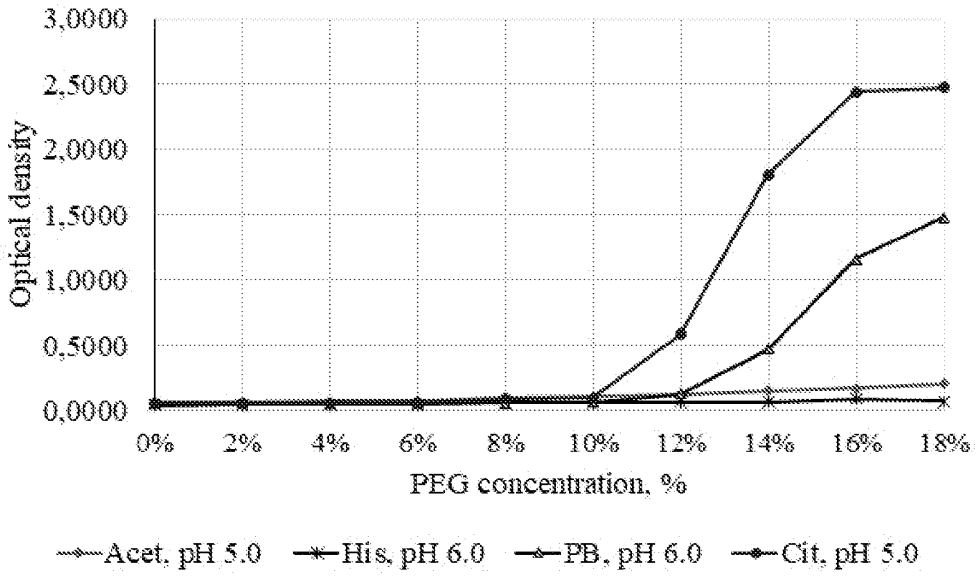

3,0000
2,5000
2,0000
1,5000
1,0000
0,5000
0,0000
Optical density
0%
2%
4%
6%
8%
10%
12%
14%
16%
18%
PEG concentration, %
Acet, pH 5.0
His, pH 6.0
PB, pH 6.0
Cit, pH 5.0

Fig. 1.

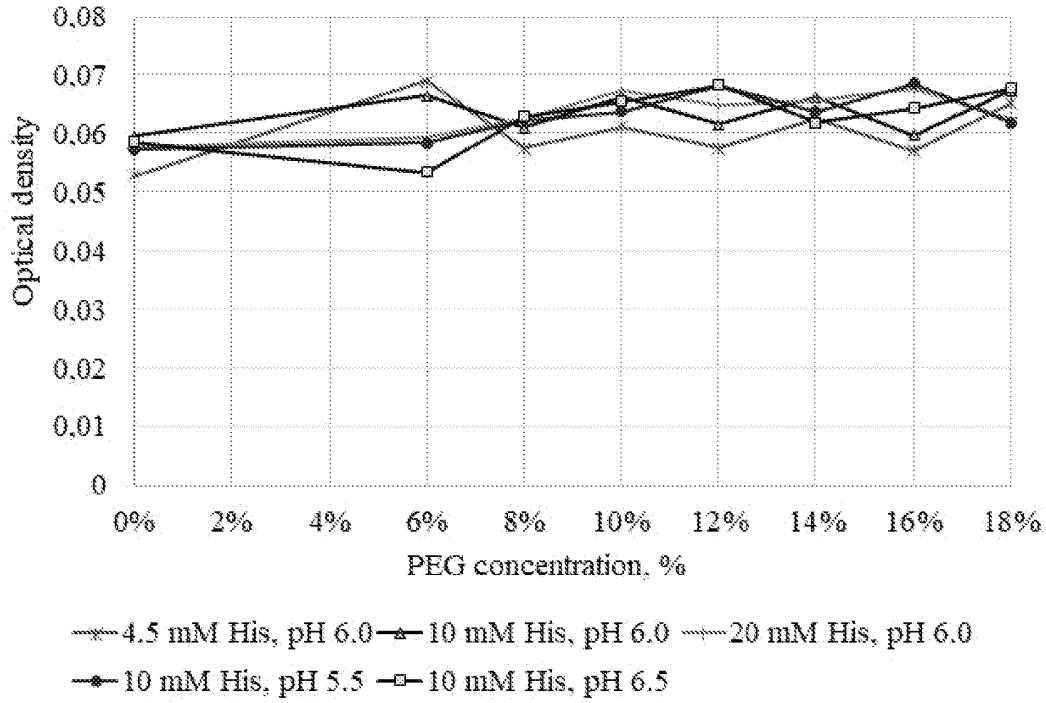

0,08
0,07
0,06
0,05
0,04
0,03
0,02
0,01
0
Optical density
0%
2%
4%
6%
8%
10%
12%
14%
16%
18%
PEG concentration, %
4.5 mM His, pH 6.0
10 mM His, pH 6.0
20 mM His, pH 6.0
10 mM His, pH 5.5
10 mM His, pH 6.5

Fig. 2.

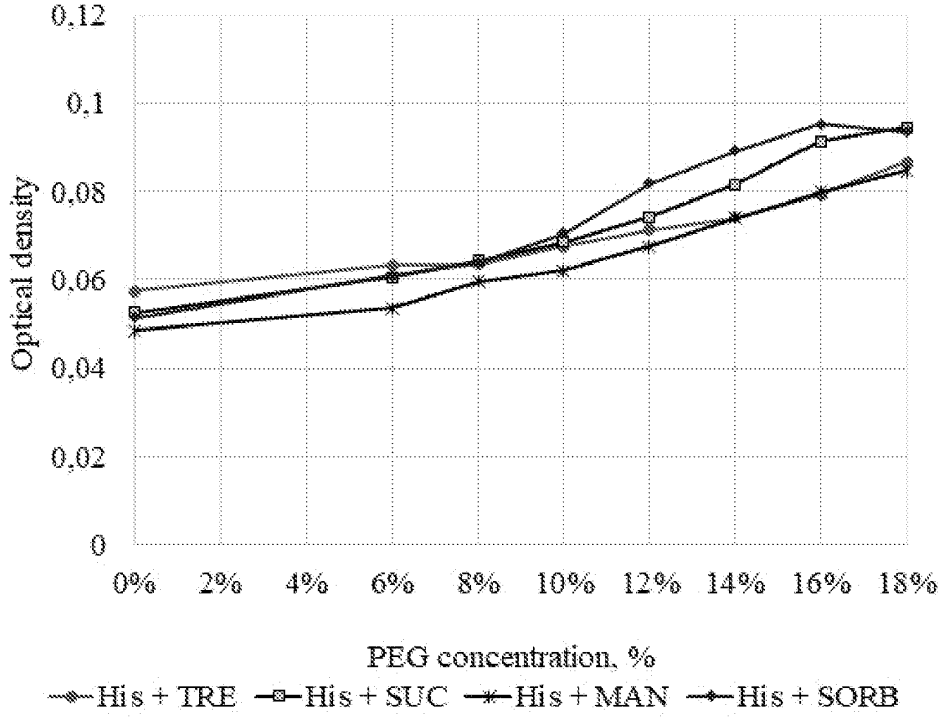

0,12
0,1
0,08
0,06
0,04
0,02
0
Optical density
0% 2% 4% 6% 8% 10% 12% 14% 16% 18%
PEG concentration, %
His + TRE
His + SUC
His + MAN
His + SORB

Fig. 3.

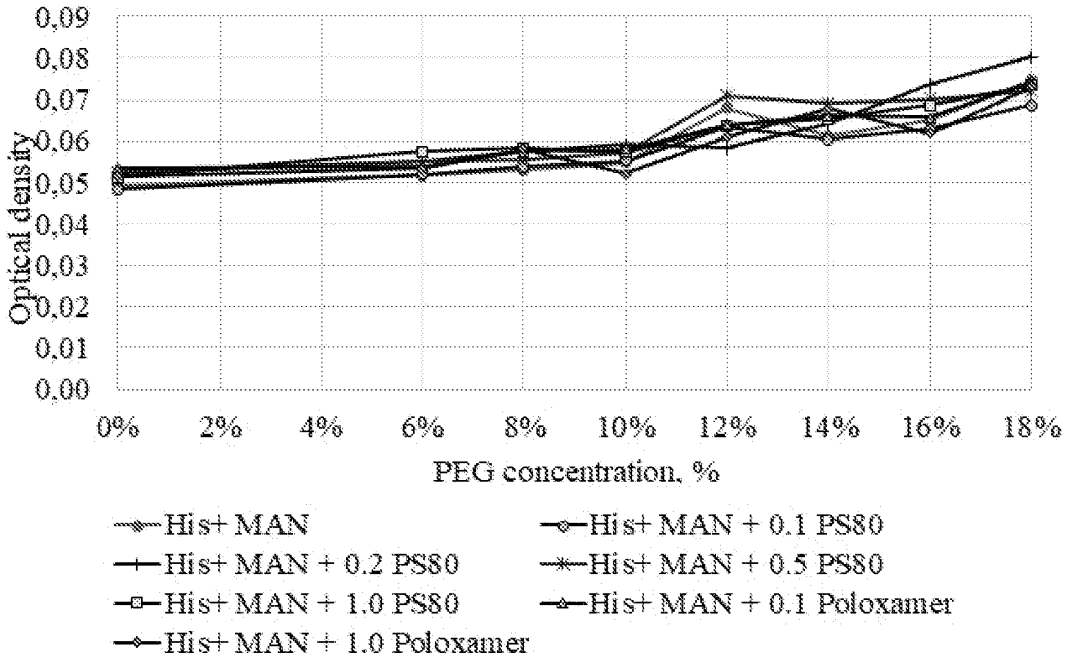

0,09
0,08
0,07
0,06
0,05
0,04
0,03
0,02
0,01
0,00
Optical density
0% 2% 4% 6% 8% 10% 12% 14% 16% 18%
PEG concentration, %
His+ MAN
His+ MAN + 0.1 PS80
His+ MAN + 0.2 PS80
His+ MAN + 0.5 PS80
His+ MAN + 1.0 PS80
His+ MAN + 0.1 Poloxamer
His+ MAN + 1.0 Poloxamer

Fig. 4

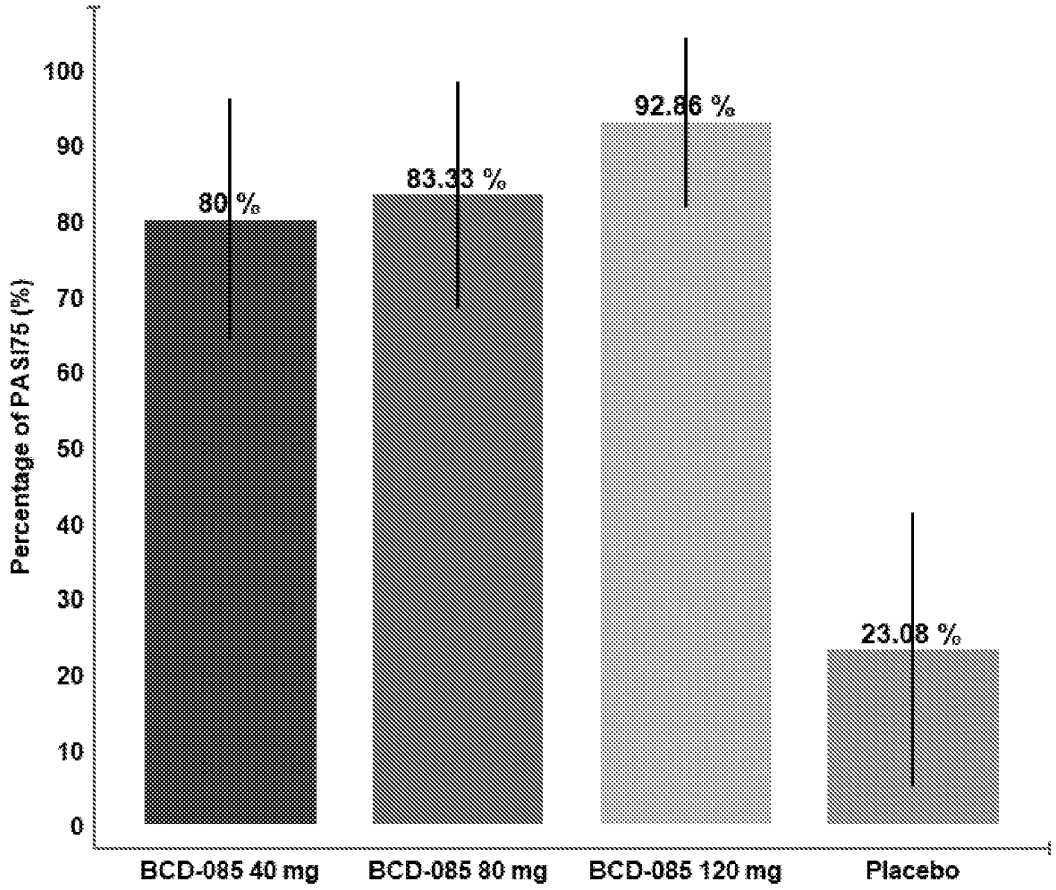

Percentage of PASI75 (%)
100
90
80
70
60
50
40
30
20
10
0
80 %
83.33 %
92.86 %
23.08 %
BCD-085 40 mg
BCD-085 80 mg
BCD-085 120 mg
Placebo

