, and accuracy were calculated to be 100%, 97%, 97%, 100%, and 98%, respectively. All patients tolerated 64Cu-DOTATATE well, with no serious adverse reactions.

CONCLUSION: 64Cu-DOTATATE PET/CT is a safe imaging technique that provides high quality images and excellent accuracy (98%) for detection of SST expressing NETs.