FDA Approves Lymphoseek

The U.S. Food and Drug Administration (FDA) announced on June 13 the approval of Lymphoseek (^{99m}Tc-tilmanocept) Injection, a diagnostic imaging agent to be used to determine the extent of squamous cell carcinoma in the head and neck. Lymphoseek is marketed by Navidea Biopharmaceuticals, Inc. (Dublin, OH). In 2013 Lymphoseek was approved to help identify sentinel nodes in patients with breast cancer or melanoma. With the new approval, Lymphoseek can be used to guide testing of sentinel lymph nodes in head and neck cancer, in many cases facilitating more limited lymph node surgeries.

For this new indication, Lymphoseek's safety and effectiveness were established in a clinical trial of 85 patients with squamous cell carcinoma of the lip, oral cavity, and skin. All patients were injected with Lymphoseek. Surgeons subsequently removed suspected lymph nodes—those identified by Lymphoseek and those based upon tumor location and surgical practice—for pathologic examination. Results showed a high correlation and that Lymphoseek–guided sentinel lymph node biopsy accurately determined whether cancer had spread through the lymphatic system. The most common side effect identified in clinical trials was pain or irritation at the injection site.

U.S. Food and Drug Administration

IAEA Nuclear Data Section at 50

On June 2, the International Atomic Energy Agency (IAEA) celebrated the 50th anniversary of the IAEA Nuclear Data Section (NDS) and work undertaken in nuclear data collection for the benefit of its member states in the peaceful uses of nuclear technology. The IAEA created the NDS, originally known as the Nuclear Data Unit, in 1964 after recognizing the importance of establishing a body to manage nuclear and atomic data. Under the supervision of the International Nuclear Data Committee, the NDS has carried out a mission to collect, compile, review, and disseminate nuclear and atomic data, while also serving as a coordinator and stimulus for nuclear data work worldwide. Its tasks have also included supporting IAEA member states, organizing international meetings and discussions among data producers, and acting as a nuclear data center.

Nuclear and atomic data are cumulative international resources produced and used globally for applications in research, education, medicine, and industry, ranging from fission reactor technology to cancer radiotherapy to exploration for oil and other minerals. Nuclear technologies rely on accurate data to ensure the safe and effective application of nuclear techniques. These data also facilitate research and innovation in new nuclear methods. The NDS's work helps to ensure that data are accurate, up-to-date and easily accessible. Developing data involves expensive and demanding procedures, and evaluating, compiling, and disseminating such data require specialized equipment and personnel as well as large amounts of processing time. This can be a challenge for member states conducting data work, particularly for developing countries with limited resources. The NDS provides support to member states by organizing coordinated research projects (CRPs) and technology transfer activities with the aim to introduce skills and local infrastructure, as well as provide training and assistance to scientists in evolving their capabilities for the generation and use of atomic and nuclear data. These projects and activities also serve as avenues for the NDS to actively identify and address gaps in data.

Throughout the last 5 decades, the NDS has embraced the evolution of technology in undertaking the IAEA's activities related to development and dissemination of atomic and nuclear data. The NDS's pioneering approach has influenced the IAEA's technological progress while supporting the IAEA's mandate to foster the exchange of scientific information for peaceful and safe use of atomic energy. As early as 1988, the NDS began using the Internet and e-mail to develop and disseminate data. The NDS became one of the first sections at the IAEA to run online agency databases and later took the lead in being among the first to launch a webpage. By 2013, the NDS's forward-looking approach led to NDS databases and information being the first to be shifted to a web server in the "cloud," and, in July 2013, the NDS launched the IAEA's first mobile application.