Fig. 5

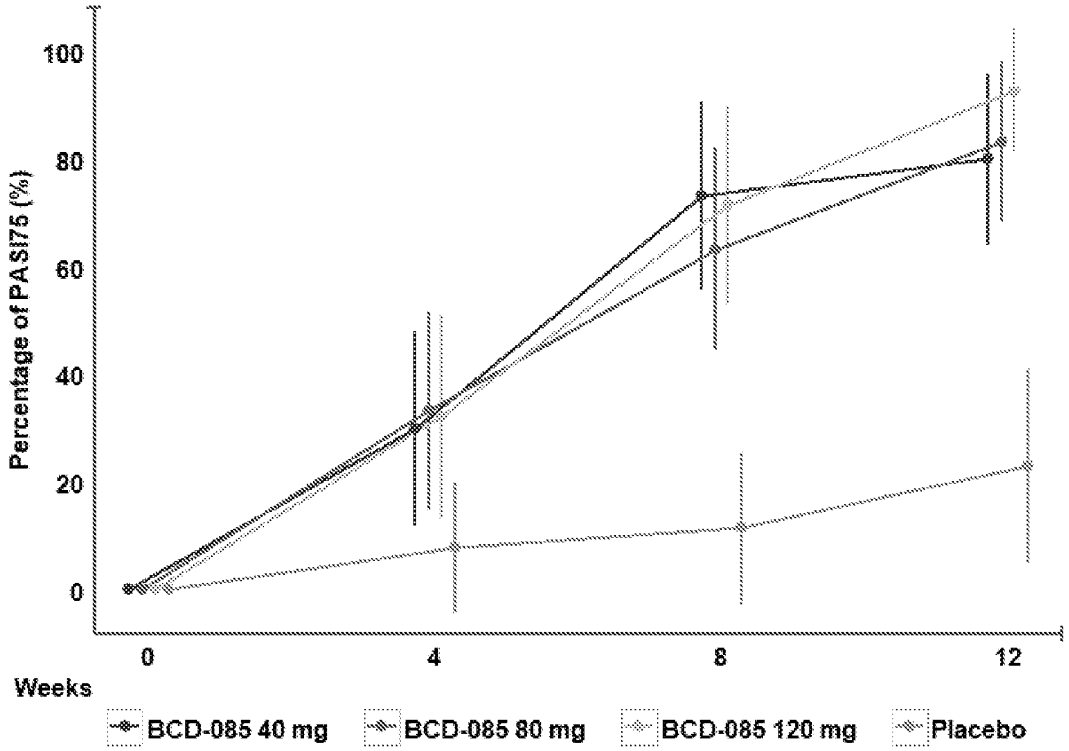

Percentage of PASI75 (%)
100
80
60
40
20
0
0
4
8
12
Weeks
BCD-085 40 mg
BCD-085 80 mg
BCD-085 120 mg
Placebo

Fig. 6

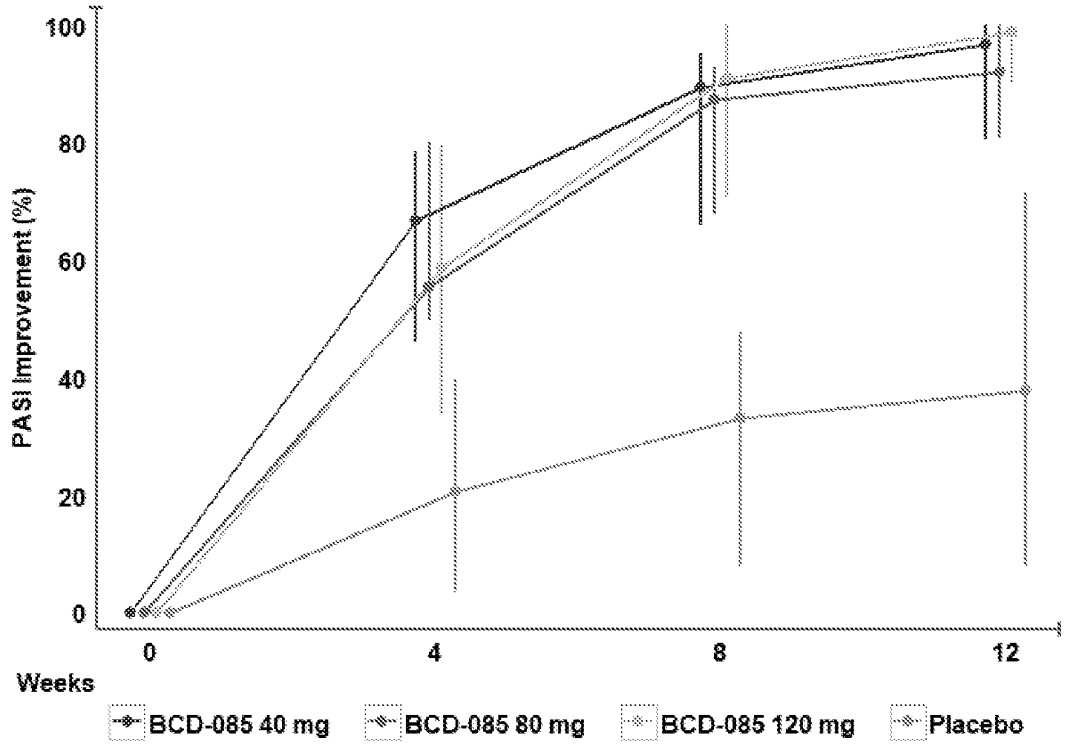

PASI improvement (%)
100
80
60
40
20
0
0
4
8
12
Weeks
BCD-085 40 mg
BCD-085 80 mg
BCD-085 120 mg
Placebo

Fig. 7

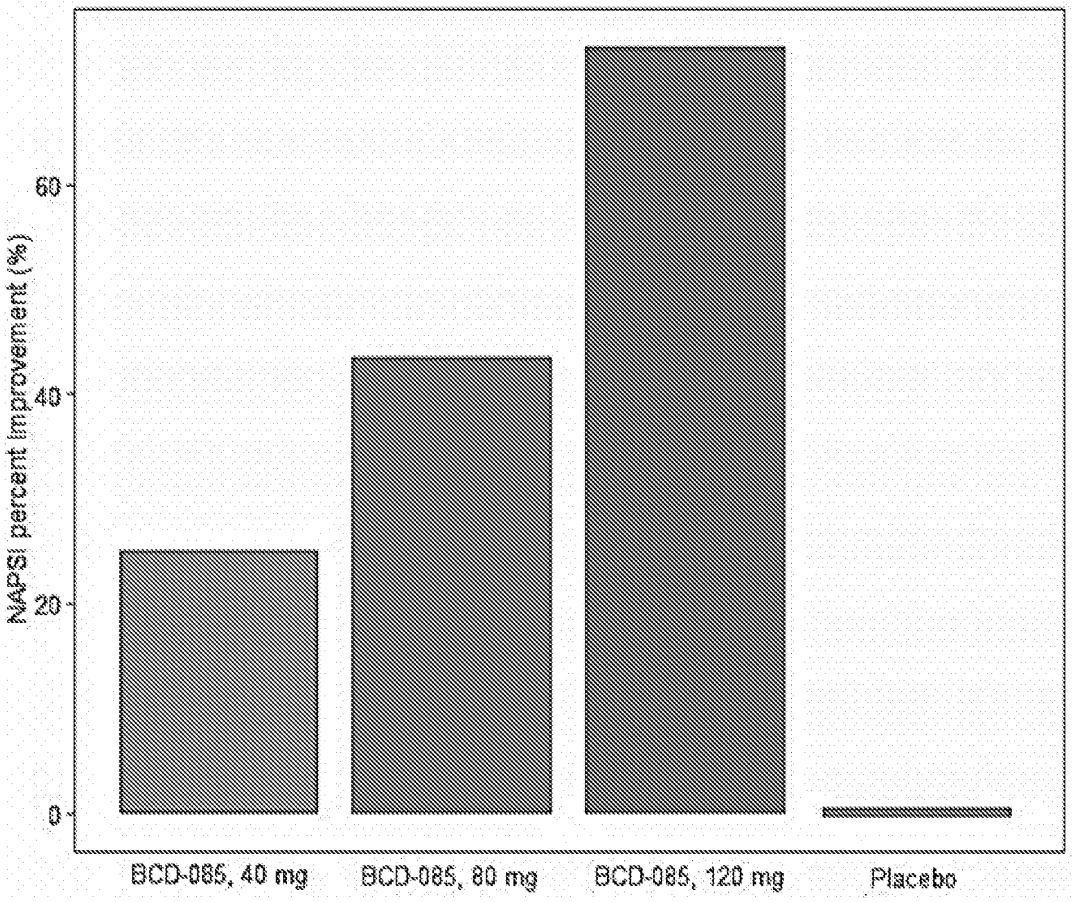

NAPSI percent improvement (%)
0
20
40
60
BCD-085, 40 mg
BCD-085, 80 mg
BCD-085, 120 mg
Placebo

Fig. 8

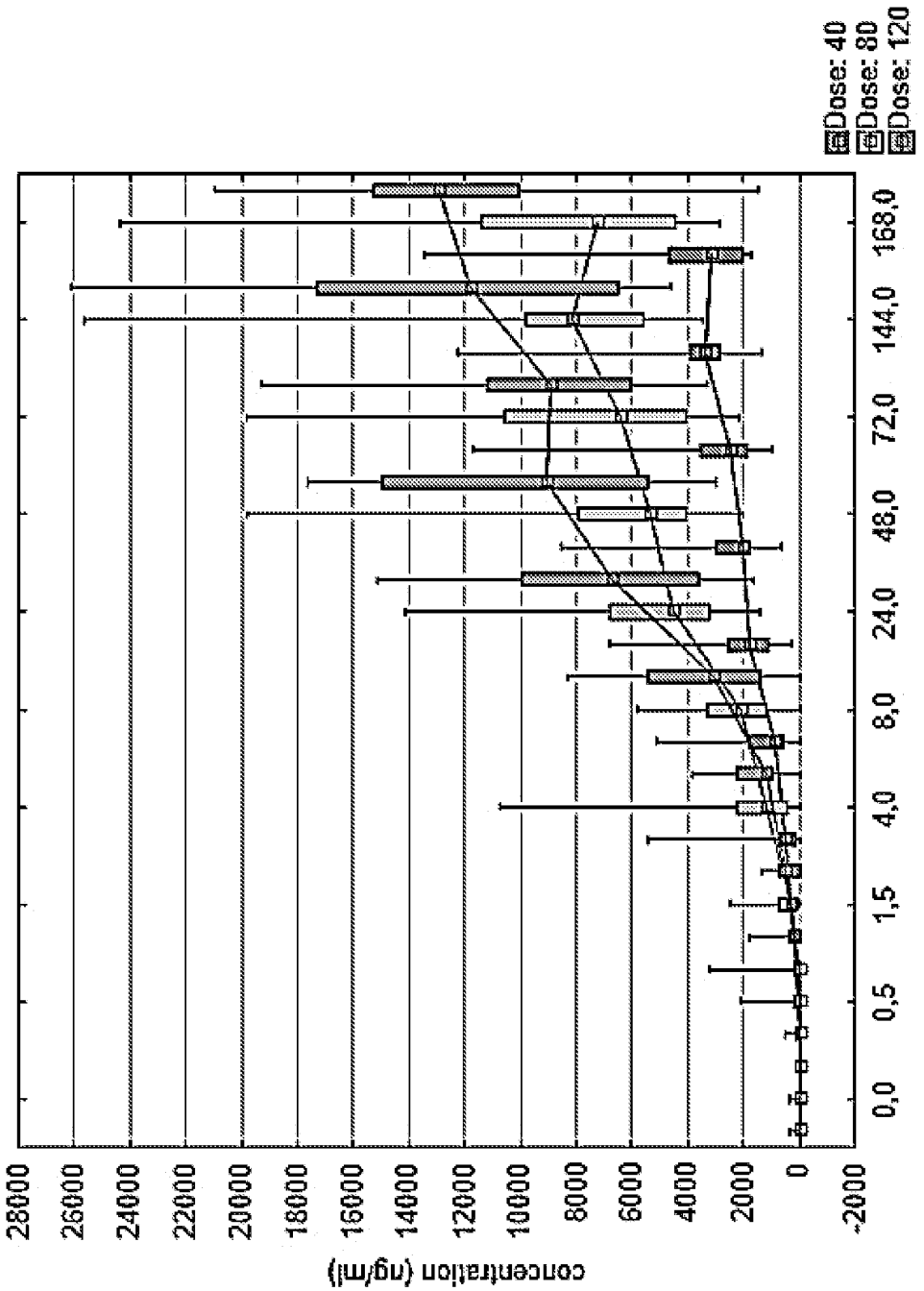

Dose: 40
Dose: 80
Dose: 120
concentration (ng/ml)
28000
26000
24000
22000
20000
18000
16000
14000
12000
10000
8000
6000
4000
2000
0
-2000
0,0
0,5
1,5
4,0
8,0
24,0
48,0
72,0
144,0
168,0
Time (h)

