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2007 Annual Meeting Poster Presentations

Prospective Study of the Safety and Efficacy of Hylan G-F 20 in Symptomatic Shoulder Osteoarthritis

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Prospective study which demonstrates that treatment of OA of the shoulder with hylan G-F 20 is well tolerated and significantly decreases pain which is maintained for up to 6 months.

The purpose of this study was to evaluate the safety and efficacy of hylan G-F 20 in patients with symptomatic osteoarthritis (OA) of the shoulder.

Prospective, multi-center, open study. Patients with gleno-humeral OA and no major rotator cuff tear received one intra-articular injection of 2 ml hylan G-F 20, and an optional second injection if their pain remained significant after 1, 2 or 3 months. Patients were followed for 6 months after the final injection.All adverse events (AEs) were recorded. Primary efficacy endpoint was change from baseline (at final injection) in the Shoulder OA Pain VAS at 3 months after the final injection. Secondary endpoints were Pain VAS scores at all other time-points, WOOS scale, Patient's and Physician's Global OA assessment, and health-related quality of life (SF-36).

Thirty-three patients (18 M; 15 F) were enrolled and received treatment. Sixteen patients (48%) received a second injection. Mean age was 57 years (range 38-80). Overall, treatment with hylan G-F 20 was well tolerated. Eight patients (24.2%) had a treatment related AE of the target shoulder. All were of mild or moderate intensity, the majority consisting of shoulder pain and injection site pain. Shoulder OA Pain decreased significantly from 61.2 mm at baseline to 32.5 mm at Month 3 ($p<0.001$), which was maintained at 6 months. The secondary efficacy endpoints showed similar results.

Treatment of OA of the shoulder with intra-articular hylan G-F 20 is well tolerated and significantly decreases pain which is maintained for up to 6 months.

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