To date, the NDS has developed a large collection of databases of nuclear, atomic, and molecular data that contain millions of data points as well as a wide range of authoritative publications. It has also supported numerous CRPs and technology transfer activities and further strengthened global data networks. The IAEA hosted an afternoon commemoration event on June 2 that was opened by Daud Mohamad, PhD, IAEA Deputy Director General of the Department of Nuclear Sciences and Applications, and Alexander Bychkov, PhD, IAEA Deputy Director General of the Department of Nuclear Energy. Speakers from the NDS shared the history and future of the group, and former NDS staff gave special presentations sharing their memories and views of working in NDS.

International Atomic Energy Agency

HHS Releases New Data and Tools

The U.S. Department of Health and Human Services (HHS) an-

nounced on June 2 the release of new data and the launch of several new initiatives. On that day, the Centers for Medicare & Medicaid Services (CMS) released its first annual update to the Medicare hospital charge data, with comparative information on average amounts hospitals bill for inpatient and outpatient services. The data, posted on the CMS website, include information comparing the average charges for services that may be provided in connection with the 100 most common Medicare inpatient stays at more than 3,000 hospitals in all 50 states and Washington, DC. Hospitals determine what they will charge for items and services provided to patients, and these "charges" are the amount the hospital generally bills for those items or services. With 2 y of data now available, researchers can begin to look at trends in hospital charges.

CMS also released a suite of other data products and tools aimed to increase transparency about Medicare payments. Data on CMS's website now include a new interactive dashboard for the CMS Chronic Conditions Data Warehouse. The dashboard allows users to explore information on chronic conditions among Medicare fee-for-service beneficiaries, including: geographic data summarized by national, state, county, and hospital referral regions levels for 2008–2012; data on disparities among specific Medicare populations, such as beneficiaries with disabilities, dual-eligible beneficiaries, and racial/ethnic groups; data on prevalence, utilization of select Medicare services, and Medicare spending; customizable information about Medicare beneficiaries with chronic conditions at state, county, and hospital referral regions levels for 2012; and chartbooks and maps. The Geographic Variation Dashboards present Medicare fee-for-service per-capita spending at the state and county levels in interactive formats. CMS calculated the spending figures in these dashboards using standardized dollars that remove the effects of geographic adjustments that Medicare makes for many of its payment rates.

Also on June 2, the U.S. Food and Drug Administration (FDA) launched a new open data initiative, designed to facilitate easier access to large public health datasets collected by the agency. OpenFDA will make FDA's publicly available data accessible in a structured, computer-readable format that will allow technology specialists, such as mobile application creators, web developers, data visualization artists, and researchers, to quickly search, query, or pull large amounts of information on an as-needed basis. The initiative is the result of extensive research to identify FDA's publicly available datasets that are often in demand but traditionally difficult to use. Based on this research, openFDA is beginning with a pilot program involving millions of reports of drug adverse events and medication errors submitted to the FDA from 2004 to 2013. The pilot will later be expanded to include the FDA's databases on product recalls and product labeling.

"These public data resources provide a better understanding of Medicare utilization, the burden of chronic conditions among beneficiaries, and the implications for our health care system and how this varies by where beneficiaries are located," said Bryan Sivak, HHS chief technology officer. "This information can be used to improve care coordination and health outcomes for Medicare beneficiaries nationwide, and we are looking forward to seeing what the community will do with these releases."

More information about CMS data products is available at: www.cms.gov/Research-Statistics-Data-and-Systems/Research-Statistics-Data-and-Systems.html. More information about the OpenFDA initiative is available at: www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM399335 or http://open.fda.gov/.

U.S. Department of Health and Human Services

FDA and Nanotechnology Development

On June 24, 3 final guidances and 1 draft guidance were issued by the U.S. Food and Drug Administration (FDA) with the intention of providing greater regulatory clarity for industry on the use of nanotechnology in FDA-regulated products. One final guidance addresses the agency's overall approach for all products that it regulates, and the other 2 final guidances and draft guidance provide specific guidance for the areas of foods, cosmetics, and food for animals, respectively.

