

22 November 2011

The Manager
Company Announcements Office
ASX Limited
20 Bridge St
SYDNEY NSW 2000

Dear Sir,

CBIO CLINICAL TRIAL DATA PRESENTED AT AMERICAN COLLEGE OF RHEUMATOLOGY MEETING

From 4-9 November 2011, CBio presented its clinical trial data as a late-breaking abstract poster to the American College of Rheumatology (ACR) Annual Scientific Meeting. CBio is pleased to make this poster available to shareholders: "Efficacy and Safety of Subcutaneous Recombinant Chaperonin10 in Patients with Active Rheumatoid Arthritis Despite Methotrexate Treatment".

For and on behalf of the Board

ROSLYNN SHAND
Company Secretary

About CBio Limited

CBio is an Australian ASX listed company established in 2000. CBio's lead product XToll is a potential new-generation drug therapy which could provide safer and more effective treatment of autoimmune diseases such as rheumatoid arthritis (RA) and lupus. Global sales of RA therapies exceeded US\$17 billion in 2008. The global lupus market is expected to reach \$2.5 billion per annum by 2017. Novo Nordisk A/S, a top 20 global pharmaceutical company and world-leader in diabetes care, has an exclusive option to enter into a licence agreement for the intellectual property rights relating to XToll. XToll has been trialled in over 330 patients with no pattern of treatment-emergent serious adverse effects. The company's largest clinical trial to date completed in Q2 2011.

Enquiries

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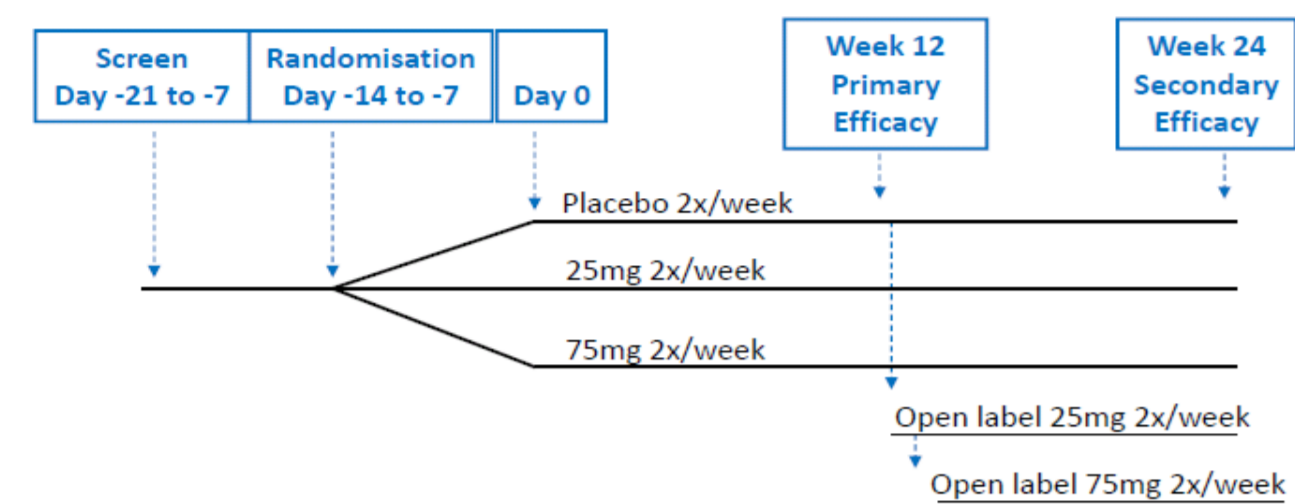
Efficacy and Safety of Subcutaneous Chaperonin 10 in Patients with Active RA Despite Methotrexate Treatment

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⁴“Ltd”Medulla Chemotherapy and Immunotherapy Clinic, Tbilisi, Georgia; ⁵“Ltd” Academician V Tsitlanadze Scientific - Practical Centre of Rheumatology, Tbilisi, Georgia; ⁶CBio Limited, Brisbane Australia.

