FDA Announces Priority Review of ^{18}F-DCFPyL NDA

The U.S. Food and Drug Administration (FDA) announced on December 9 the acceptance of the New Drug Application (NDA) for PyL™ (^{18}F-DCFPyL), a prostate-specific membrane antigen–targeted PET agent for prostate cancer. Priority Review status was granted, with a Prescription Drug User Fee Act assigned action date of May 28, 2021. The FDA indicated in the NDA filing acceptance notification that it is not currently planning to hold an advisory committee meeting to discuss the application. The NDA was filed by Lantheus Holdings, Inc. (North Billerica, MA), the parent company of Lantheus Medical Imaging, Inc., and Progenics Pharmaceuticals, Inc.

The PyL NDA is supported by data from 2 industry-sponsored studies designed to establish safety and diagnostic performance across the prostate cancer disease continuum. The Phase 2/3 OSPREY trial assessed the diagnostic performance of PyL to detect prostate cancer in pelvic lymph nodes in men with high-risk, locally advanced prostate cancer (Cohort A) and distant metastases in men with metastatic or recurrent prostate cancer (Cohort B). In Cohort A, ^{18}F-DCFPyL showed a specificity of 96%–99%, sensitivity of 31%–42%, and positive predictive value of 78%–91% in detecting disease in pelvic lymph nodes, although the trial did not meet one of its primary endpoints. In Cohort B, ^{18}F-DCFPyL showed a sensitivity of 93%–99% and a positive predictive value of 81%–88% in detecting metastatic lesions. Overall, high diagnostic performance was documented in detecting nodal and distant metastatic prostate cancer.

The Phase 3 CONDOR trial evaluated the diagnostic performance and clinical impact of ^{18}F-DCFPyL in men with biochemical recurrence and inconclusive/uninformative baseline imaging with conventional modalities. The CONDOR trial achieved its primary endpoint, with a correct localization rate of 84.8%–87.0% among the 3 independent readers. More than 63% of subjects in the CONDOR trial had a change in intended disease management plans as a result of ^{18}F-DCFPyL PET, a key secondary endpoint of the trial. These changes included salvage local therapy to systemic therapy, observation to initiating therapy, noncurative systemic therapy to salvage local therapy, and planned treatment to observation.

The PyL agent has been administered in ~3,500 subjects globally, including in the 2 Lantheus-sponsored studies, multiple investigator-sponsored studies, and clinical use reported in the literature, with a positive safety profile.

U.S. Food and Drug Administration
Lantheus Holdings

SNMMI and Coalition Support Senate Bill Waiving Budget Neutrality

On December 14, SNMMI and a coalition of 77 medical societies sent a letter to Congress in support of S. 5007, a bill to halt pending Medicare payment cuts resulting from planned evaluation and management (E/M) code changes that were slated for implementation on January 1, 2021. Although SNMMI noted agreement with the intent of the new E/M coding structure recommended by the American Medical Association, this would result in significant payment reductions to nuclear medicine (~8%) and radiology (~11%) services unless the government removes budget neutrality requirements. The planned decrease in the 2021 conversion factor would be below the 1994 conversion factor of $32.9050 (worth ~$58.02 today). The Medicare Physician Fee Schedule (MPFS) final rule would also negatively affect SNMMI members who, to a large extent, provide few E/M services.

The proposed legislation recognizes the importance of allowing significant, scheduled increases in reimbursement for primary care physicians and others who chiefly provide E/M services while also avoiding the devastating corresponding cuts for physician and nonphysician providers that would occur because of Medicare's budget neutrality requirements. In a statement on the legislation, SNMMI said, "Given the ongoing COVID-19 pandemic, it is more important than ever to halt the implementation of any payment reductions that could inadvertently limit patient access to care as well as further exacerbate the financial instability of health care provider practices."

S. 5007, introduced on December 10 by Senator John Boozman (R-AR), is virtually identical to H.R. 8702, the Holding Providers Harmless From Medicare Cuts During COVID-19 Act of 2020, which has 97 cosponsors. Both bills would protect Medicare payment rates for services provided by SNMMI members and other health care providers, establishing 2020 Medicare reimbursements as the floor for payments in both 2021 and 2022.

Individuals can contact their members of Congress through a template letter provided by SNMMI at https://snmmi.quorum.us/campaign/29180/. The CY 2021 proposed MPFS is available with other associated data at http://www.snmmi.org/IssuesAdvocacy/content.aspx?ItemNumber=6502&navItemNumber=24949. Updates to the status of the bill are likely and can be accessed through the SNMMI website at www.snmmi.org.