"Our goal remains to ensure transparent and predictable regulatory pathways, grounded in the best available science, in support of the responsible development of nanotechnology products," said FDA Commissioner Margaret A. Hamburg, MD. "We are taking a prudent scientific approach to assess each product on its own merits and are not making broad, general assumptions about the safety of nanotechnology products."

"Final Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology" outlines overarching considerations for all FDA-regulated products, identifying points to consider when determining whether a product involves the use of nanotechnology. It is intended to help industry and others identify when potential implications should be considered for regulatory status, safety, effectiveness, or public health impact that may arise with the application of nanotechnology in FDA-regulated products. "Final Guidance for Industry: Safety of Nanomaterials in Cosmetics" describes the FDA's current thinking on the safety assessment of nanomaterials when used in cosmetic products and encourages manufacturers to consult with the FDA on test methods and data needed to support substantiation of a product's safety. "Final Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes,

Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives" alerts manufacturers to the potential impact of any significant manufacturing process change, including changes involving nanotechnology, on the safety and regulatory status of food substances. "Draft Guidance for Industry: Use of Nanomaterials in Food for Animals" addresses issues related to the use of nanotechnology in food ingredients intended for use in animals.

U.S. Food and Drug Administration

NIH and NSF Partner on I-Corps

A collaboration announced on June 18 between the National Science Foundation (NSF) and the National Institutes of Health (NIH) will give NIH-funded researchers training to help them evaluate their scientific discoveries for commercial potential, with the aim of accelerating biomedical innovations into applied health technologies. I-Corps at NIH is a pilot of the NSF Innovation Corps (I-Corps) program tailored for biomedical research. Academic researchers and entrepreneurs with Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR) Phase I awards from participating NIH institutes will be eligible to apply to I-Corps at NIH. NIH began outreach to the small business research community with a June 25 program briefing at the 2014 BIO International Convention in San Diego (CA) and a webinar on July 2.

The I-Corps Teams curriculum is a 9-week boot camp in which experienced business-savvy instructors work closely with teams of researchers to help them explore potential markets for their federally funded innovations. I-Corps instructors take a scientific method–based approach to customer discovery. Although I-Corps instructors typically have a wide range of expertise, I-Corps at NIH will be taught by instructors who have biomedical business experience. NIH institutes participating in the pilot program are the National Cancer Institute; the National Heart, Lung and Blood Institute; the National Institute of Neurological Disorders and Stroke; and the National Center for Advancing Translational Sciences.

Michael Weingarten, MD, MBA, director of the NCI SBIR Development Center, said he and his colleagues initially reached out to NSF because they witnessed the difference I-Corps made for graduates. To date, more than 300 3-person teams have completed the NSF I-Corps training, including those supported by the Department of Energy Advanced Research Projects Agency. "I-Corps will help teach NIH-funded start-ups how to build scalable business models around new technologies they're developing for the detection and treatment of disease. The program sheds new light on how companies can deal with important business risks such as protecting intellectual property and developing regulatory and reimbursement strategies," Weingarten said.

I-Corps will supplement SBIR/STTR awardees' scientific skills with real-time interactions with more than 100 potential customers to validate their technology's market potential. The 24 selected teams will receive supplemental funding from NIH to support entrepreneurial training, mentorship, and collaboration opportunities. In addition to the pilot, existing NIH-funded programs can apply to become new NSF I-Corps sites to broaden the I-Corps network. These programs include the NIH Centers for Accelerated Innovation and Research Evaluation and Commercialization Hubs, which focus on academic researchers with technologies that have not yet led to the formation of a startup or have been licensed by an existing company. All individuals and organizations involved in I-Corps become part of the NSF-established National Innovation Network, a nationwide web created to leverage the community that has developed among the grantees to increase the program's impact.

For more information about I-Corps at NIH, see http://sbir.cancer.gov/icorps and http://grants.nih.gov/grants/guide/pa-files/PAR-14-261.html. For more information about NSF I-Corps, see www.nsf.gov/news/special_reports/i-corps.

National Institutes of Health