Fig. 9

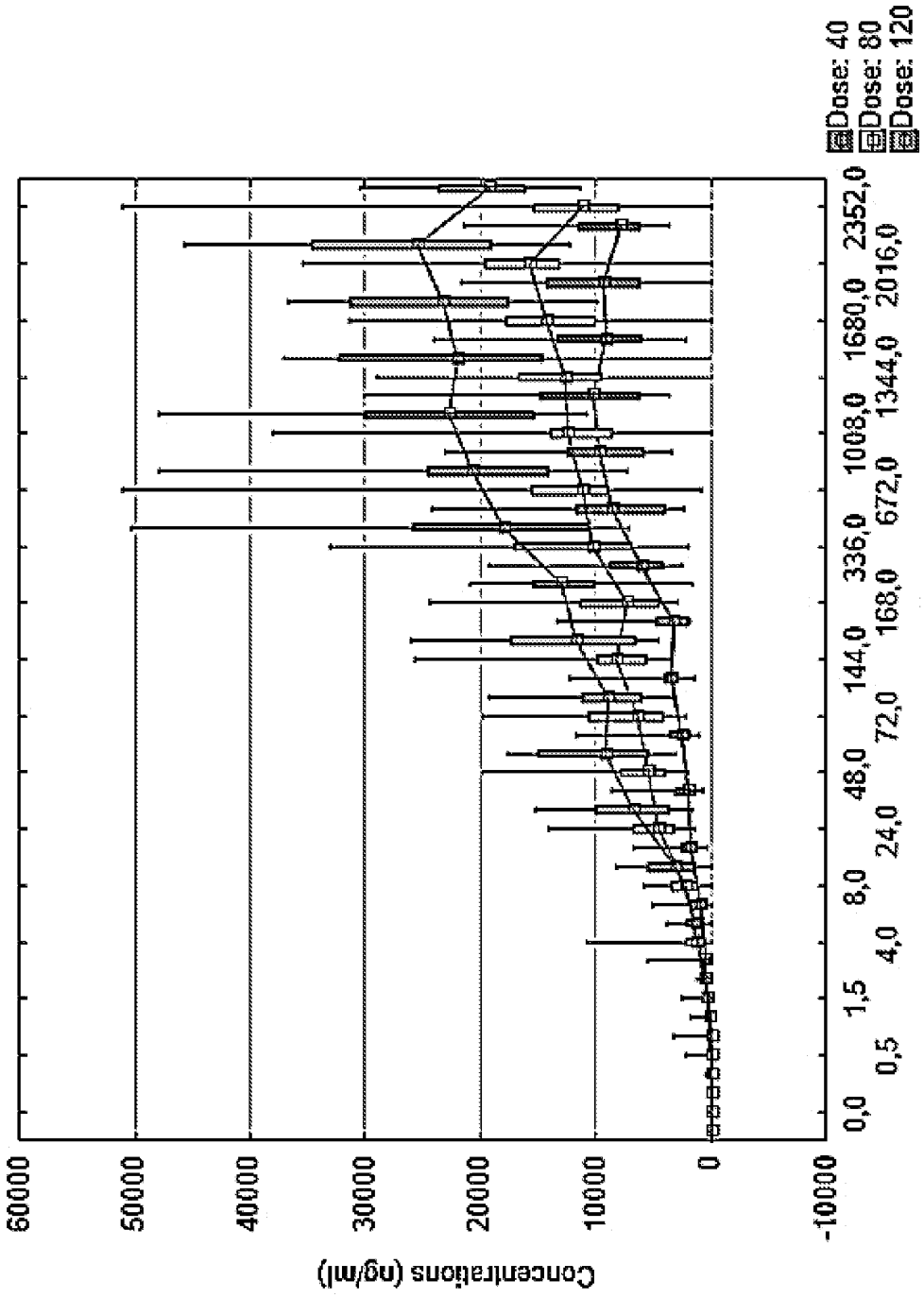

Dose: 40
Dose: 80
Dose: 120
60000
50000
40000
30000
20000
10000
0
-10000
Concentrations (ng/ml)
0,0
0,5
1,5
4,0
8,0
24,0
48,0
72,0
144,0
168,0
336,0
672,0
1008,0
1344,0
1680,0
2016,0
2352,0
Time(h)

Fig. 10

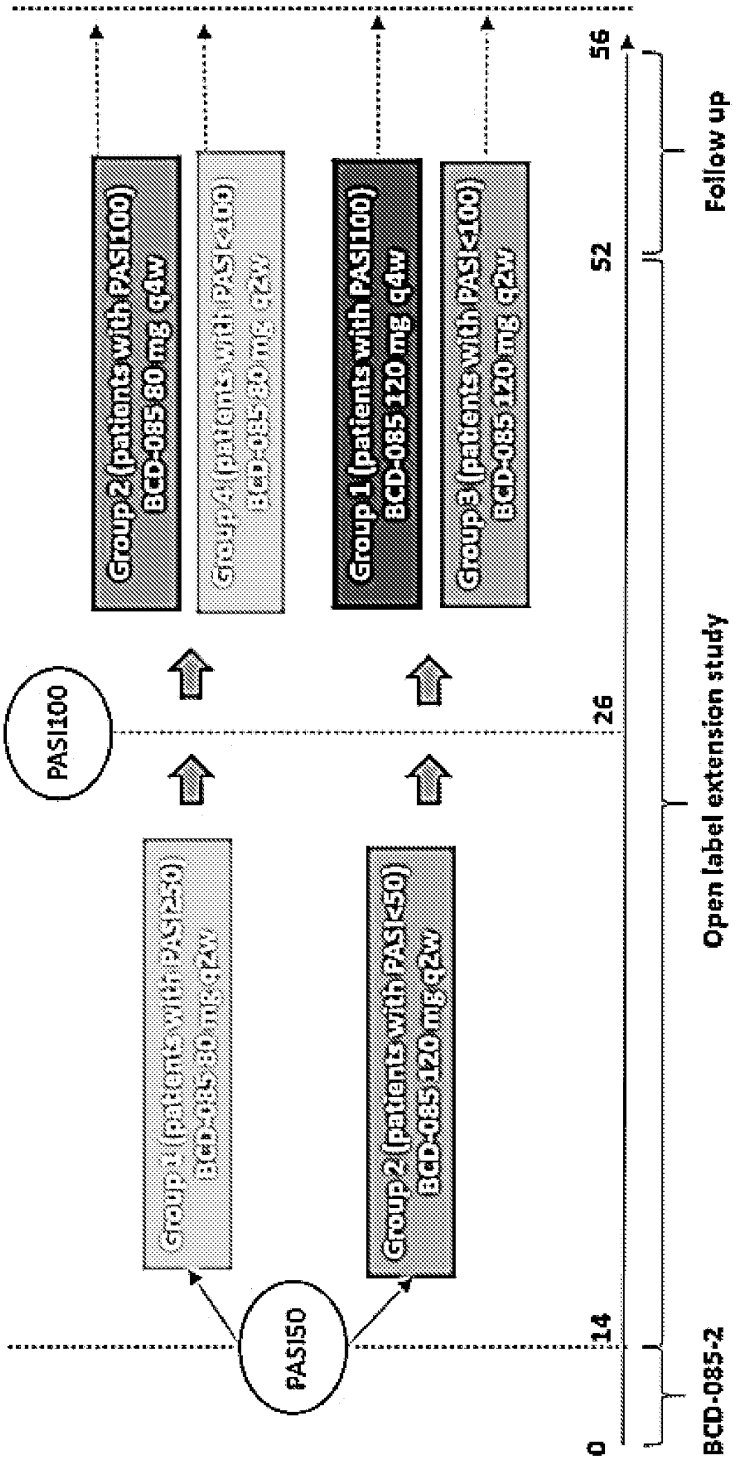

Group 2 (patients with PASI100) BCD-085 80 mg q4w
Group 4 (patients with PASI<100) BCD-085 80 mg q2w
Group 1 (patients with PASI100) BCD-085 120 mg q4w
Group 3 (patients with PASI<100) BCD-085 120 mg q2w
PASI100
Group 4 (patients with PASI<50) BCD-085 80 mg q2w
Group 2 (patients with PASI<50) BCD-085 120 mg q2w
PASI50
0
14
26
52
56
BCD-085-2
Open label extension study
Follow up

Fig. 11

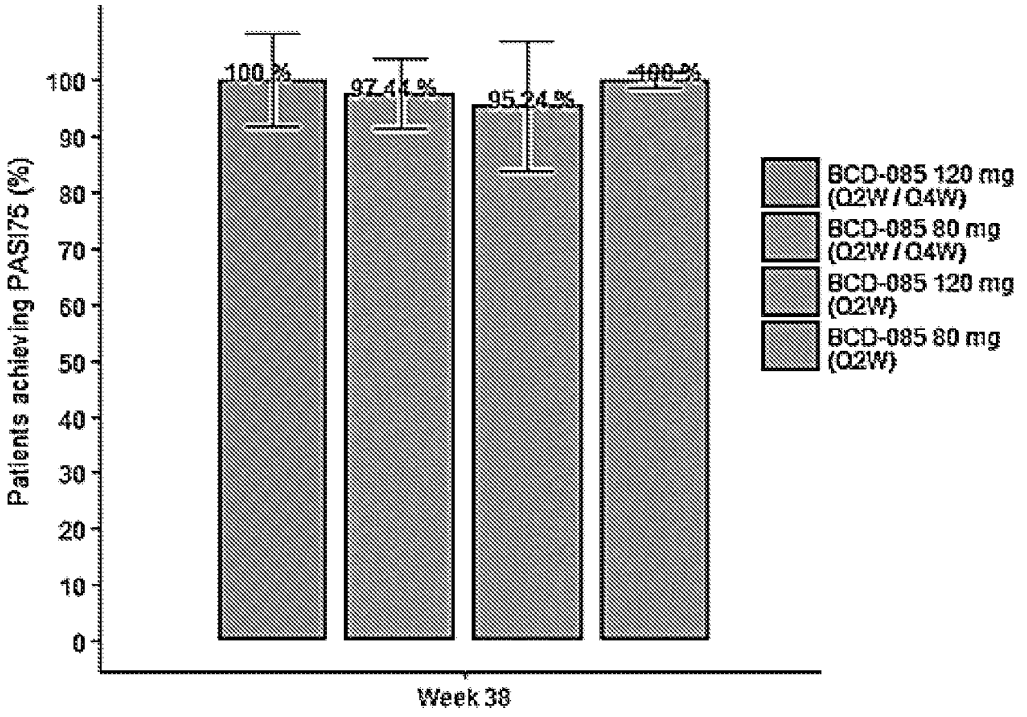

Patients achieving PASI75 (%)
100
90
80
70
60
50
40
30
20
10
0
100 %
97.44 %
95.24 %
100 %
Week 38
BCD-085 120 mg (Q2W / Q4W)
BCD-085 80 mg (Q2W / Q4W)
BCD-085 120 mg (Q2W)
BCD-085 80 mg (Q2W)

