Evenity™ Meets Primary and Secondary Endpoints in Phase 3 Study

Amgen and UCB announced that the Evenity™ (romosozumab) ARCH study met both primary endpoints and the key secondary endpoint.

Evenity is an investigational bone-forming agent that simultaneously rapidly increases bone formation and reduces bone resorption, increases bone mineral density, and reduces risk of fracture. In the study, postmenopausal women with osteoporosis received subcutaneous injection of Evenity monthly for 12 months followed by oral alendronate weekly for at least 12 months. At 24 months, women in the Evenity treatment group experienced a statistically significant 50% reduction in the relative risk of a new vertebral (spine) fracture compared to those receiving alendronate alone. Women in the Evenity treatment group also experienced a statistically significant 27% reduction in the relative risk of clinical fracture (non-vertebral fracture and clinical vertebral fracture) at the primary analysis. In addition, non-vertebral fractures were statistically significantly reduced by 19% in the Evenity treatment group, including a nominally significant reduction in hip fractures. An imbalance in positively adjudicated cardiovascular serious adverse events was observed as a new safety signal (2.5% Evenity versus 1.9% alendronate at 12 months).


Pixie Smart Pads for Urinary Tract Infections Registered With U.S. Food and Drug Administration

Pixie Scientific has completed U.S. Food and Drug Administration registration for Pixie Smart Pads. The Class I medical device uses a patented sensor and software platform to monitor incontinent older adults for an analyte commonly associated with urinary tract infections (UTIs). Pixie’s patented platform comprises a biosensor, mobile application, and secure cloud architecture that uses machine learning for analysis and disseminates information to remote care teams.

Clinicians can use this information, along with other symptoms, to order additional patient evaluation or more specific diagnostics in a timely manner, which may lower the rate of comorbidities and hospital admissions due to UTIs and improve antibiotic stewardship.