Trial Design



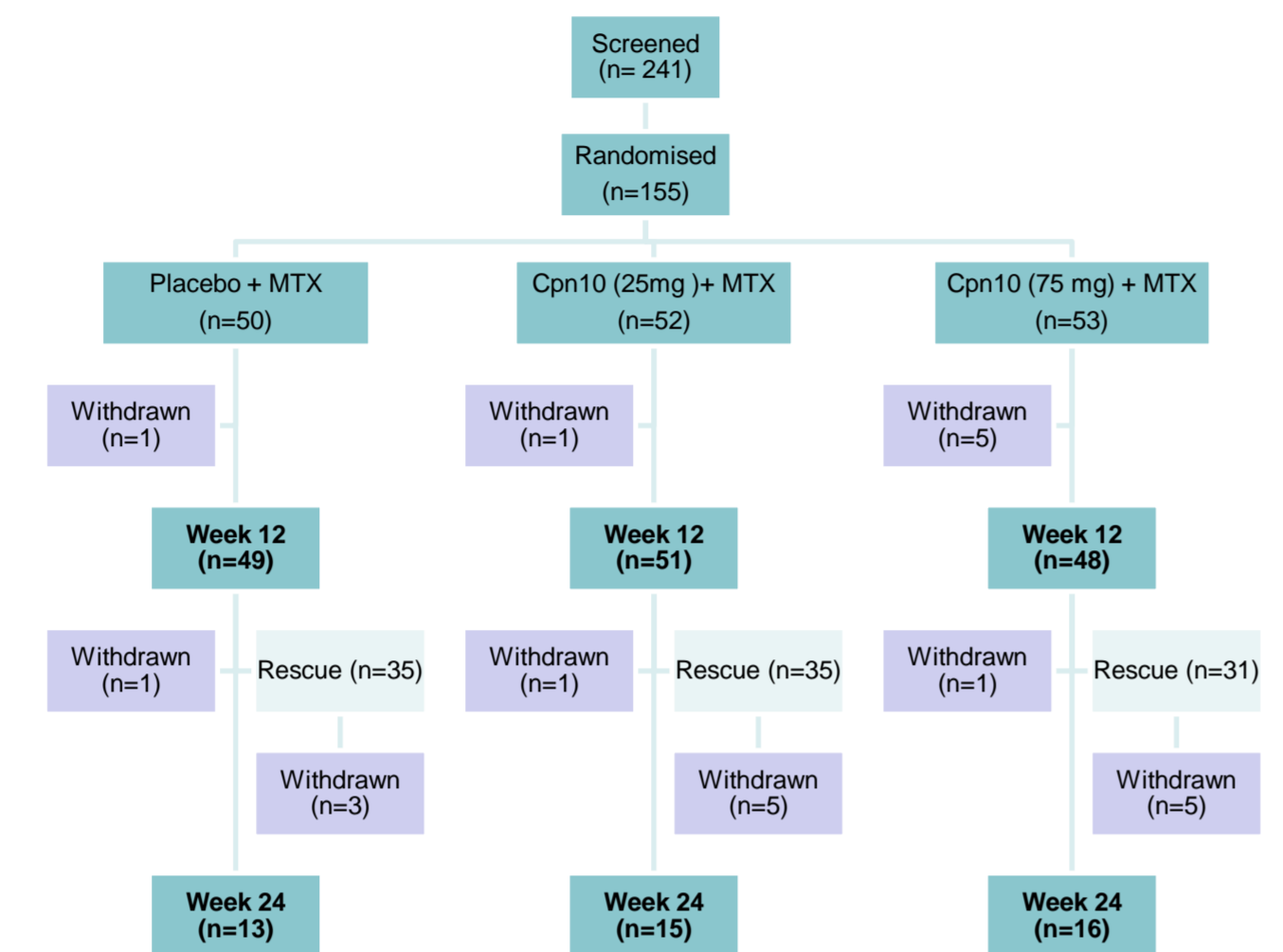
Inclusion / Exclusion Criteria

- Inclusion**
- Male or female aged 18-80 years
 - RA Functional class 1-3 diagnosed >6 months prior to screen
 - Active Disease despite stable MTX treatment at the maximum tolerated dose (10-30mg/week)
 - DAS28 >3.2, and
 - ESR > 25 mm/hr or CRP > 10 mg/L and
 - ≥ 6 tender and ≥ 6 swollen joints out of 68 examined
 - Failed at least one DMARD, but not more than 5
 - All other DMARDs, NSAIDs and Prednisolone (<10mg/day) stable dose
- Exclusion**
- Diagnosis of Juvenile Rheumatoid Arthritis
 - Treatment with > 1 biological agent for RA
 - Active or latent bacterial, fungal, viral or atypical mycobacterial infections at the time of screening
 - History of opportunistic infections within the past 6 months
 - History of malignancy within the past 5 years

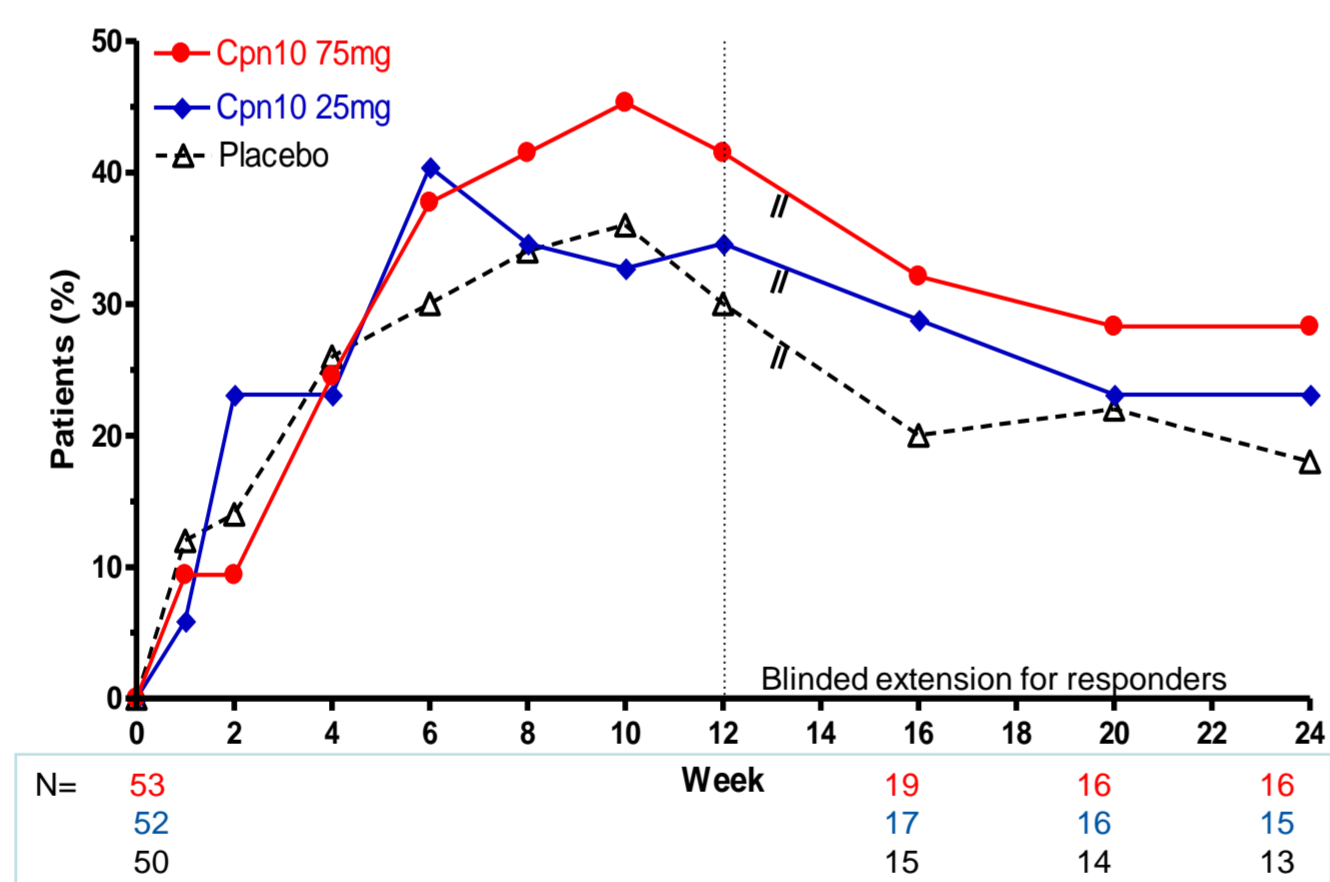
Baseline Demography and Clinical Measures