Fig. 12

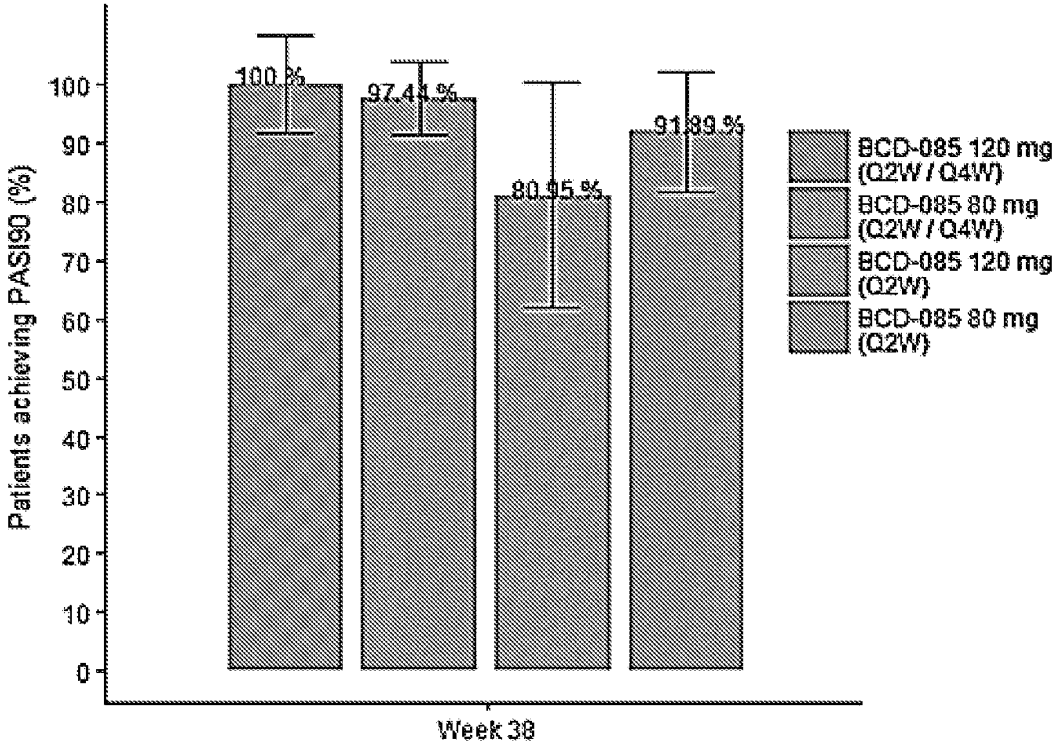

Patients achieving PASI90 (%)
100
90
80
70
60
50
40
30
20
10
0
100 %
97.44 %
80.95 %
91.89 %
Week 38
BCD-085 120 mg (Q2W / Q4W)
BCD-085 80 mg (Q2W / Q4W)
BCD-085 120 mg (Q2W)
BCD-085 80 mg (Q2W)

Fig. 13

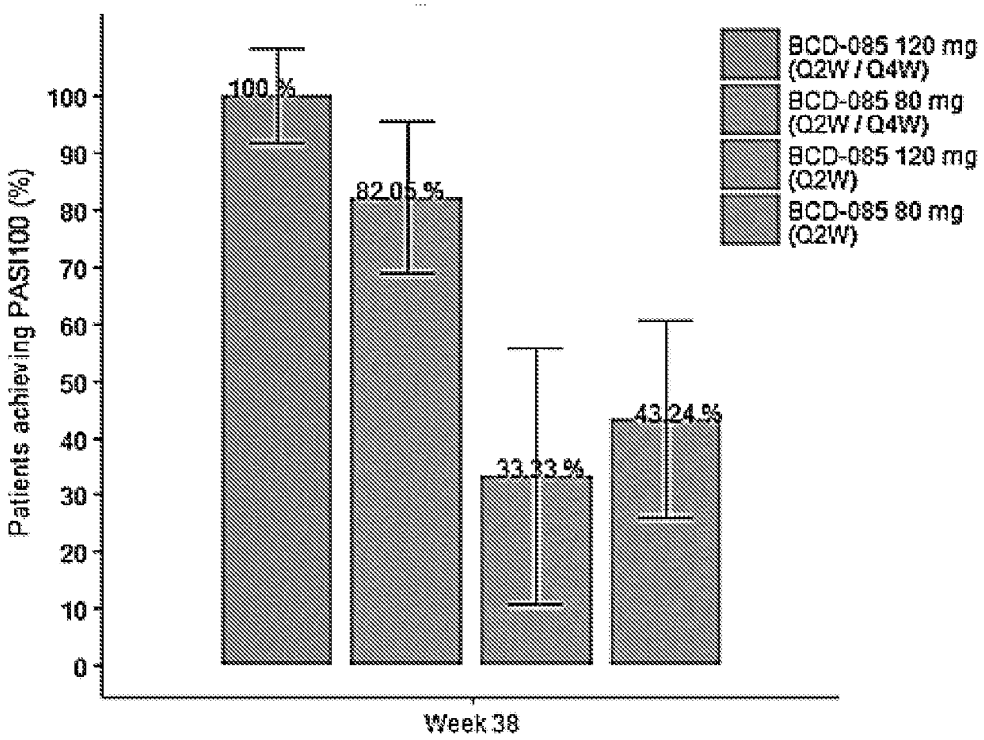

BCD-085 120 mg (Q2W / Q4W)
BCD-085 80 mg (Q2W / Q4W)
BCD-085 120 mg (Q2W)
BCD-085 80 mg (Q2W)
Patients achieving PASI100 (%)
0
10
20
30
40
50
60
70
80
90
100
100 %
82.05 %
33.33 %
43.24 %
Week 38

Fig. 14

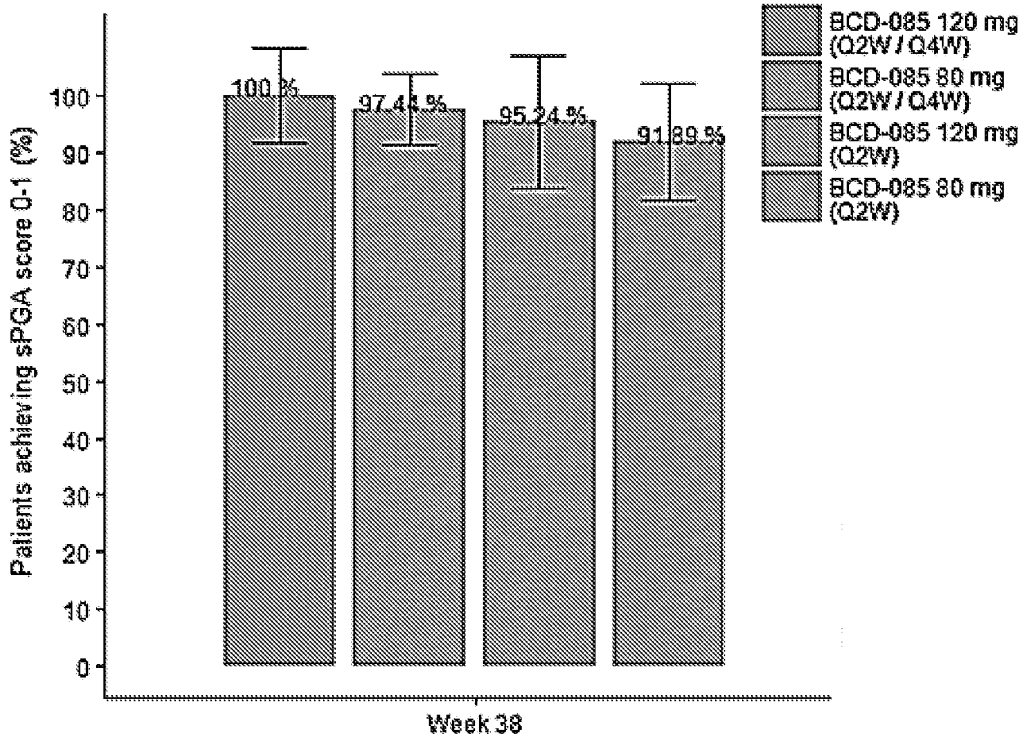

BCD-085 120 mg (Q2W / Q4W)
BCD-085 80 mg (Q2W / Q4W)
BCD-085 120 mg (Q2W)
BCD-085 80 mg (Q2W)
Patients achieving sPGA score 0-1 (%)
0
10
20
30
40
50
60
70
80
90
100
100 %
97.44 %
95.24 %
91.89 %
Week 38

Fig. 15

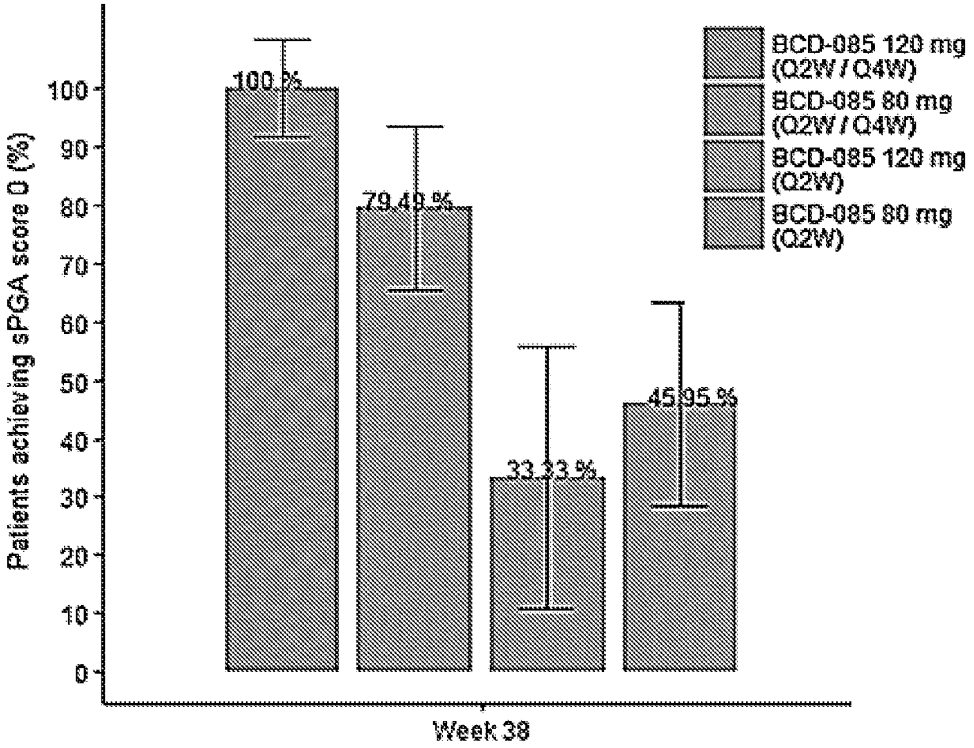

Patients achieving sPGA score 0 (%)
100
90
80
70
60
50
40
30
20
10
0
100 %
79.49 %
33.33 %
45.95 %
Week 38
BCD-085 120 mg (Q2W / Q4W)
BCD-085 80 mg (Q2W / Q4W)
BCD-085 120 mg (Q2W)
BCD-085 80 mg (Q2W)

