

## FDA Approval of Imaging Agents: An Exciting Investment in Nuclear Medicine

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**W**ith the recent U.S. Food and Drug Administration (FDA) approval of 2 new PET diagnostic drugs, Axumin (fluciclovine  $^{18}\text{F}$  injection), for detecting biochemical recurrence of prostate cancer, and NETSPOT ( $^{68}\text{Ga}$ -dotatate injection), for localization of somatostatin receptor-positive neuroendocrine tumors (NETs) in adult and pediatric patients, the field of nuclear medicine and molecular imaging is beginning the new year on a high note.

The approval of these PET diagnostic drugs is especially good news for patients. In addition to providing improved imaging, NETSPOT delivers a lower radiation dose than the SPECT alternative for NET imaging, which makes it more convenient. The SPECT study can require up to 72 hours, whereas NETSPOT provides results within 2 hours. Axumin offers the availability of an  $^{18}\text{F}$ -labeled PET diagnostic for prostate cancer recurrence that can be produced offsite and distributed to a larger number of hospitals than the currently approved  $^{11}\text{C}$  diagnostic. In addition, local Centers for Medicare & Medicaid Services reimbursement for both Axumin and NETSPOT followed their FDA approval, so patients can immediately benefit from use of these PET drugs.

I am pleased to report that SNMMI's Clinical Trials Network (CTN) was instrumental in the approval process for both Axumin and NETSPOT—helping with some of the key components of the Axumin trial (e.g., providing reader training) and facilitating a shortened regulatory review for NETSPOT.

SNMMI's Nuclear Medicine Clinical Trial Group, LLC, assists sponsors with effectively incorporating molecular imaging agents in multicenter trials through a variety of proven CTN-developed tools. It has developed

reader training for both Axumin and NETSPOT that is available for free online.

As this issue of the magazine goes to print, we are awaiting word on FDA approval of Lutathera ( $^{177}\text{Lu}$ -dotatate), which was granted priority review in June last year, with a decision set for December 28, 2016. Lutathera is a new peptide-receptor radionuclide therapy (PRRT) that targets neuroendocrine carcinoid tumors with radiolabeled somatostatin analogue peptides. Lutathera would work in tandem with NETSPOT—first diagnosis of the target cancer tissue using NETSPOT, then delivery of the PRRT to cancer cells identified by NETSPOT. Such companion diagnostics are truly the future of personalized medicine!

Once Lutathera is approved, the Therapy Center of Excellence will conduct outreach to referring physicians and has already planned an educational session for the 2017 SNMMI Annual Meeting in Denver, CO.

The effectiveness of these new imaging agents and their success in gaining FDA approval and reimbursement hold promise for further investment in nuclear medicine and molecular imaging. In turn, more physicians and scientists will be encouraged to pursue a molecular imaging career path. The future is, indeed, bright for our field!

I wish everyone a happy, productive new year and look forward to working with you to expand the frontiers of molecular imaging and provide ever more effective health care.



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(Continued from page 19N)

wider audience of interested scholars and researchers. It is clear that this effort will require a long-term investment of time and dollars. As a result, SNMMI, in collaboration with the Education and Research Foundation for Nuclear Medicine and Molecular Imaging, is developing a Heritage Fundraising Campaign for both the short and long terms. The expectation is for the Heritage Campaign to raise funds from individuals, corporate partners, and foundations that will provide the

support needed to move into the next phase of our archive plan as well as for long-term storage and management of these materials. The Heritage Campaign will be launched in early 2017, and SNMMI members will be kept informed of opportunities to participate.

Please visit our website at [www.snmmi.org/history](http://www.snmmi.org/history), and do not hesitate to contact me ([historian@snmmi.org](mailto:historian@snmmi.org)) with any questions or comments.