

My name is Sue Peschin and I serve as President and CEO of the Alliance for Aging Research. The Alliance is the leading nonprofit organization dedicated to accelerating research to improve aging and health. The Alliance receives financial support from the product sponsor however we maintain several safeguards to ensure our independence.

I am pleased to offer a comment today, both professionally and personally. Both of my parents have severe osteoarthritis, which they have managed over many years with exercise and physical therapy, surgeries, one implanted medical device, one rollator walker, various OTC and pharmaceutical medications, and extra-strength doses of perseverance and humor.

The burden of persistent pain for older adults is significant. Approximately 65 percent of adults 65 years of age and older report suffering from pain, and 30 percent report suffering from chronic pain. Persistent pain in older adults results in reduced mobility, avoidance of activity, falls, depression, anxiety, isolation, and sleep impairment. Osteoarthritis is one of the most common conditions causing persistent pain in older adults. No current treatments exist to slow or reverse the destruction of joint structures that lead to pain and disability for the condition. The chronic nature of the condition and the absence of safe and effective analgesics for late-stage osteoarthritis make this one of the largest areas of unmet medical need for older adults.

The potential promise of a new non-opioid treatment for those with moderate to severe osteoarthritis, for whom other treatments are ineffective or inappropriate, is encouraging. As the Arthritis and the Drug Safety and Risk Management Advisory Committees review the application for tanezumab, we at the Alliance for Aging Research urge you and the FDA to carefully examine osteoarthritis patients' perspectives on clinical outcomes of importance.

Furthermore, we ask you to specifically evaluate benefit-risk considerations of tanezumab to best serve this patient community's interests. Risk tolerance discussions should include pain management versus the potential for OA disease progression. Recent studies suggest that the risk of rapidly progressive OA with tanezumab was greatest when co-administered with NSAIDs, with higher dosage levels, and in those with subchondral insufficiency fractures—all important considerations for clinician and patient shared decision-making. If approved, the health care providers prescribing tanezumab must be well informed about the medication's potential side effects and the patient population for which this treatment is most appropriate. We urge the sponsor, advisory committees, and the FDA to consider that older adults with chronic pain will sometimes “overdo” activity if they experience good days, potentially risking injury. Informing patients about their role in moderating activity levels while on treatment may be beneficial.

Thanks to all of you for engaging in this critical area of clinical development for older adults.