Fig. 16

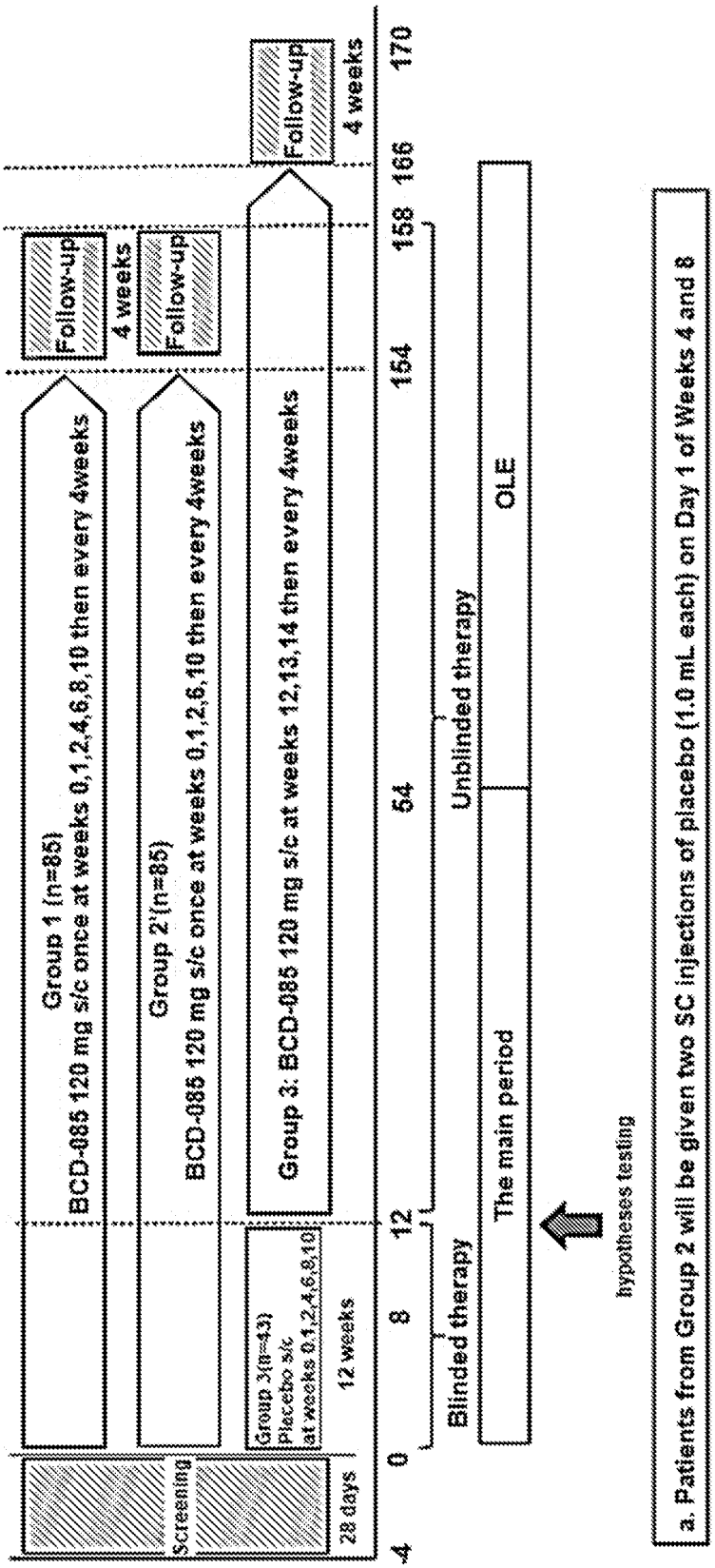

Group 1 (n=85)
BCD-085 120 mg s/c once at weeks 0,1,2,4,6,8,10 then every 4weeks
Group 2'(n=85)
BCD-085 120 mg s/c once at weeks 0,1,2,6,10 then every 4weeks
Group 3: BCD-085 120 mg s/c at weeks 12,13,14 then every 4weeks
Group 3(n=43)
Placebo s/c
at weeks 0,1,2,4,6,8,10
Follow-up
4 weeks
Follow-up
Follow-up
4 weeks
Screening
28 days
12 weeks
Blinded therapy
Unblinded therapy
The main period
OLE
hypotheses testing
-4
0
8
12
54
154
158
166
170
a. Patients from Group 2 will be given two SC injections of placebo (1.0 mL each) on Day 1 of Weeks 4 and 8

Fig. 17

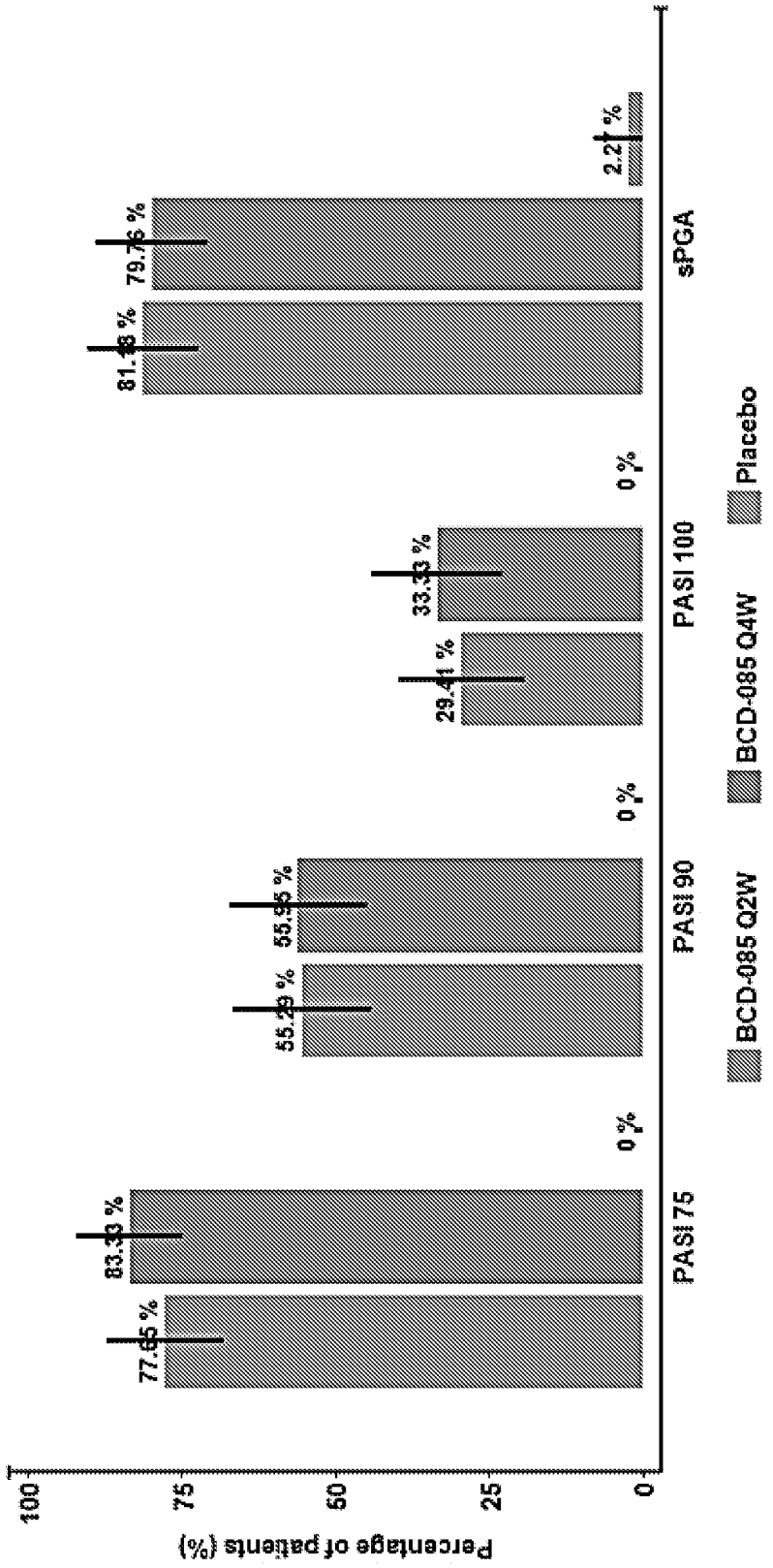

Percentage of patients (%)
100
75
50
25
0
PASI 75
PASI 90
PASI 100
sPGA
77.65 %
83.33 %
0 %
55.29 %
55.95 %
0 %
29.41 %
33.33 %
0 %
81.18 %
79.76 %
2.2 %
BCD-085 Q2W
BCD-085 Q4W
Placebo

Fig. 18

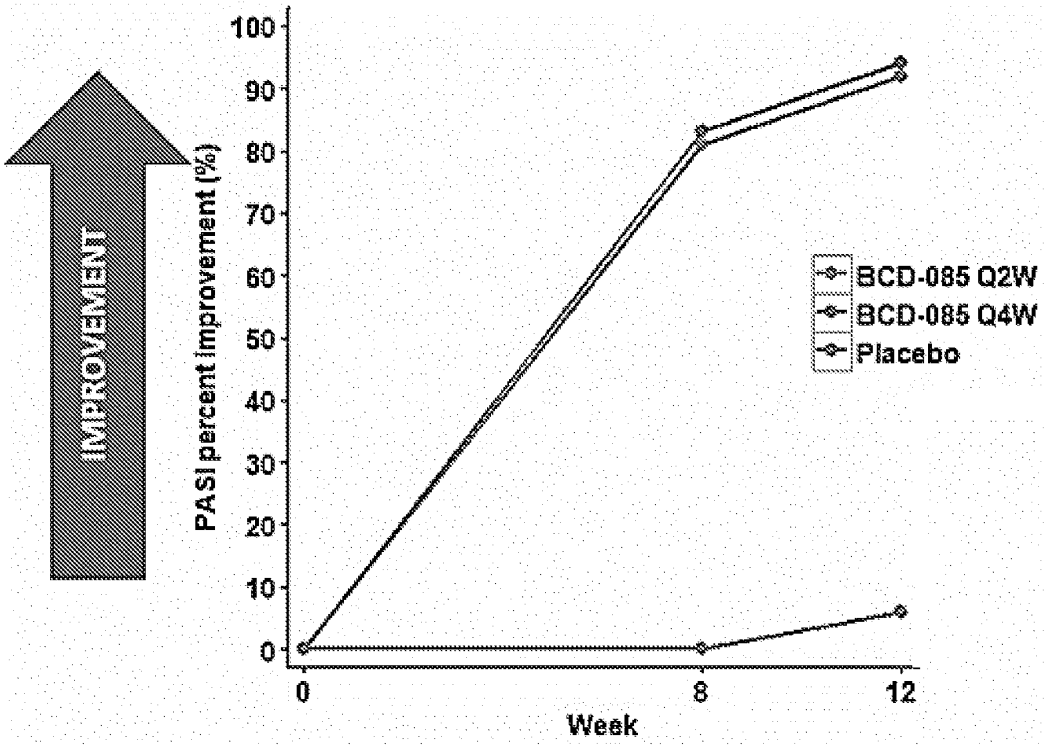

IMPROVEMENT
PASI percent improvement (%)
100
90
80
70
60
50
40
30
20
10
0
0
8
12
Week
BCD-085 Q2W
BCD-085 Q4W
Placebo

Fig.19

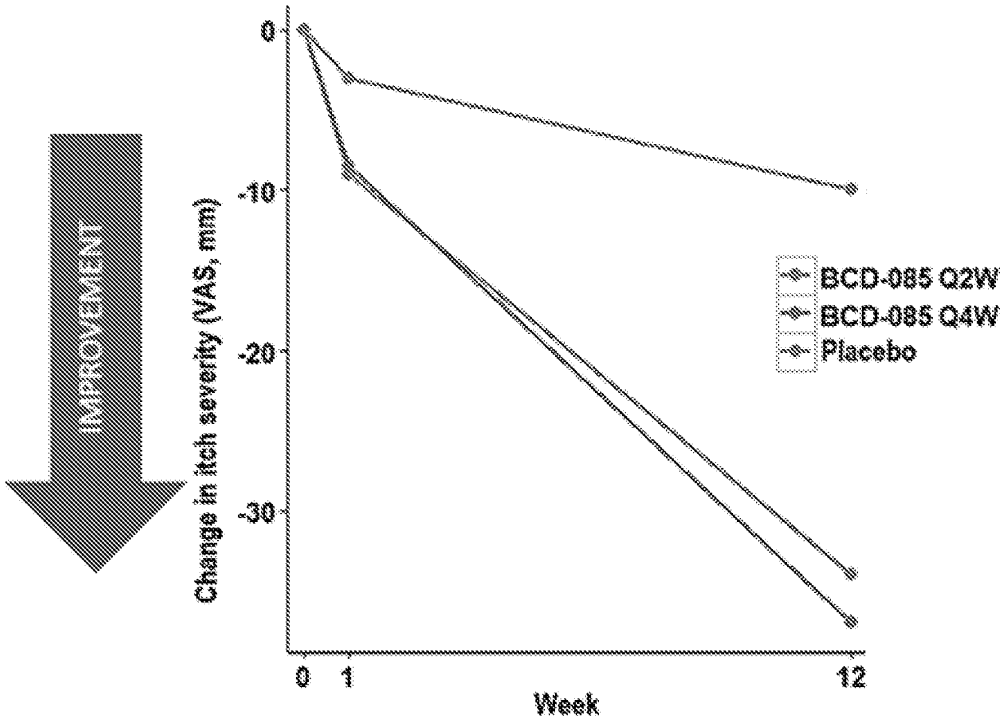

IMPROVEMENT
Change in itch severity (VAS, mm)
0
-10
-20
-30
0
1
12
Week
BCD-085 Q2W
BCD-085 Q4W
Placebo

