Safety and efficacy of intra-articular injection of JTA-004, a novel viscosupplement, in symptomatic knee osteoarthritis: a randomized, double-blind controlled phase II/III study

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Objective: The objective was to assess the safety and efficacy of a single intra-articular administration of JTA-004, a novel viscosupplement, in patients suffering from symptomatic knee osteoarthritis (OA) at 6 months.

Design and methods: In this prospective, multicenter, double-blind phase II/III trial (NCT02740231), 164 patients with primary OA knee pain were randomly assigned to one of the three JTA-004 strengths or the comparator treatment (Hylan G-F 20) in a 1:1:1:1 ratio. Safety was assessed by monitoring and reporting vital signs, physical examination, adverse events and concomitant medications. The primary efficacy endpoint was the change from baseline at 6 months in WOMAC® VA3.1 pain subscale.

Results: JTA-004 was shown to be well tolerated at all strengths evaluated. At 6 months, patients in the three JTA-004 groups showed a better improvement in pain compared to patients in the comparator group although statistical significance was not achieved. As the three JTA-004 strengths had a similar efficacy, a post hoc analysis was subsequently performed between the pooled JTA-004 treated patients and the comparator group. The exploratory analysis showed a 26.1±2.4 (adjusted mean±SE) mm improvement in pain in the pooled JTA-004 group vs. 15.6±4.1 mm in the comparator group at 6 months, demonstrating a statistically significant superiority of JTA-004 over the comparator (p = 0.030).

Conclusions: This study provides first evidences of safety and efficacy of JTA-004 in the treatment of symptomatic knee OA. Efficacy will be further confirmed in a subsequent pivotal Phase III study.