

Update on CardioGen-82

On January 12, The U.S. Food and Drug Administration (FDA) released a “safety announcement” about preliminary findings from the ongoing investigations following Bracco Diagnostics, Inc. voluntary recall of CardioGen-82 in July 2011. The announcement stated that multiple investigations suggest “that improper usage of CardioGen-82 at certain clinical sites is responsible for the exposure of some patients to more radiation than is typically associated with a CardioGen-82 scan. This increased radiation exposure was due to the administration of CardioGen-82 generator eluates that contained excessive concentrations of ^{82}Sr and ^{85}Sr .” This excessive release of ^{82}Sr and ^{85}Sr in generator eluates is known as “strontium breakthrough.” The announcement added that the FDA believed it to be “unlikely that this excessive exposure posed significant risks to patients, though exposure to any excessive radiation is undesirable.”

The recalled CardioGen-82 generators that were functional following shipping were tested by the manufacturer to identify potential structural or functional causes of strontium breakthrough, and none showed signs of breakthrough. The FDA announcement added that: “The manufacturer is currently conducting studies of clinical sites across the nation to help assess the extent to which patients may have been exposed to excessive radiation. Participation in this study is voluntary, and the preliminary data show that, of 375 patients who were surveyed at 43

clinical sites, 54 patients were planned for further radiation testing because of abnormal screening test results. All 54 patients are from 2 clinical sites. Both sites appear to have insufficient documentation of compliance with the CardioGen-82 labeling recommendations for strontium breakthrough testing.”

In a letter to customers dated December 29, 2011, Bracco listed actions initiated over the course of the recall and announced that it would close out the recall process. Among actions initiated by the company in 2011 were: (1) inspections of all recalled generators, as noted by the FDA, with results indicating that ^{82}Sr and ^{85}Sr levels were within specification limits; (2) an ongoing clinical study at all participating institutions that administered CardioGen-82 to patients in 2011; (3) an ^{82}Rb generator quality review program, including reinforced customer training and education; (4) a manufacturing process review; and (5) enhanced labeling and user training. Bracco proposed to FDA a controlled and phased reintroduction of CardioGen-82 generators to user facilities, with data collection and evaluation of actual field use to begin in early 2012. Specific customer generator delivery schedules were not available but were expected to be announced early in the year.

*U.S. Food and Drug Administration
Bracco Diagnostics, Inc.*

MOLECULAR IMAGING UPDATE

SNM and AACR Announce Joint Conference

Achieving the ultimate goal of curing cancer will require the collaborative efforts of cancer researchers and the molecular imaging community at all levels—basic, translational, and clinical. SNM and the American Association for Cancer Research (AACR) are thrilled to announce a joint effort to present the SNM–AACR conference on State-of-the-Art Molecular Imaging in Cancer Biology and Therapy, to be held February 27 through March 2, 2013, at the Manchester Grand Hyatt in San Diego, CA.

With our program committee, including Christopher Contag, Kim Kelly, Hisataka Kobayashi, Steve Larson, Jason Lewis, Martin Pomper, and Zena Werb, we have designed a 3-d conference to bring together imaging scientists with biologists specializing in basic, translational, and clinical cancer research to discuss the latest developments in the field of imaging and its applications in cancer biology. The goal of this conference is to provide a forum for the collaborative exchange of information and to provide background for imagers on cancer biology, while educating cancer biologists on how we can advance cancer research with the latest imaging research and ways in which it can be used toward diagnosing and monitoring treatment of cancer. The speakers will be expert molecular imaging scientists, medical oncologists, chemical engineers, basic cancer biologists, and systems biologists.

The primary focus of the conference will be on areas in cancer biology that interface with molecular imaging technolo-

gies and/or imaging agent development. Sessions will emphasize the role of imaging in visualizing cancer stem cells, the tumor microenvironment, stroma, premetastatic conditions, cancer metabolism, and immune cell migration. Other topics include innovative cancer therapies guided by imaging in real time for the improvement of patient outcomes.

We aim to encourage discussion by following scientific talks with panel discussions addressing some of the more controversial topics. We will present opportunities for participation from junior scientists by offering mentoring breakfasts and short talks selected from the highest-rated abstracts. We will also feature preconference educational workshops on selected topics and both these sessions and the conference will offer continuing medical education credit.

We are confident that this conference will prove to be a fruitful union between state-of-the-art molecular imaging and cancer research, 2 important branches of science that together will enhance the ability to fight cancer by combining new discoveries in the diagnosis, staging, and treatment of patients with cancer.

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