Fig.20

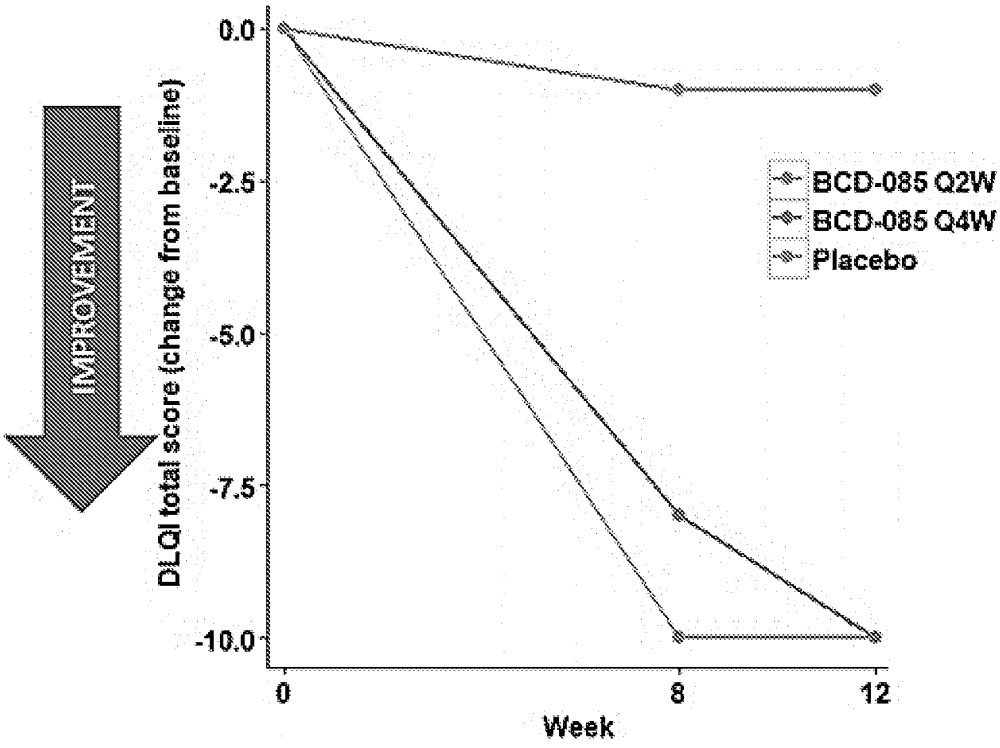

IMPROVEMENT
DLQI total score (change from baseline)
0.0
-2.5
-5.0
-7.5
-10.0
0
8
12
Week
BCD-085 Q2W
BCD-085 Q4W
Placebo

Fig.21

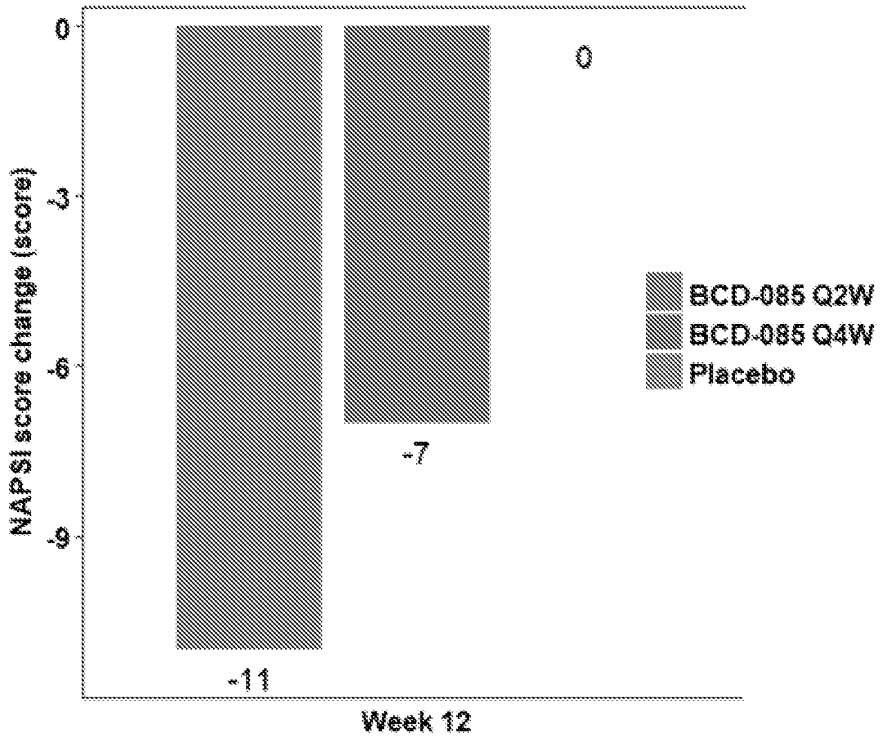

NAPSI score change (score)
0
-3
-6
-9
-11
-7
0
Week 12
BCD-085 Q2W
BCD-085 Q4W
Placebo

Fig. 22

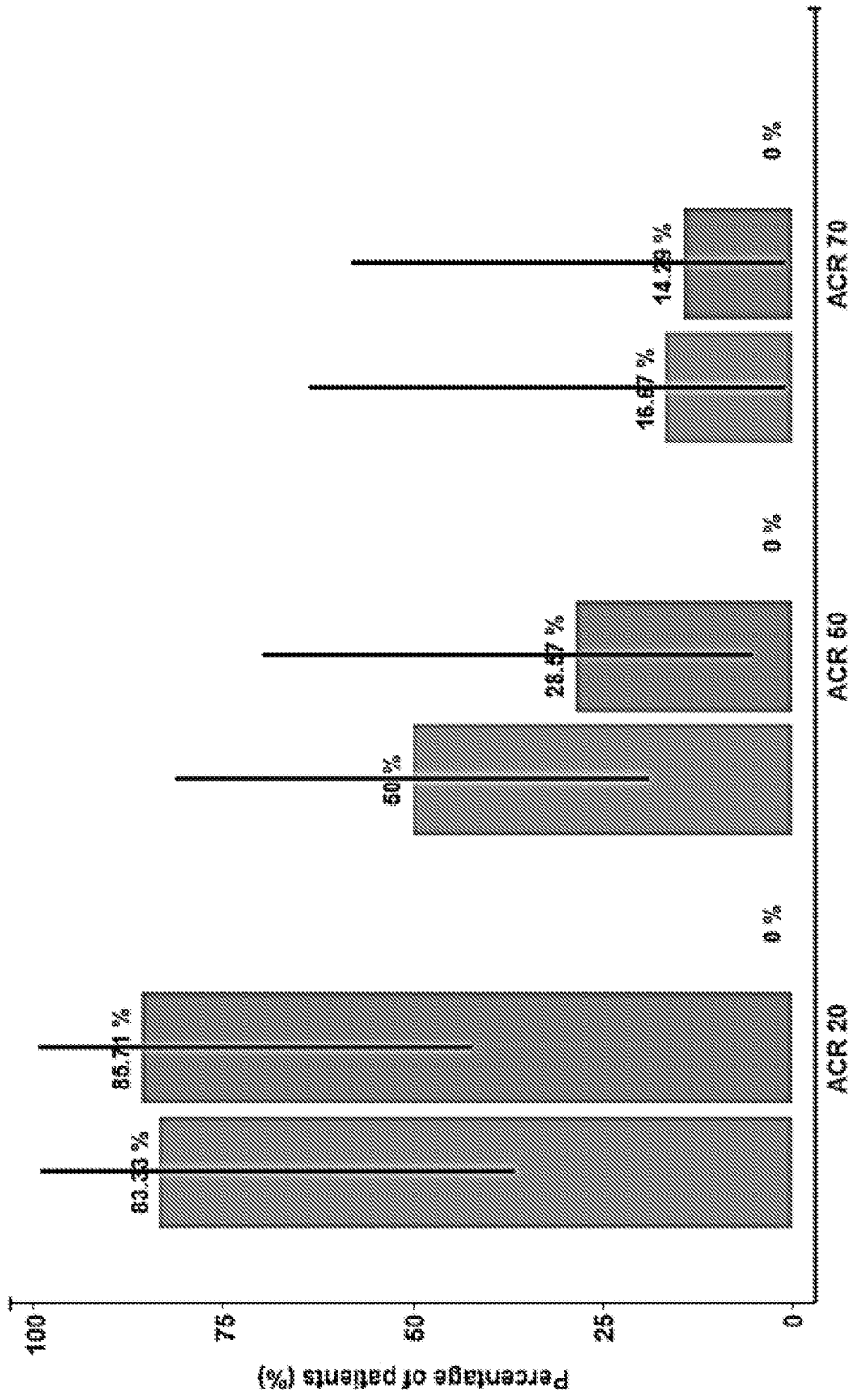

Percentage of patients (%)
100
75
50
25
0
ACR 20
ACR 50
ACR 70
83.33 %
85.71 %
0 %
50 %
28.57 %
0 %
16.67 %
14.29 %
0 %
BCD-085 Q2W
BCD-085 Q4W
Placebo

Fig. 23

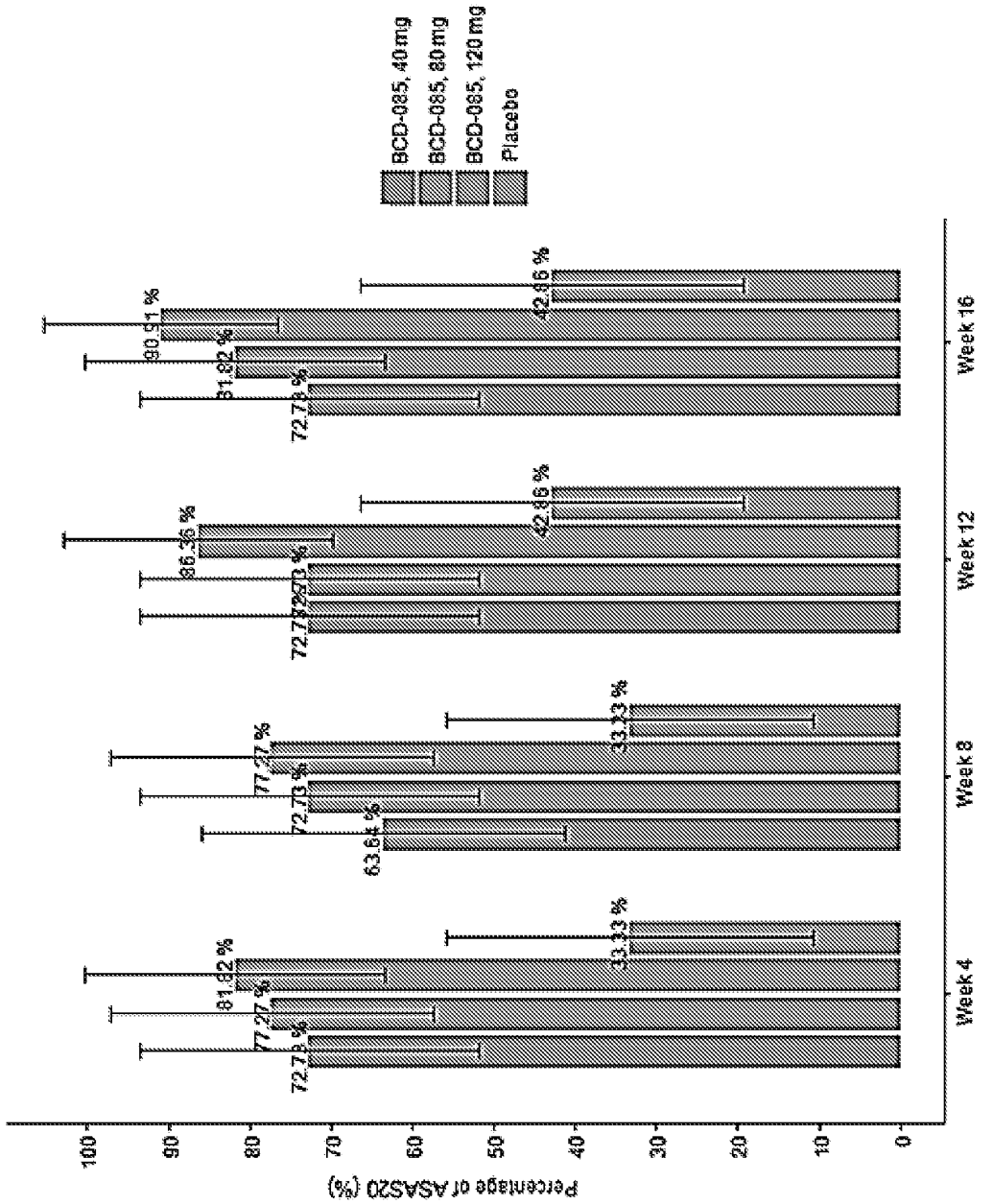

BCD-085, 40 mg
BCD-085, 80 mg
BCD-085, 120 mg
Placebo
Percentage of ASAS20 (%)
100
90
80
70
60
50
40
30
20
10
0
Week 4
Week 8
Week 12
Week 16
72.73 %
77.27 %
81.82 %
90.91 %
63.64 %
72.73 %
77.27 %
33.33 %
72.73 %
86.36 %
42.86 %
72.73 %
81.82 %
90.91 %
42.86 %

