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Loxecivint Injection for Knee Osteoarthritis Appeared Safe and Well Tolerated: Pooled Data from Three Randomized Controlled Trials

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Teaser Summary: Safety concerns with current pharmacologic treatments for knee osteoarthritis highlight an unmet need for new therapies. Lorcivint, a novel intra-articular Wnt pathway modulator, has appeared safe and well tolerated in clinical trials to date.

Background: There is an unmet need for safe and effective osteoarthritis (OA) therapies. Lorcivint (LOR) is a novel intra-articular (IA) Wnt pathway modulator in development as a potential knee OA treatment. Data from 3 clinical trials were analyzed.

Methods: Safety data were pooled from one 52-week and two 24-week randomized controlled trials evaluating 4 doses (0.03, 0.07, 0.15, 0.23 mg) of a single IA injection of LOR in subjects with knee OA. Incidence of adverse events (AEs), serious AEs (SAEs), and bone health AEs were compared between combined LOR-treated and control groups.

Results: AE incidence was similar in LOR-treated (350/848 [41.3%]) and control subjects (138/360 [38.3%]). SAE incidence was 20/848 (2.4%) in LOR-treated subjects and 4/360 (1.1%) in control subjects; no SAEs were deemed related to LOR by investigators. Individual AEs were reported at similar rates between groups; arthralgia was the most common AE (LOR-treated 7.6%, control 7.2%). Of 16 bone health-related AEs in 9/848 (1.1%) LOR-treated subjects and 3/360 (0.8%) control subjects, 14 were fractures caused by trauma; all healed uneventfully.

Conclusion: In exposure of 848 subjects, IA LOR for knee OA treatment appeared safe and well tolerated. Combined with clinical trial results demonstrating symptomatic improvements out to one year following a single injection, these data support the continued evaluation of LOR as a potential knee OA treatment.

Significance/Clinical Relevance: Based upon the safety profile observed in completed clinical trials to date, lorcivint appeared safe and well tolerated. These data support continued development of lorcivint as a potential knee osteoarthritis treatment.