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TARGETING CANCER CARE

Statement of
The American Society for Radiation Oncology (ASTRO)
Before the Nuclear Regulatory Commission's Advisory Committee on the Medical Use of Isotopes
April 17, 2012

ASTRO appreciates the opportunity to provide this statement before the NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI) on the licensing of Radium-223 chloride.

ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science and advocacy. ASTRO's highest priority has always been ensuring patients receive the safest, most effective treatments.

There are currently two marketed bone-seeking radionuclides in the United States, samarium-153 (Quadramet) and strontium-89 (Metastron). Both are beta emitters principally used for the palliation of pain from osteoblastic metastases. Radium-223 chloride represents the first entity within a novel class of alpha-emitting, bone-seeking radiopharmaceuticals. A recent pivotal Phase III randomized controlled trial for patients with metastatic prostate cancer showed a significant improvement in quality of life, decrease in PSA and alkaline phosphatase, reduction in skeletal-related events, and even a significant improvement in overall survival compared to the placebo controls.

The actual administration of radium-223 chloride is performed in the same manner as samarium-153 or strontium-89, over a slow IV push by a qualified authorized user in the outpatient clinic setting. The same radiation safety precautions and post-administration radiation survey is performed by the radiation safety officer or his/her designate.

ASTRO believes that those physicians who are certified by the American Board of Radiology for the practice of radiation oncology are qualified to administer therapeutic doses of Radium-223 chloride. To require additional training above and beyond what is already required would impose undue burden on physicians, which will in turn limit patient access to safe and effective treatments.

Furthermore, current regulations (10 CFR 35.390) already allow for "the parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required." ASTRO believes that the requirements found in this section are sufficient for regulating the use of Radium-223 chloride. We urge the NRC to revise 10 CFR 35.390 to include alpha particles in addition to the beta and photon–emitting particles currently recognized. We would have concerns about the NRC licensing Radium-223 chloride under a different, more restrictive section of current regulations because physicians would be required to obtain extra training to use a radionuclide whose route of administration is no different from ones already on the market, and would thus limit patient access to this radionuclide.

ASTRO believes that this, and other alpha-emitting agents, should be made available with the easiest and safest route possible for both the patient and the practitioner.

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