Fig. 24

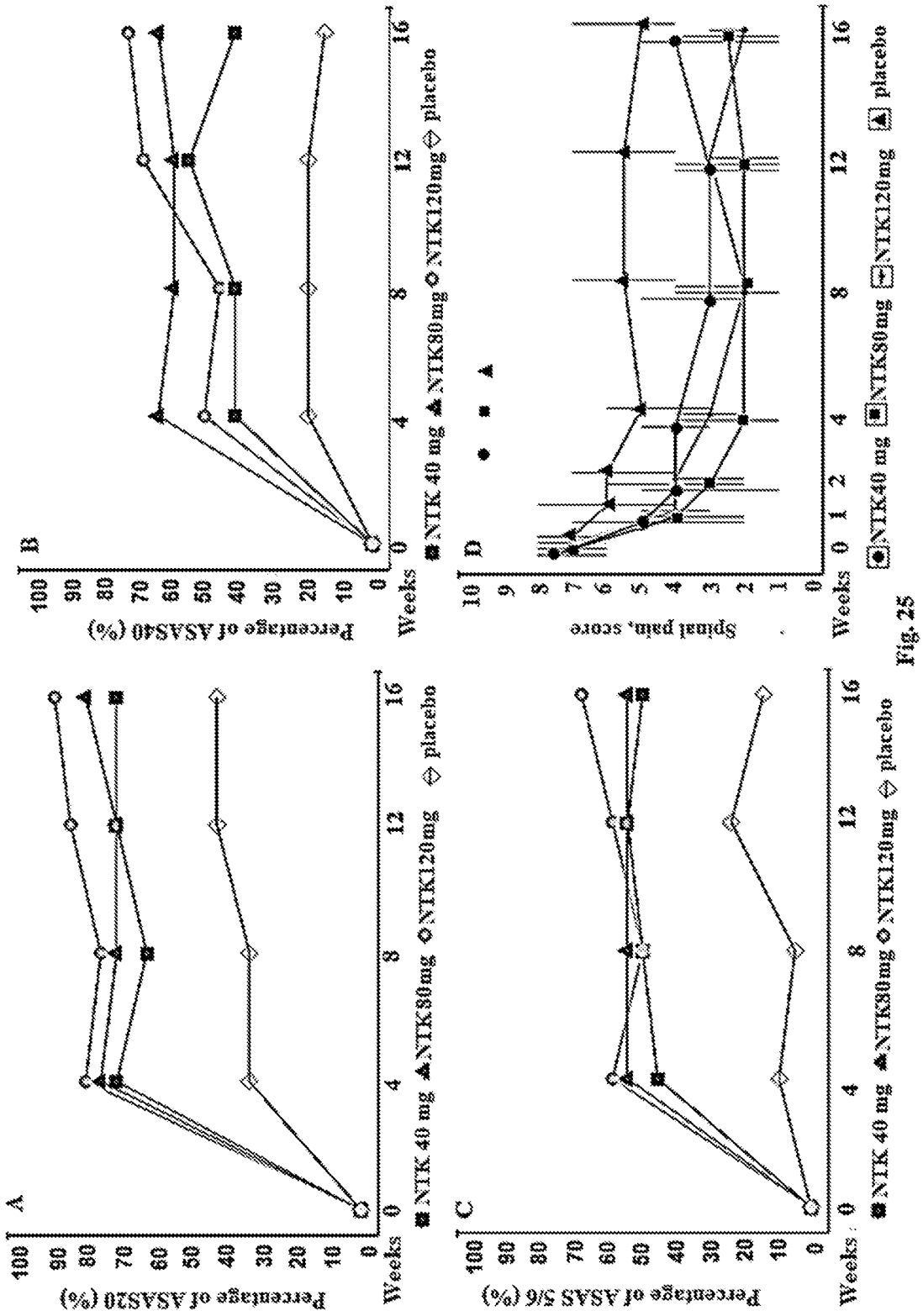

A
Percentage of ASAS20 (%)
Weeks
NTK 40 mg
NTK80mg
NTK120mg
placebo
B
Percentage of ASAS40 (%)
C
Percentage of ASAS 5/6 (%)
D
Spinal pain, score

Fig. 25

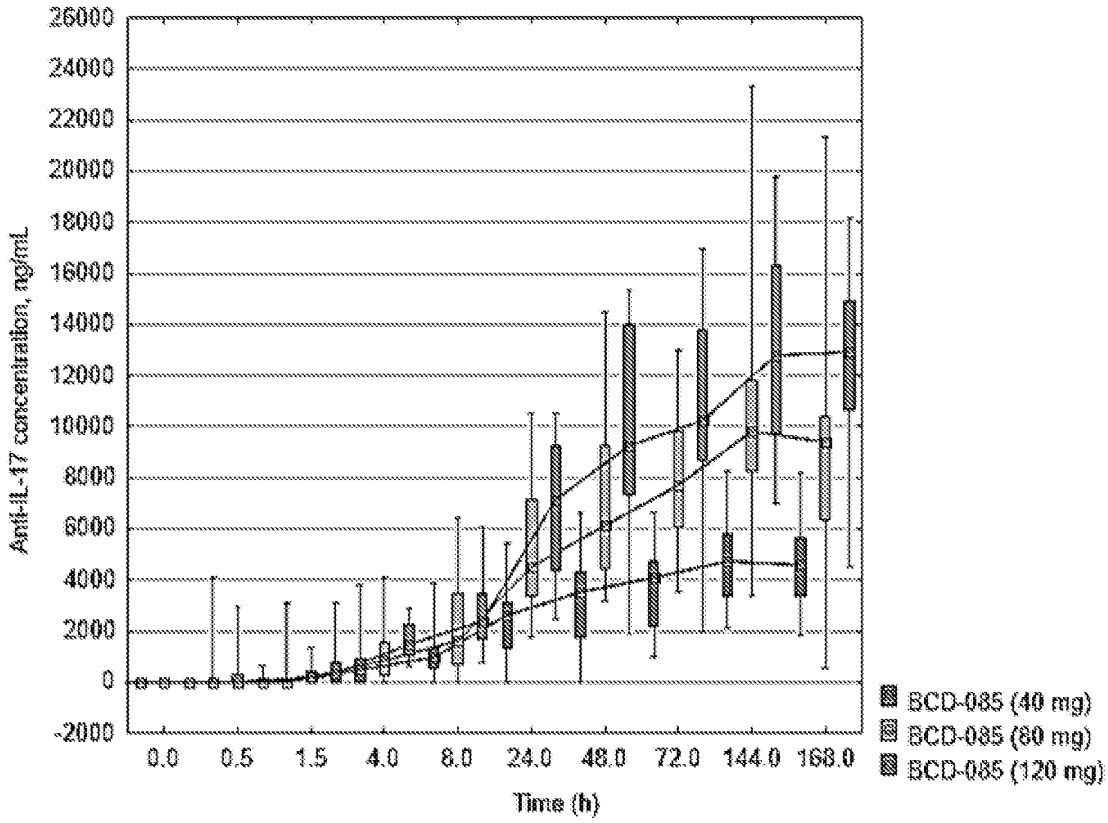

26000
24000
22000
20000
18000
16000
14000
12000
10000
8000
6000
4000
2000
0
-2000
Anti-IL-17 concentration, ng/mL
0.0
0.5
1.5
4.0
8.0
24.0
48.0
72.0
144.0
168.0
Time (h)
BCD-085 (40 mg)
BCD-085 (80 mg)
BCD-085 (120 mg)

Fig. 26

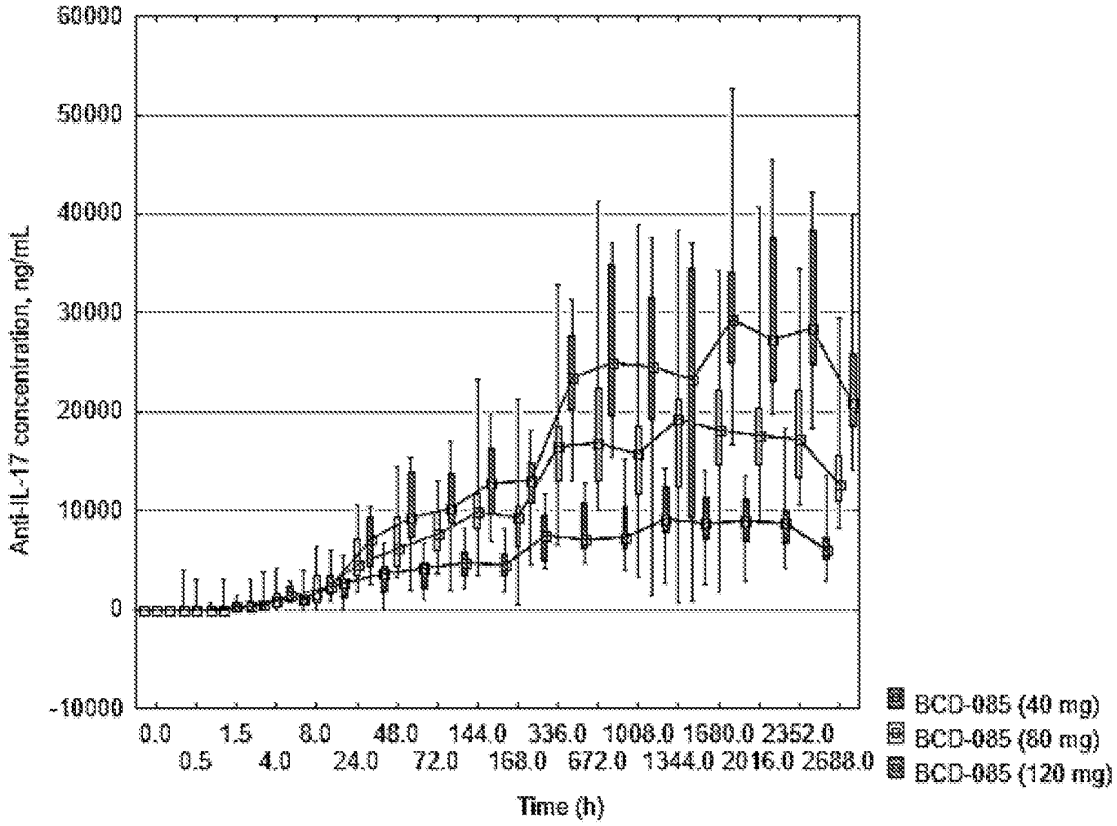

60000
50000
40000
30000
20000
10000
0
-10000
Anti-IL-17 concentration, ng/mL
0.0
0.5
1.5
4.0
8.0
24.0
48.0
72.0
144.0
168.0
336.0
672.0
1008.0
1344.0
1680.0
2016.0
2352.0
2688.0
Time (h)
BCD-085 (40 mg)
BCD-085 (80 mg)
BCD-085 (120 mg)

