Support for the SABRE Project's Request to Qualify Bone Mineral Density as a Surrogate Endpoint for Fractures in Anti-Osteoporosis Drug Trials

Dear US Food and Drug Administration,

As leading international research societies, national women's health, aging, family caregiver and bone health patient advocacy organizations, and physician and nursing organizations, we are writing to express our strong support for the Study to Advance BMD as a Regulatory Endpoint (SABRE) project and the recent submission of a full qualification plan to the Food and Drug Administration (FDA) to utilize bone mineral density (BMD) as a surrogate endpoint for fractures in future trials of new anti-osteoporosis drugs.

Osteoporosis is a prevalent and serious health concern, affecting more than 53 million people in the United States. The economic and human costs associated with osteoporosis-related fractures are staggering, amounting to an estimated $52 billion annually. The reduction in the length and cost of clinical trials made possible by using BMD as a surrogate endpoint has the potential to accelerate drug development, fostering innovation, and ultimately alleviating the burden on patients and healthcare systems.

The significance of this initiative cannot be overstated, as fractures are currently the primary outcome measure in clinical trials for osteoporosis drugs. The potential qualification of BMD as a surrogate endpoint under the 21st Century Cures Act is groundbreaking and could revolutionize the drug development process for osteoporosis, offering a reliable and non-invasive alternative to fractures as a trial endpoint.

The SABRE project, supported by the Foundation for the National Institutes of Health (FNIH) and the American Society for Bone and Mineral Research (ASBMR), has conducted extensive research and assembled a comprehensive database of individual patient data from randomized controlled trials to demonstrate the efficacy of BMD as a predictor of fracture risk reduction. This collaborative effort involving researchers from across the globe, the National Institutes of Health (NIH), industry experts, professional societies and patient advocacy partners underscores the importance of this undertaking.

In addition, we believe that the qualification of BMD as a surrogate endpoint aligns with the FDA's commitment to advancing innovative approaches in drug development while ensuring patient safety. The potential benefits in terms of reduced trial duration and costs, coupled with the accelerated availability of effective anti-osteoporosis drugs, make this initiative a pivotal step in addressing a critical public health issue.

Thank you for your attention to this matter, and we trust that the FDA will continue to play a crucial role in advancing public health through thoughtful evaluation and support of innovative initiatives like SABRE.

Sincerely,
Ann E. Van Heest, AOA President, 2023-2024