differ significantly ($p>0.05$) between treatment groups. There were 7 SAE in the HCQ and 15 in the PBO group. No new safety issues were detected

Table 1. Results of the covariance analysis (ANCOVA)-adjusted mean values and 95%-confidence intervals for primary and secondary outcomes at W52, as well as a p-value for group comparison

Outcome	Adj. Mean HCQ	95%-CI HCQ	Adj. Mean PBO	95%-CI PBO	P-value HCQ x PBO
AUSCAN Function	48.1	43 53.3	51.3	46.6 56	0.36
AUSCAN Pain	26.7	23.9 29.4	26.5	23.9 29.1	0.92
tender joint	6.4	4.8 7.9	7.1	5.4 8.7	0.49
swollen joint	2	1.3 2.7	2.1	1.4 2.7	0.93
ESR (mm/h)	8.2	6.9 9.6	11.7	10.1 13.5	<0.01
HAQ	0.9	0.8 1	0.8	0.7 0.9	0.46
Phys. Global	3.2	2.8 3.6	3.5	3 3.9	0.39
Pat. Global	4.5	3.9 5.1	5.2	4.6 5.8	0.14
SF36 mental	48.8	46.6 51	50.8	48.7 52.8	0.22
SF36 physical	39.8	38 41.6	39.9	38.2 41.6	0.95
Morning Stiffness (min)	30.2	24 36.3	16.3	10.3 22.3	0.001
Modif. Kallmann Score	53.6	52.1 55.1	52.8	51.4 54.2	0.24

The associated BL value or, if available, a mean value from BL and screening was included in the ANCOVA model as a covariate.

Conclusion: The OATREAT trial examined the clinical and radiological efficacy and safety of HCQ as a treatment option for inflammatory and erosive OA over 52 weeks. OATREAT is the first large randomized PBO controlled trial focusing on erosive hand OA. HCQ was no more effective than PBO for changes in pain, function and radiographic scores in the 52-week period. Overall safety findings were consistent with the known profile of HCQ. Thus, our data failed to show that HCQ is effective in patients with inflammatory, erosive hand OA

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OP0187

DETERMINING OPTIMAL COOLING AND ADMINISTRATION METHODS FOR CNTX-4975 INTRA-ARTICULAR INJECTION IN SUBJECTS WITH MODERATE TO SEVERE OSTEOARTHRITIS KNEE PAIN

R. Stevens¹, P. Hanson¹, P. Tiseo¹, K. Guedes¹, J. Campbell¹, J. Connolly¹, S. Ruggiero¹, M. Corliss¹, V. Smith², P. G. Conaghan³. ¹Centrexion Therapeutics Corp, Boston, United States of America; ²Premier Research, Durham, United States of America; ³University of Leeds, West Yorkshire, United Kingdom

Background: CNTX-4975 is a highly purified, synthetic capsaicin being developed to provide long-term analgesia after a single intra-articular (IA) injection for patients with moderate to severe osteoarthritis (OA) knee pain. CNTX-4975 IA administration is associated with short-term post-procedural pain that can be attenuated with preemptive joint cooling.

Objectives: To evaluate cooling and administration procedures for CNTX-4975 IA injection, with goals of balancing patient comfort and ease of use and assessing clinical response 8 weeks after injection.

Methods: This phase 3, open-label, 8-week study (NCT03661996) enrolled subjects aged 40–95 y with Kellgren-Lawrence grade 1–4, BMI ≤ 45 kg/m², and stable, moderate to severe OA knee pain and who failed ≥ 2 therapies. Subjects were assigned to unilateral/bilateral CNTX-4975 1 mg IA injections as determined by OA pain/joint replacement status, then randomized by study site to 1 of 5 treatment regimens (Figure). The primary outcome measure assessed Breg cooling control vs other cooling regimens on day 1 using a combined sum of 1) pain (0, none; 4, severe) 30 minutes after CNTX-4975 injection; 2) subject satisfaction (SS) with cooling/injection procedures; and 3) investigator satisfaction (IS) with procedures. SS and IS were measured on a 1–7 scale (1, completely dissatisfied; 7, completely satisfied); pain was reverse scored and normalized (1, severe; 7, none) for equal weighting. Geometric mean ratios (GMR) with 95% CIs were constructed for each regimen vs Breg control (ANCOVA); lower 95% CI >0.7 was considered clinically acceptable. Secondary endpoints included

percentage of subjects by subject type meeting criteria for Outcome Measures in Rheumatology-Osteoarthritis Research Society International (OMERACT-OARS) responders 8 weeks after injection. Safety assessments included TEAEs.

Results: The intent-to-treat population included 848 subjects. The primary combined outcome showed that all cooling and administration regimens were clinically acceptable, with the evaluated cold gel wraps being at least as effective as the Breg circulating ice-water wrap (Table). For subjects with unilateral OA, OMERACT-OARS response rates were 67% in those with no/mild nonindex knee pain and 81% in those with nonindex knee single joint replacement. For subjects with bilateral knee OA receiving bilateral injections, response rates for index and nonindex knees were 73% and 79%. TEAEs were reported in 22% of subjects; $<1\%$ were serious. TEAEs occurring in $>2\%$ of subjects were procedural pain (2.9%), arthralgia (2.2%), and nausea (2.1%), with no meaningful differences across groups.

Conclusion: All cooling regimens for CNTX-4975 IA administration were clinically acceptable and well tolerated, offering feasible options for use in routine practice. Importantly, high levels of clinical response were observed 8 weeks after unilateral or bilateral knee injections for moderate to severe OA knee pain.

Study Design

Primary Combined Endpoint Outcome in the Index Knee, Normalized Scale, by Cooling and Administration Procedure (ANCOVA Model)

	Breg Cooling Control N=162	Gel Pack Cooling N=179	Shortened Gel Pack Cooling N=175	Single Needle Injection, Gel Pack Cooling, 2% Lidocaine N=160	Single Needle Injection, Gel Pack Cooling, 1% Lidocaine N=172
Mean (SD)	17.23 (2.660)	18.23 (2.023)	16.81 (2.891)	17.57 (3.049)	16.43 (3.138)
Geometric LS	17.18 (1.016)	18.26 (1.015)	16.48 (1.016)	17.40 (1.016)	16.00 (1.015)
Mean (SE)					
95% CI	16.66, 17.72	17.74, 18.80	15.99, 16.99	16.87, 17.95	15.53, 16.49
Comparison vs Breg Cooling					
GMR (SE)		1.06 (1.022)	0.96 (1.022)	1.01 (1.022)	0.93 (1.022)
95% CI		1.02, 1.11	0.92, 1.00	0.97, 1.06	0.89, 0.97
Clinically Acceptable?		Yes	Yes	Yes	Yes

LS, least squares; SD, standard deviation; SE, standard error. GMR lower 95% CI >0.7 considered clinically equivalent.

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