Xofigo Supply, Treatment Interruptions

On October 21, Bayer HealthCare Pharmaceuticals (Whippany, NJ) released a customer letter addressing shortages of Xofigo, its ^{223}Ra-dichloride injection product first approved by the U.S. Food and Drug Administration (FDA) in 2013. It is currently approved for treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases, and no known visceral metastases. Earlier in October Bayer had announced that recently produced Xofigo drug product batches had not passed routine quality checks. Although none of the affected batches were released for distribution, production was stopped until the quality issues could be addressed.

The October 21 letter stated that Bayer was working with the FDA but experiencing shortages: "At this point Bayer is unable to anticipate when distribution of Xofigo can be resumed. This may have an impact on treatment decisions for patients. Bayer is in regular communications with physicians and investigators who treat patients with Xofigo to provide information on product availability."

Because of the short half-life of the radioisotope, the shortage will lead to interruption of patients' treatment and inability to initiate treatment for new patients until production is resumed. In addressing these issues, Bayer referred to data from the Phase III Alpharadin in Symptomatic Prostate Cancer (ALSYMPCA) study on treatment delays, which contained the following advice about delaying a dose: "Study visits during the treatment period should occur at 4 weeks intervals (within a window of –3 days to +7 days). The same visit interval (4 weeks) applies between all treatments. A study drug administration may be delayed by no more than 4 weeks for recovery of adverse events. In case of a treatment delay greater than 4 weeks, treatment should be discontinued." Bayer referred to an ad hoc analysis of this trial, in which ~30% of 600 patients experienced a delay in receiving ^{223}Ra. Of these 178 patients, 56 patients had delays caused by an adverse event and the remaining 122 patients had delays caused by other reasons. The results of a full course (6 injections) of ^{223}Ra was similar regardless of whether or not patients experienced a delay. The analysis suggested similar benefits overall survival regardless of whether patients experienced delays.

Bayer advised that for those patients currently on Xofigo who have experienced a cancellation or a dosing delay, their treating physician should take into consideration the duration of the delay as well as alternative treatment options when determining the best care for their patient and that "when Xofigo production resumes, continued treatment with Xofigo should be considered after careful benefit/risk evaluation."

The letter concluded with information on reporting adverse events as well as a statement of Bayer's commitment to working to resolve the production issues "as quickly as possible. Customers with additional questions were advised to contact Bayer at 1-888-842-2937 or visit www.Xofigo.com.

Bayer HealthCare Pharmaceuticals

Late-breaking news: On November 3, Bayer Healthcare announced that it had resumed production of Xofigo and had released an initial lot that would be immediately available for patient treatment. The company noted that it would work closely with regulatory authorities to ensure that long-term supply levels were re-established as quickly as possible.

SNMMI Wagner–Torizuka Fellowship Recipients

SNMMI announced on September 2 the recipients of the 2014–2016 SNMMI Wagner–Torizuka Fellowship. This 2-year fellowship, founded in 2008 by the late Henry N. Wagner, Jr., MD, and the late Kanji Torizuka, MD, PhD, is designed to provide training and experience in the fields of nuclear medicine and molecular imaging for Japanese physicians in the early stages of their careers.

The 2014–2016 fellows, each receiving an annual stipend of $24,000, are: (1) Mitsutomi Ishiyama, MD, St. Luke's International Hospital (Tokyo, Japan), whose research interest is in functional imaging using modalities such as PET/CT, SPECT/CT, and MR to elucidate the pathophysiology of various diseases. Ishiyama works as a clinical fellow (PET/CT fellowship program) at the Department of Radiology of the University of Washington, Seattle, under the supervision of advisor Satoshi Minoshima, MD, PhD. (2) Masayoshi Nakano, MD, Ehime University Graduate School of Medicine (Japan), whose research interest focuses on elucidation of neuropsychiatric disorders involving the insula using PET, is conducting research in nuclear medicine in the Russell H. Morgan Department of Radiology and Radiological Science, Johns Hopkins University Medical School (Baltimore, MD) under the supervision of advisor Dean F. Wong, MD, PhD. (3) Kensuke Tateishi, MD, PhD, Yokohama City University, Department of Neurosurgery (Kanagawa, Japan), whose major field of interest is elucidating treatment-resistant mechanisms in brain tumors through several PET tracers, is studying at the Department of Neurosurgery, Massachusetts General Hospital (Boston), under the supervision of advisor Daniel Cahill, MD, PhD.