SNMMI

NIH to Support Diversity and Inclusion Among Biomedical Faculty

The National Institutes of Health (NIH) on December 8 expanded on details of programs to support institutions in recruiting diverse groups or cohorts of early-stage research faculty and to prepare them to thrive as NIH-funded researchers. In its announcement, NIH noted that although progress has been made to increase participation of historically underrepresented groups in biomedical research training stages, members of these groups remain less likely to be hired into positions as independently

funded faculty researchers. These include underrepresented racial and ethnic groups, individuals with disabilities, individuals from disadvantaged backgrounds, and women. Two new funding announcements were released as part of the NIH Common Fund's Faculty Institutional Recruitment for Sustainable Transformation (FIRST) program to enhance inclusive excellence at NIH-funded institutions.

The FIRST program will provide funds for faculty recruitment and to establish inclusive environments at participating institutions to help those faculty succeed. The NIH Scientific Workforce Diversity office leads the NIH effort to diversify the national biomedical science workforce and expand recruitment and retention. Its efforts and vision guided the development and implementation of the FIRST Common Fund program. The program's estimated budget is $241 million over 9 years. Funding through the FIRST cohort awards will enable biomedical research institutions to hire a diverse cohort of early-stage research faculty committed to inclusive excellence and diversity. The program will also support development and strengthening of institution-wide approaches facilitating the success of cohort members and future faculty from a diversity of backgrounds. For cohort members, this is likely to include mentoring, sponsorship, and networking opportunities. For institutions, this may include training faculty in approaches known to foster inclusive excellence and changing the rubric for interviewing processes.

The FIRST program will also fund a coordination and evaluation center, which will develop and guide collection of common data metrics to rigorously assess the effects of new faculty cohorts on institutional culture. Lessons learned by the hiring institutions, captured and analyzed by the center, will be shared with the broader biomedical research community.

The program is expected to fund 12 awards over the next 3 years. Applications are due March 1, 2021, with awards to be announced in 2021. Additional information, including important eligibility criteria for applicant institutions and organizations, are available at http://www.snmmi.org/IssuesAdvocacy/content.aspx?ItemNumber=6502&navItemNumber=24949.

National Institutes of Health

IAEA and African Experts Establish First Regional Imaging QC Protocols

The International Atomic Energy Agency (IAEA) and African experts announced in December the establishment of the continent's first harmonized quality control (QC) guidance for nuclear medicine and diagnostic radiology. The project team collaboratively developed protocols with practical guidance on how to perform routine QC measurements to monitor the performance of X-ray and nuclear medicine systems. The development of more harmonized QC in Africa was first proposed in March 2020, and a task force was established to draft QC protocols, beginning with a June 1 virtual meeting. The QC guidance was peer reviewed by medical physics experts from Africa and Europe, under the coordination of IAEA Technical Officers. It will enable hospitals in Africa to closely align their quality assurance programs by standardizing both data collection and analysis and will facilitate comparison and verification of results, including in support of collaborative clinical trials. The QC guidance can be adopted by individual countries that have not yet established their own national QC programs. The protocols also include nuclear medicine evaluation testing and image-processing parameters, particularly as they relate to in-house IAEA software (NMQC), a plug-in used to evaluate the performance and quality of nuclear medicine QC images.

"This important document provides key support to African countries whose capacities for quality assurance were limited in the fields of radiology and nuclear medicine," said Imen Bentouhami, IAEA Program Management Officer in charge of the initiative. "This will not only result in enhancing the quality and safety of imaging services in Africa, but will furthermore facilitate a comparison of results, as well as knowledge- and experience-sharing across the region."

"This document will strengthen the work of the medical physicists, especially in countries where no minimum standards are required by regulatory authorities. A unified harmonized approach will make the learning curve for new colleagues less steep," said Chris Trauernicht, PhD, a medical physicist at the Tygerberg Hospital (Cape Town, South Africa), who served as a member of the task force.

International Atomic Energy Agency

Radiobiology of Molecular Radiotherapy Virtual Workshop

The Radiobiology of Molecular Radionuclide Therapy European Working Group will hold the 1st International Workshop on Radiobiology of Molecular Radiotherapy on March 17 and 18. The meeting will be virtual and free to registrants. This is the first of a series of workshops to be held in Europe every 2 years, intended to identify and answer specific questions relevant to clinical molecular radionuclide therapy from a radiobiologic perspective. The meeting is open to all stakeholders, including radiobiologists, medical physicists, radiochemists, radiopharmacists, nuclear medicine clinicians, radiation oncologists, medical oncologists, technologists, referring clinicians, radiation protection advisors, radioactive waste advisors, professional society representatives, industry partners, and funding bodies where radiobiology is highlighted as a priority research area. The workshop was originally scheduled to be held in May 2020 at the Institut de Recherche en Cancérologie de Montpellier (France). The program and information on registration are available at: https://www.mrtradiobiology.com/workshop/.

Radiobiology of Molecular Radionuclide Therapy European Working Group