	Placebo group (n=50)	25mg group (n=52)	75mg group (n=53)
Age (years)	55.1 (9.6)	51.6 (11.8)	55.2 (11.4)
No. of females (%)	43 (86.0%)	42 (80.8%)	41 (77.4%)
RA Duration, (years)	9.40 (8.59)	8.42 (7.42)	8.50 (7.89)
No. of Prior DMARDs	1.5 (1.3)	1.7 (1.6)	1.7 (1.8)
No. of Current DMARDs	1.3 (0.6)	1.3 (0.6)	1.3 (0.7)
No. on Glucocorticoids (%)	28 (56%)	27 (52%)	24 (45%)
No. on NSAIDs (%)	27(54%)	25 (48%)	30 (57%)
ANZ/ Europe (n)	26/24	24/28	26/27
BMI (kg/m ²)	28.46 (5.44)	27.81 (5.89)	27.31 (4.88)
Tender Joint Count (68)	28.26 (13.43)	27.23 (12.95)	28.11 (14.93)
Tender Joint Count (28)	14.80 (6.77)	14.85 (6.58)	15.64 (7.15)
Swollen Joint Count (66)	16.50 (8.09)	17.60 (10.25)	17.26 (6.83)
Swollen Joint Count (28)	10.52 (4.93)	11.52 (4.81)	12.02 (3.99)
DAS28	5.73 (0.75)	5.66 (0.95)	5.76 (0.86)
HAQ	1.46 (0.54)	1.57 (0.57)	1.44 (0.66)
RF positive (%)	96%	84.6%	92.5%
Anti-CCP3 positive (%)	86.4%	80.4%	86.9%
RF concentration (kIU/L)	397.6 (697.8)	235.6 (452.1)	240.7 (429.2)
ESR (mm/hr)	38.5 (20.9)	37.6 (19.4)	40.3 (19.8)
CRP (mg/L)	20.97 (32.06)	15.97 (21.21)	16.72 (22.38)

