Call to Action for Federal Research Funding

SNMMI and the Academy of Radiology and Biomedical Imaging Research announced on December 14 a partnership to urge the U.S. Congress to pass an FY22 appropriations package with support for the National Institutes of Health (NIH) and biomedical imaging and to curtail the use of harmful continuing resolutions. In early December, Congress passed its second continuing resolution for the 2022 fiscal year, which should have begun on October 1, 2021. That continuing resolution will keep the government funded until February 18, which means there will be no increases in government funding until well after the first third of the 2022 fiscal year. NIH, for example, does not know its final funding level for the year already in progress. NIH and other research agencies cannot issue new funding awards until formal appropriations are determined. In addition, researchers working on existing awards may receive notification of funding cuts to maintain conservative spending levels mandated by the continuing resolution. Early career researchers and those with new proposals are especially adversely affected as they wait for federal support for research plans already determined to be meritorious. In their December 14 statement, SNMMI and the Academy of Radiology and Biomedical Imaging Research said "This extended delay will only hold back research. Already, research has suffered greatly due to the negative scientific and economic effects of the COVID-19 pandemic. We must remain committed to assisting Congress in the nation's recovery from the pandemic and support the continuous funding of scientific and medical research to ensure improved patient outcomes and U.S. competitiveness." Members of the nuclear medicine and molecular imaging and therapy communities were urged to contact their members of Congress to emphasize the importance of biomedical research and the deleterious effects of chronic continuing resolutions. Additional information is available at: https://www.acadrad.org/take-action/#/5.

SNMMI

CMS Grants Pass-Through Payment Status for ^{18}F-Piflufolastat

On November 22, the Centers for Medicare & Medicaid Services (CMS) granted transitional pass-through payment status for ^{18}F-piflufolastat (Pylarify; ^{18}F-DCFPyL), increasing patient access to prostate-specific membrane antigen (PSMA)–based imaging in prostate cancer. The decision was effective as of January 1. The Medicare Transitional Pass-Through Payment program is designed to facilitate patient access to cutting-edge treatments by allowing adequate payment for new agents while permanent reimbursement rates are being established.

^{18}F-piflufolastat is the first fluorinated PSMA agent approved for reimbursement by CMS. The agent, manufactured by Lantheus Holdings (North Billerica, MA), was approved in May 2021 by the U.S. Food and Drug Administration for PET imaging of PSMA-positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy or with suspected disease recurrence based on elevated serum prostate-specific antigen levels.

"We have been thrilled with the response to Pylarify in the prostate cancer community," said Mary Anne Heino, president and chief executive officer of Lantheus. "Pylarify is a transformative diagnostic tool that identifies disease earlier and more accurately than conventional imaging, providing more information to guide treatment decisions. The granting of transitional pass-through payment status for Pylarify further facilitates patient access to our game-changing PSMA-targeted imaging agent for prostate cancer."

Centers for Medicare & Medicaid Services
Lantheus Holdings

2022 Hal O'Brien Rising Star Award

Attila Feher, MD

Yale University School of Medicine (New Haven, CT) announced in December that Attila Feher, MD, a clinical fellow in cardiovascular medicine at the Yale Translational Research Imaging Center, would receive the Hal O'Brien Rising Star Award at the High Country Nuclear Medicine Conference (HCNMC) to be held in Sun Valley, ID, March 5–8. The award honors junior faculty, postdoctoral trainees, and fellows performing exemplary work in the radiopharmaceutical sciences, clinical applications, or research in oncology, cardiology, and neurology. A $1,000 travel grant included in the award is intended to enable travel to the meeting and presentation of research as part of HCNMC proceedings.

Dr. Feher is being recognized for his work in development of imaging tools to evaluate microcirculation in heart transplant recipients. Albert Sinusas, MD, director of the Yale Translational Research Imaging Center, said, "Attila is one of the best fellows that I have had the pleasure of training over my 30-year career on faculty at Yale. He has received multiple awards, including a recent award for the best manuscript in the *Journal of the American College of Cardiology: CardioOncology.* He is an outstanding clinician scientist who excels both in clinical care and translational and clinical research. He is also a humble and caring person."

The Rising Star Award was created to celebrate the leadership legacy of the High Country meeting and to recognize the vision of Hal O'Brien, MD, in creating a unique and productive format for bringing together leaders from across the spectrum of nuclear medicine and molecular imaging. The conference includes experts from academia and industry, with leaders in medical specialties, the regulatory agencies, and health care researchers in an informal setting to facilitate exchanges of ideas. The Education and Research Foundation for Nuclear Medicine and Molecular Imaging manages the program as an endowed fund to support the award in perpetuity. Each year in July the HCNMC Award Subcommittee initiates a call for nominations directed to the SNMMI Councils and Centers of Excellence and to the American Society of Nuclear Cardiology. The subcommittee reviews nominations and selects the awardee.

A preliminary program for the 2022 meeting, including streaming sessions, is available at: https://www.hcnmc.org/.

FDA Approves Near-Infrared Imaging Agent for Ovarian Cancer

The U.S. Food and Drug Administration (FDA) on November 29 approved Cytalux (pafolacianine), an optical imaging agent indicated in patients with ovarian cancer as a near-infrared adjunct to intraoperative identification of malignant lesions. The drug is manufactured by On Target Laboratories (West Lafayette, IN) and was previously granted Orphan Drug, Priority, and Fast Track designations.

"The FDA's approval of Cytalux can help enhance the ability of surgeons to identify deadly ovarian tumors that may otherwise go undetected," said Alex Gorovets, MD, deputy director of the Office of Specialty Medicine in the FDA Center for Drug Evaluation and Research. "By supplementing current methods of detecting ovarian cancer during surgery, Cytalux offers health care professionals an additional imaging approach for patients with ovarian cancer."

The drug is administered intravenously 1–9 h before surgery and binds to and fluoresces folate receptors. Cytalux is used with a near-infrared fluorescence imaging system cleared by the FDA for specific use with pafolacianine.

The safety and effectiveness of Cytalux was evaluated in 3 trials, including a randomized, multicenter, open-label study of women diagnosed with ovarian cancer or with high clinical suspicion of ovarian cancer who were scheduled to undergo surgery. The study included 134 women (ages, 33–81 y) who received a single dose of Cytalux and were evaluated under both normal and fluorescent light during surgery. More than a fourth of participants (26.9%) had at least 1 cancerous lesion detected under fluorescence imaging not observed by stand-ard visual or tactile inspection.

U.S. Food and Drug Administration
On Target Laboratories