"SNMMI is proud to sponsor the Wagner–Torizuka Fellowship. This program honors 2 international pioneers and helps to promote continued research in the field of nuclear medicine and molecular imaging," said Gary L. Dillehay, MD, SNMMI immediate past president and chair of the SNMMI Awards Committee. The SNMMI Wagner–Torizuka Fellowship program, sponsored by Nihon Medi-Physics Co. Ltd. in Japan, is now entering its 8th year. The program has

successfully graduated 17 fellows since its inauguration in 2008; currently, 6 fellows are studying at host institutions across the United States. Applications and additional information about requirements for the 2015–2017 SNMMI Wagner–Torizuka Fellowship are available online at www.snmmi.org/grants. Applications are due January 31, 2015.

SNMMI

Kocemba-Slosky Fellowship

The Ursula Mary Kocemba-Slosky, PhD, Professional Fellowship, supported by a grant from the Education and Research Foundation for Nuclear Medicine and Molecular Imaging, provides a young professional in nuclear medicine and molecular imaging with direct, personal exposure to SNMMI professional relations activities as they relate to other medical societies and organizations. The 2014 recipient of the fellowship was Alexandru Bageac, MD, of Portland, OR.

The application window for the 2015 fellowship opened on November 1 and will close on December 15, 2014. The fellowship is designed to provide a gifted and highly motivated young nuclear medicine or molecular imaging professional with first-hand experience in the professional intersociety relations process. A young professional is defined as an MD, scientist, or technologist who has completed at least 3 years but no more than 10 years of post-training experience in the field.

The fellowship is named for Ursula Marianna Kocemba-Slosky, PhD, who with her husband, Jack Slosky, PhD, believed that it is essential for professional organizations in a highly regulated and diverse area, such as nuclear medicine and molecular imaging, to have leaders with experience-based understanding, of the challenges faced by the field. Dr. Kocemba-Slosky died in 2012. Full details about the application and planned activities for fellows are available at: http://snmmi.files.cms-plus.com/docs/Grants_and_Awards/2015%20Ursula%20Mary%20Kocemba-Slosky%20PhD%20Professional%20Relations%20Fellowship.pdf.

SNMMI

NIH BD2K Awards Announced

The National Institutes of Health (NIH) announced on October 9 a wide-ranging series of grants intended to develop new strategies to analyze and leverage increasingly complex biomedical data sets, often referred to as "Big Data." These NIH multi-institute awards constitute an initial investment of nearly $32 million in fiscal year 2014 by NIH's Big Data to Knowledge (BD2K) initiative, which is projected to have a total investment of nearly $656 million through 2020, pending available funds.

With the advent of transformative technologies for biomedical research, such as DNA sequencing and imaging, biomedical data generation is exceeding researchers' ability to capitalize on the data. The BD2K awards will support the development of new approaches, software, tools, and training programs to improve access to these data and the ability to make new discoveries using them. Investigators hope to explore novel analytics to mine large amounts of data, while protecting privacy, for eventual application to improving human health. Examples include an improved ability to predict who is at increased risk for breast cancer, heart attack, and other diseases and conditions and to explore more effective ways to treat and prevent disease.

The funding will establish 12 centers that will each tackle specific data science challenges. The awards will also provide support for a consortium to cultivate a scientific community-based approach to the development of a data discovery index and for data science training and workforce development. The 4 main components of the initial BD2K initiative are 11 Centers of Excellence for Big Data Computing, a BD2K-LINCS Perturbation Data Coordination and Integration Center, the BD2K Data Discovery Index Coordination Consortium, and Training and Workforce Development awards.

The BD2K initiative, launched in December 2013, is a trans-NIH program with funding from all 27 institutes and centers, as well as the NIH Common Fund. NIH's effort is being developed in the context of a number of related projects elsewhere in the world, including those under development in the United Kingdom and Australia and by the European Union. For more information about the recipients of the new grants, see http://bd2k.nih.gov/FY14.html.

National Institutes of Health