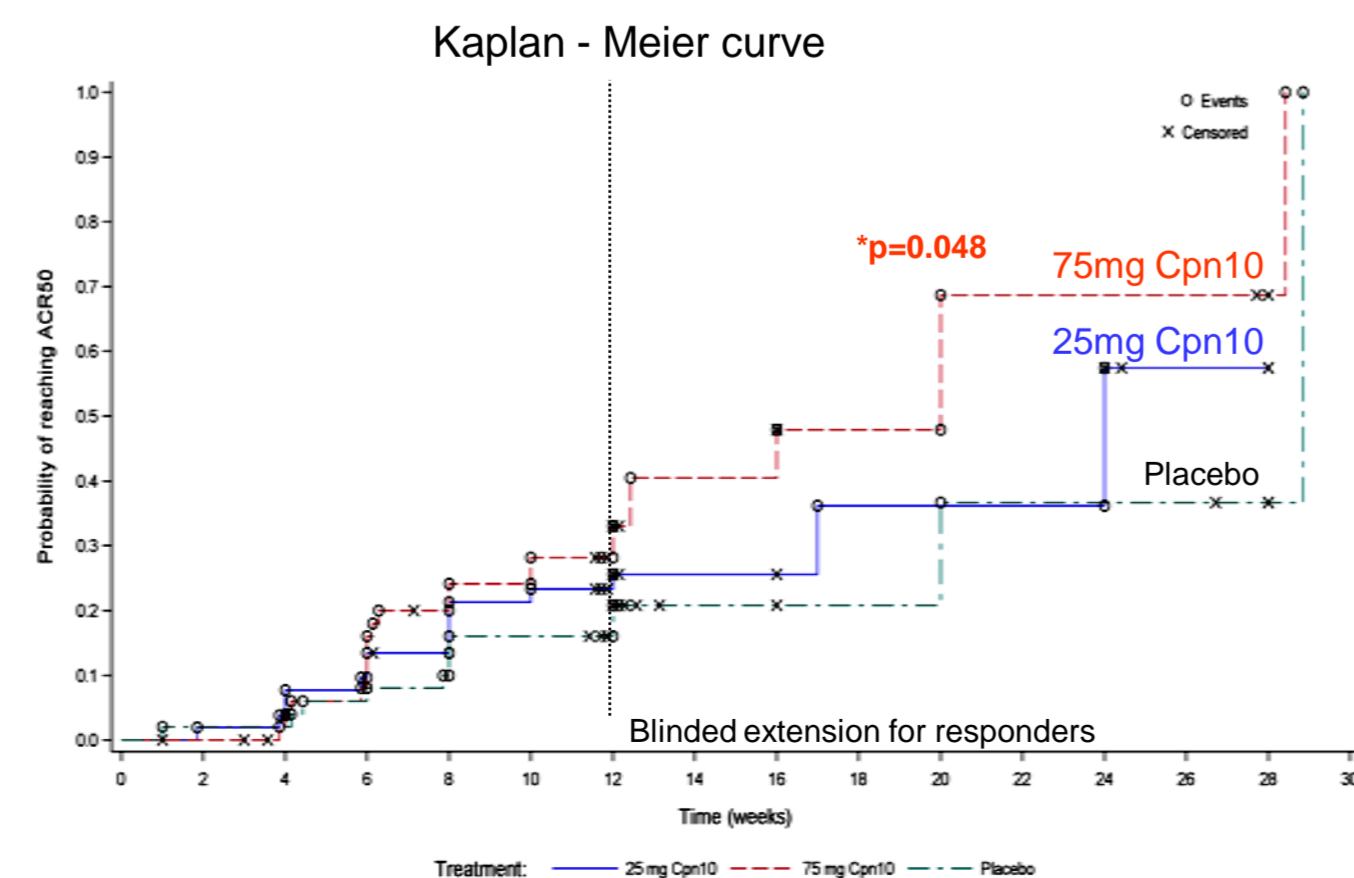
Trial Patient Disposition



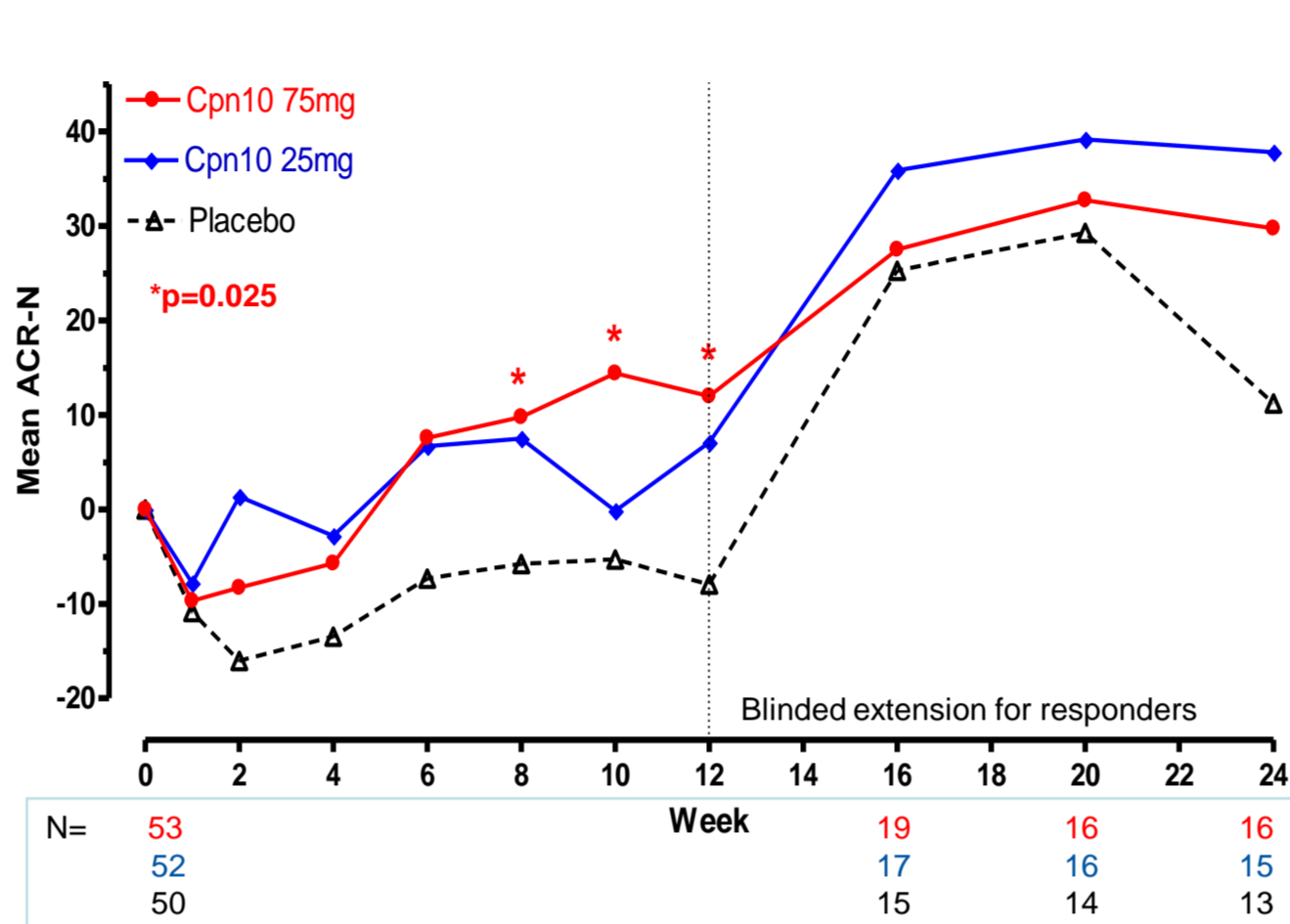
Primary endpoint ACR 20



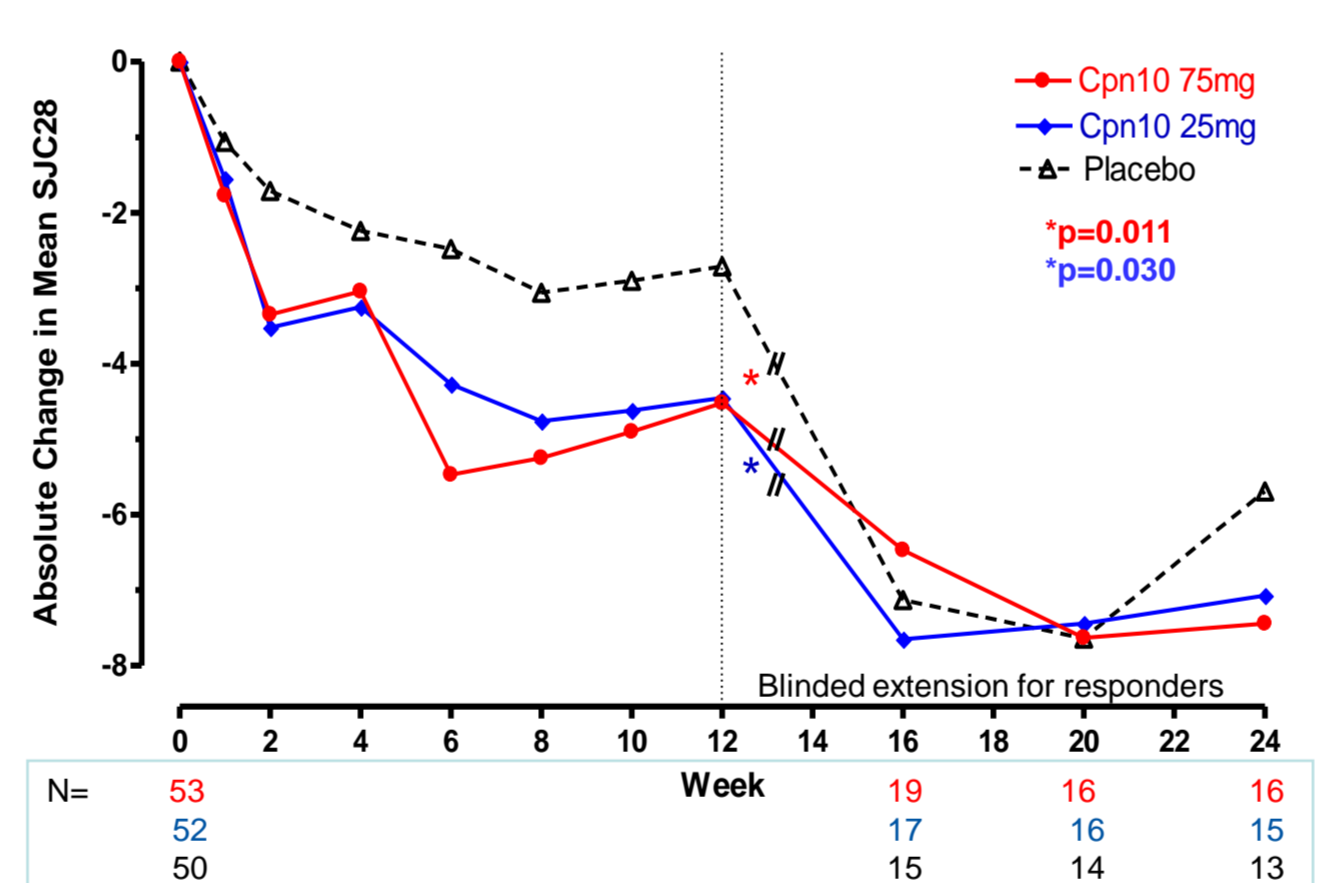
Significant Improvement Time to ACR50



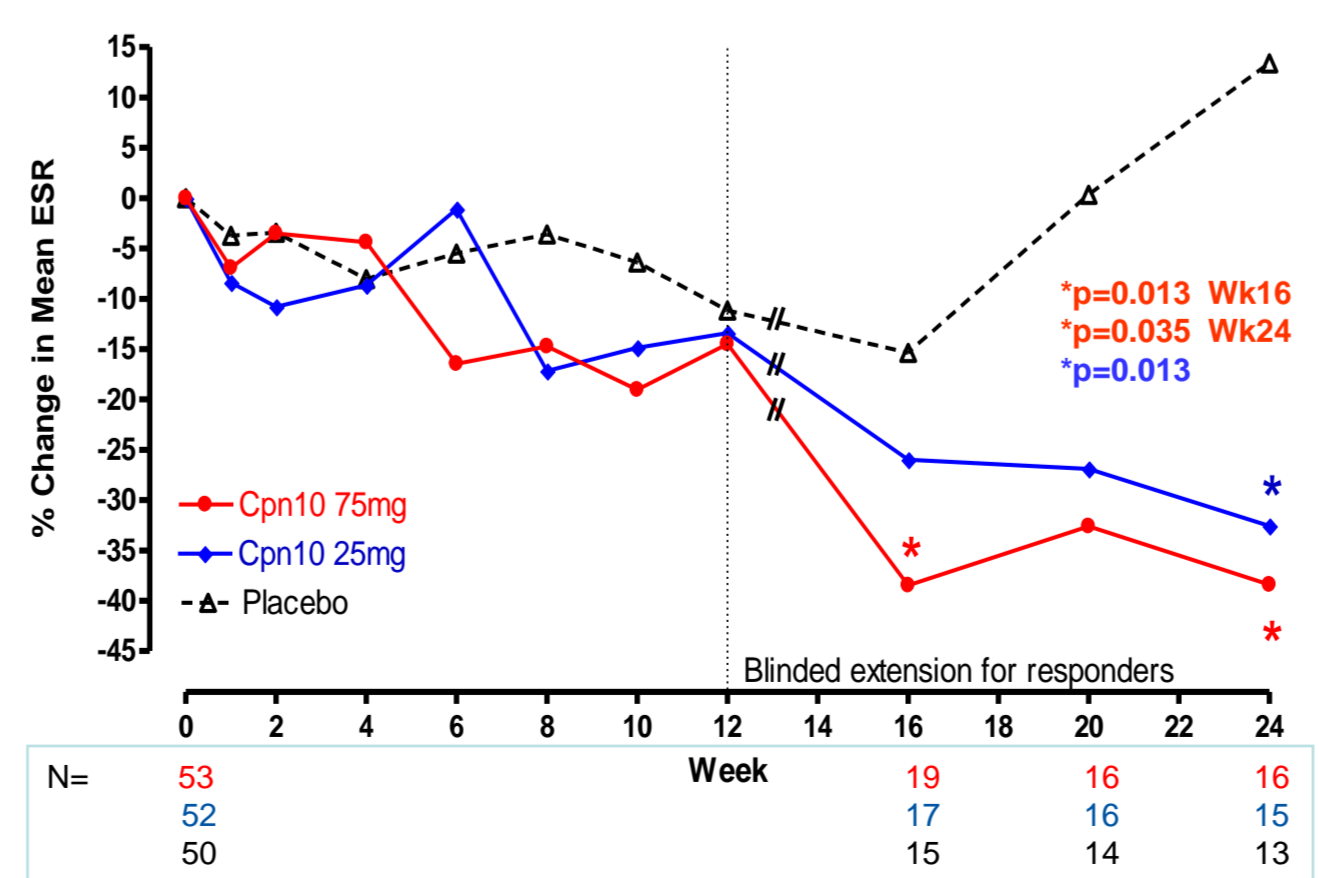
Significant Improvement ACR-N



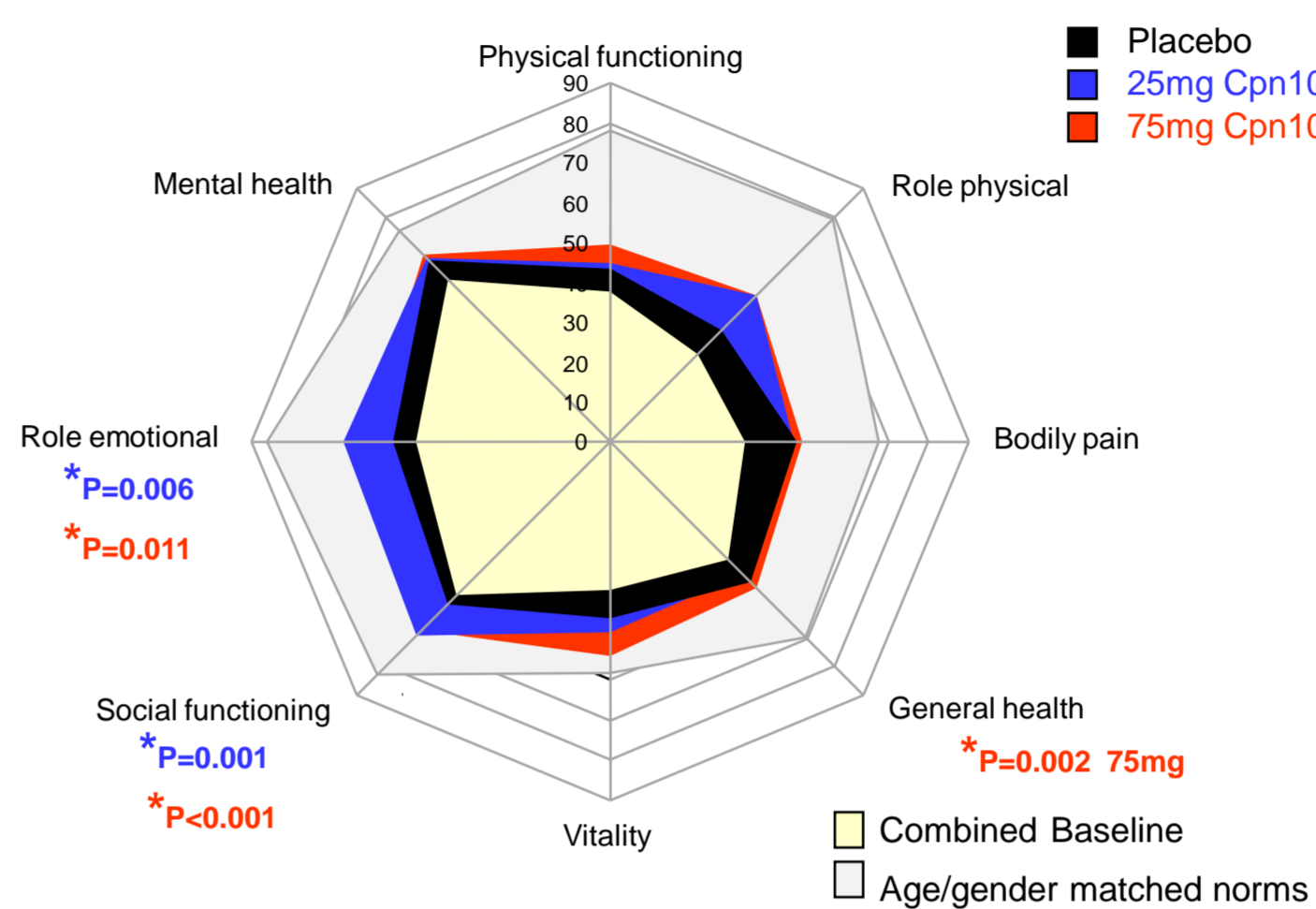
Significant Improvement SJC28



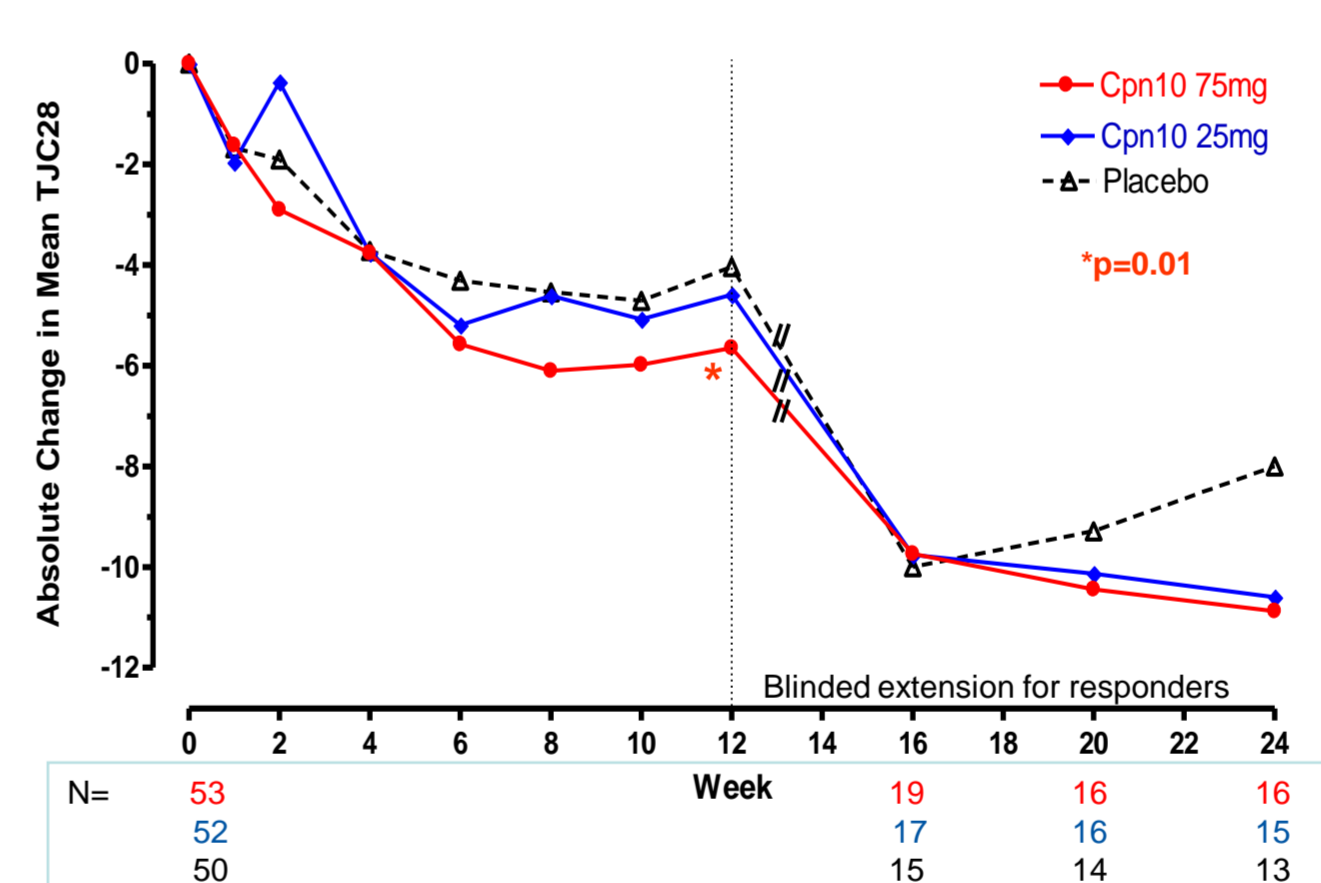
Significant Improvement ESR



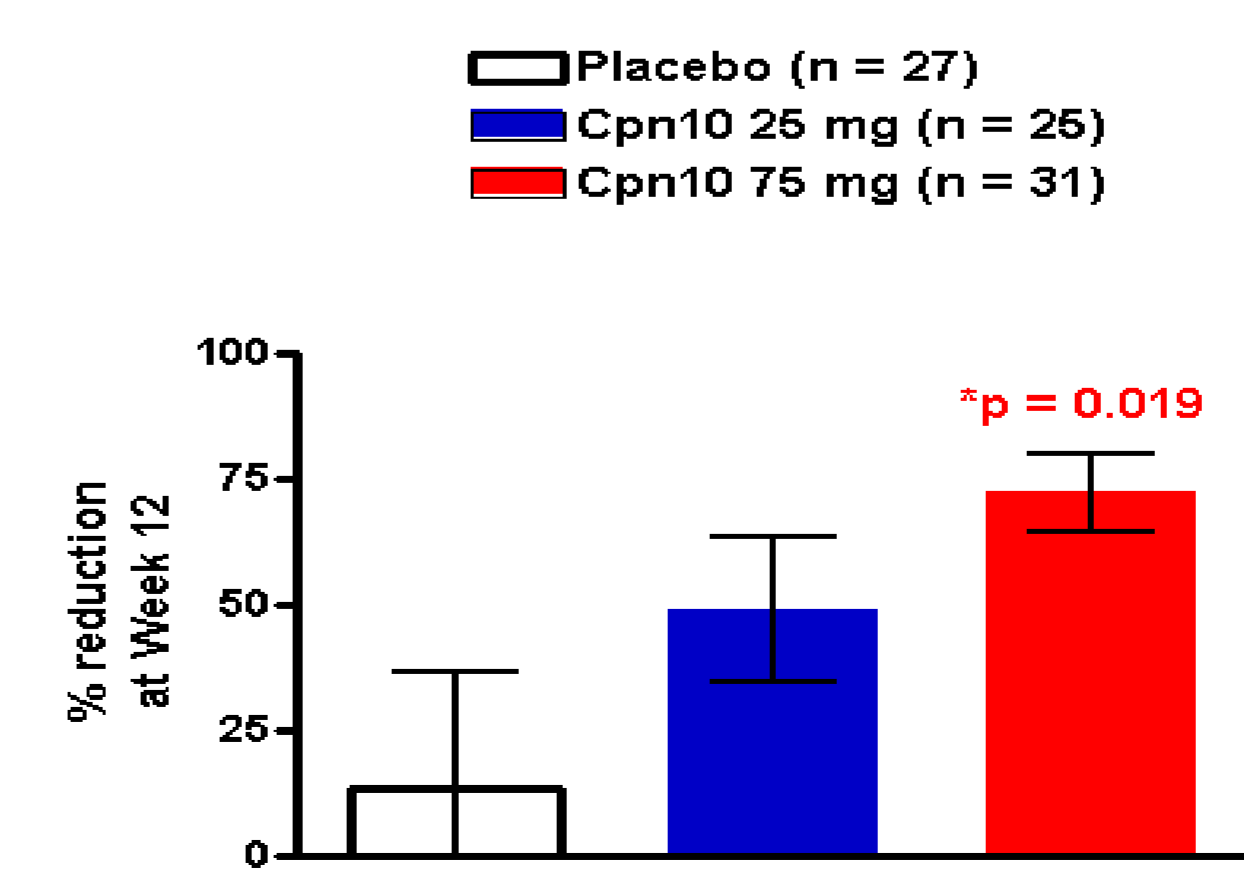
SF-36 All Treatment Groups Week 12



Significant Improvement TJC28



Significant Reduction in serum IL-6



Adverse Events

Weeks 0-12 n (%)	Placebo group (n=50)	25mg group (n=52)	75mg group (n=53)
Injection site reaction	3 (6.0%)	8 (15.4%)	17 (32.1%)
Respiratory tract infection	1 (2.0%)	8 (15.4%)	3 (5.7%)
Urinary tract infection	1 (2.0%)	6 (11.5%)	1 (1.9%)
Headache	4 (8.0%)	9 (17.3%)	2 (3.8%)
Arthralgia	2 (3.8%)	0 (0%)	3 (6.0%)
Worsening of RA	2 (3.8%)	1 (1.9%)	3 (6.0%)
Nausea	3 (6.0%)	1 (1.9%)	2 (3.8%)
Rash	3 (6.0%)	5 (9.6%)	2 (3.8%)
Diarrhoea	3 (6.0%)	3 (5.8%)	1 (1.9%)

Weeks 13-24 n (%)	Placebo group (n=13)	25mg group (n=15)	75mg group (n=16)	25mg OL group (n=107)	75mg OL group (n=63)
Respiratory tract infection	1 (7.7%)	3 (20.0%)	1 (6.3%)	7 (6.5%)	3 (4.8%)
Injection site reaction	0 (0%)	0 (0%)	1 (6.3%)	6 (5.6%)	6 (9.5%)

Serious Adverse Events

ID/ Dose	AE	Rating	Comments	Days since first dose
501/ 25mg	Hospitalised- possible pulmonary embolism/ chest infection	remote	Smoker, granuloma on screening CXR	14
2601/ 75mg	Hospitalised- for investigation of pain and warmth left leg	possible	Ultrasound excluded thrombophlebitis	66
2601/ 75mg	Respiratory tract infection (Pseudomonas aeruginosa)	possible	Identified during hospitalisation	76
508/ Placebo	Hospitalised- disease flare	unrelated	RA	NA
104/ Placebo	Hospitalised- treatment for Wolf Parkinson White Syndrome	unrelated	Wolf Parkinson White Syndrome	NA
101/ 75mg	Myocardial Infarction (death)	unrelated	Ischaemic heart disease, ventricular astyole, ventricular ectopic beats, sleep apnoea.	89
103/ 25mg	Hospitalised- correction to Dupuytren's contracture	unrelated	Dupuytren's contracture	96

Pharmacokinetics

- Subcutaneous PK profile more variable in RA patients compared to healthy volunteers (>30%CV)
- Some RA subjects did not receive the exposure levels expected based on phase 1 data in healthy volunteers
- 75mg may not be the top of the dose-response curve

Conclusion

- Primary endpoint of ACR20 at week 12 not achieved.
- However, Cpn10 treatment resulted in significant reductions in:
 - ACR-N and time to ACR50
 - Swollen and Tender Joint Count
 - Role emotional, social functioning and general health components of SF-36, plus SF6D
 - ESR
 - IL-6 (which approached normative values)
- Trends to improvement in ACR20, ACR50, ACR70, HAQ-DI and DAS28
- Vitality component of SF36 approached normative values
- Most common adverse events reported were injection site reactions which were well treated with antihistamines
- Reformulation will be required in advance of any future dose range clinical trial as the existing formulation is not optimal for s.c. delivery