Fig. 27

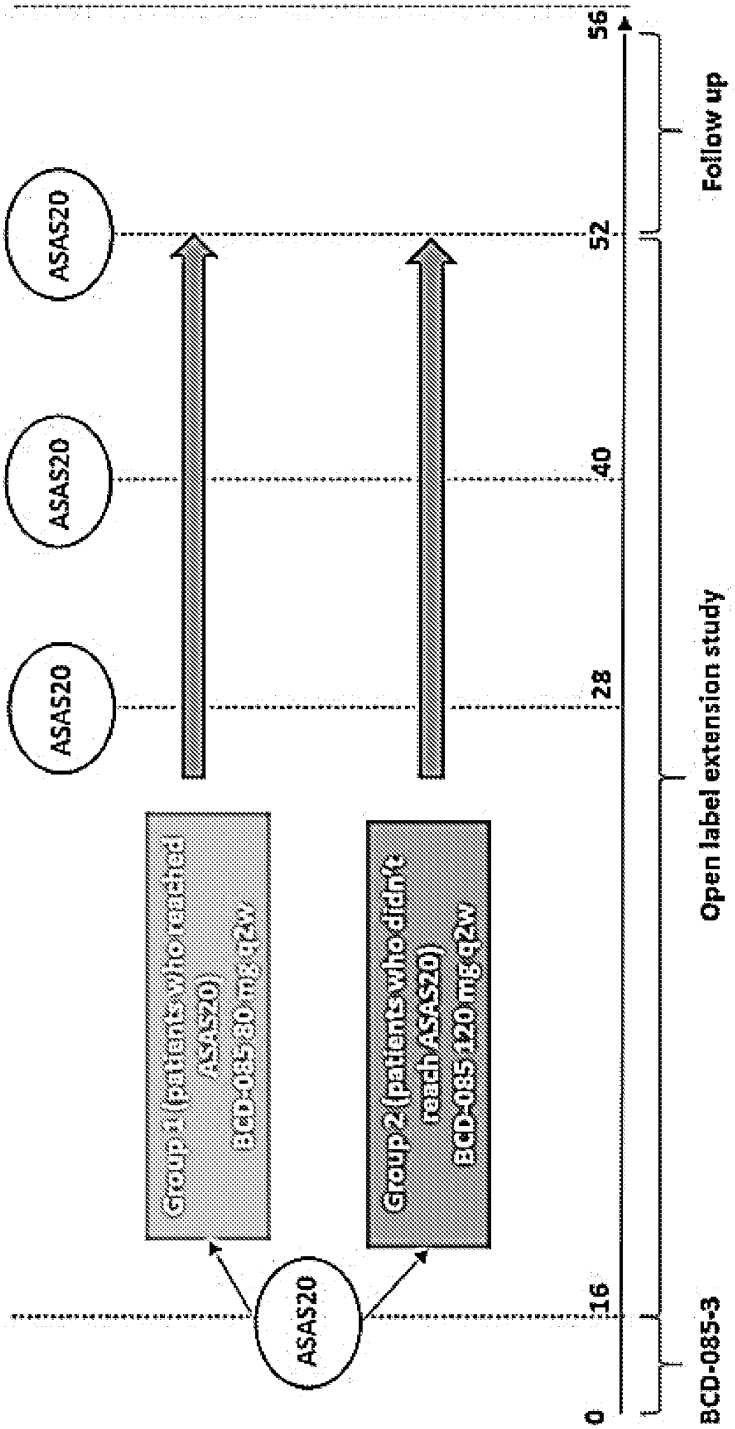

ASAS20
ASAS20
ASAS20
Group1(patients who reached ASAS20)
BCD-085-30 mg q2w
Group2(patients who didn't reach ASAS20)
BCD-085-120 mg q2w
ASAS20
0
16
28
40
52
56
BCD-085-3
Open label extension study
Follow up

Fig. 28

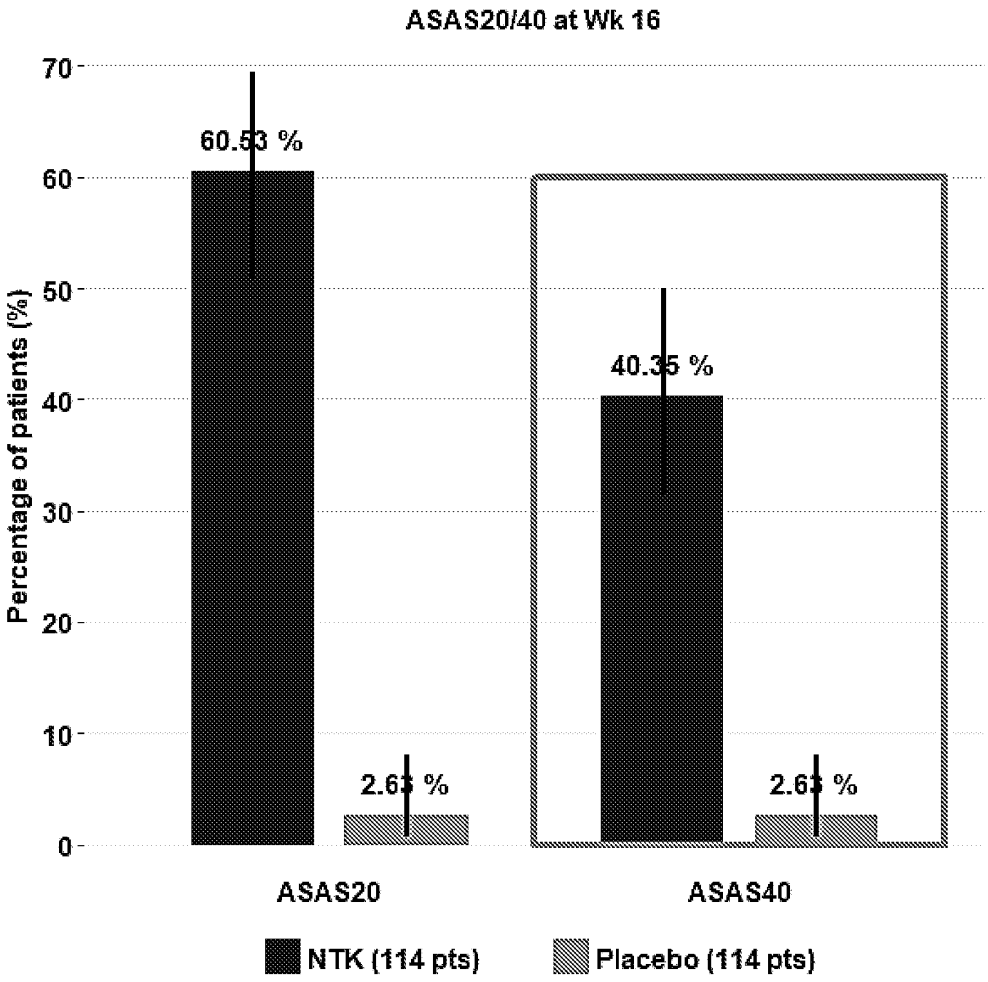

ASAS20/40 at Wk 16
Percentage of patients (%)
70
60
50
40
30
20
10
0
60.53 %
2.63 %
40.35 %
2.63 %
ASAS20
ASAS40
NTK (114 pts)
Placebo (114 pts)

Fig. 29

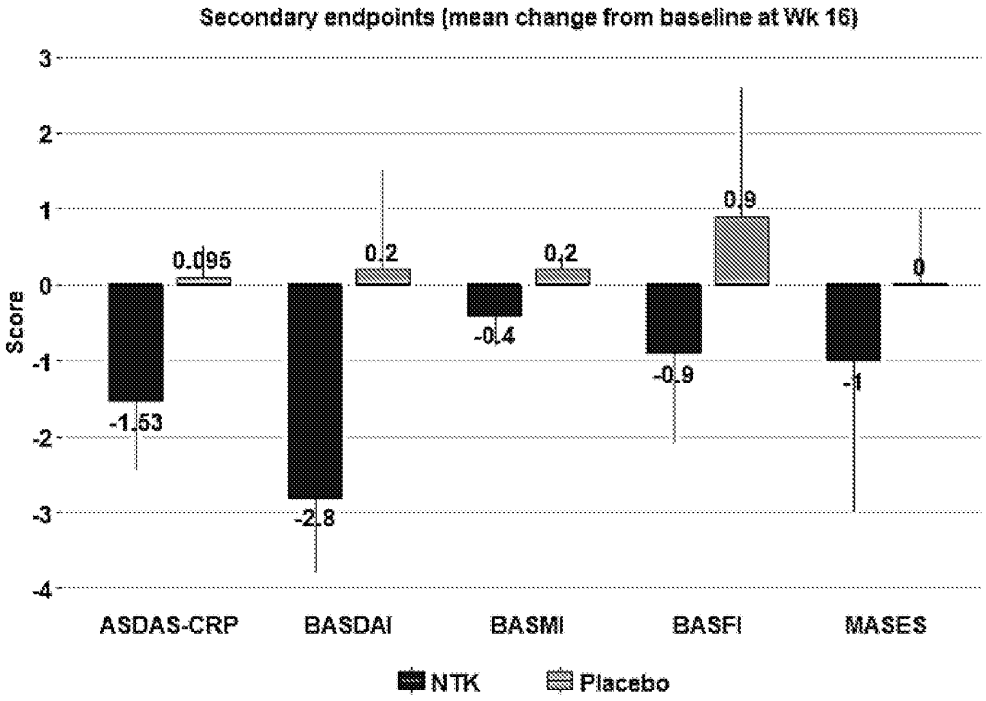

Secondary endpoints (mean change from baseline at Wk 16)
Score
3
2
1
0
-1
-2
-3
-4
-1.53
0.095
-2.8
0.2
-0.4
0.2
-0.9
0.9
-1
0
ASDAS-CRP
BASDAI
BASMI
BASFI
MASES
NTK
Placebo

Fig. 30

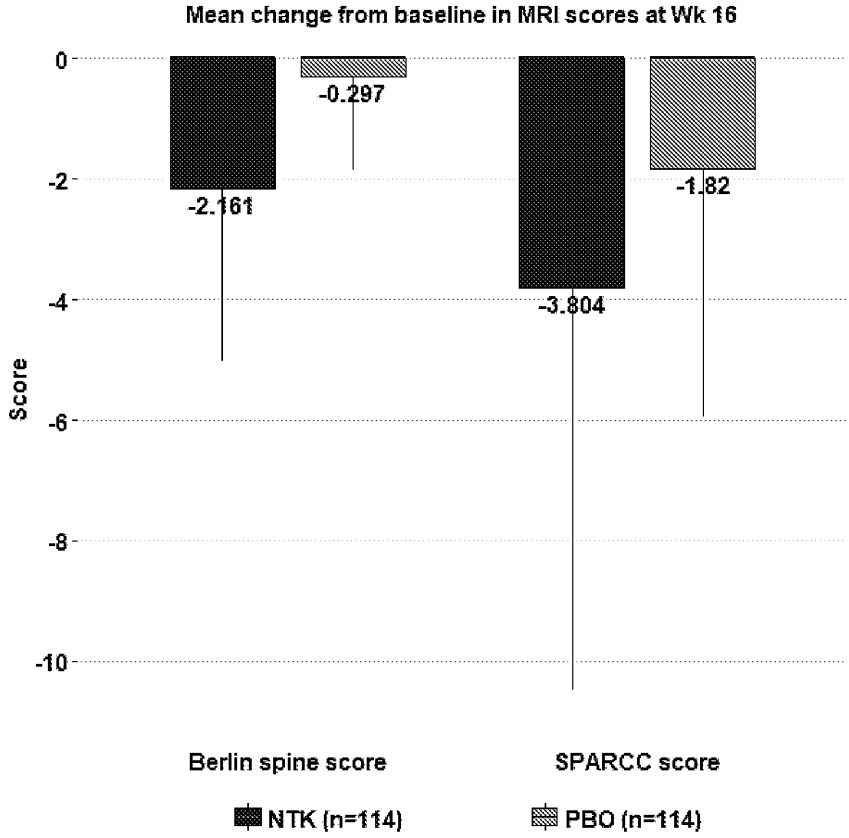

Mean change from baseline in MRI scores at Wk 16
Score
0
-2
-4
-6
-8
-10
-2.161
-0.297
-3.804
-1.82
Berlin spine score
SPARCC score
NTK (n=114)
PBO (n=114)

Fig. 31

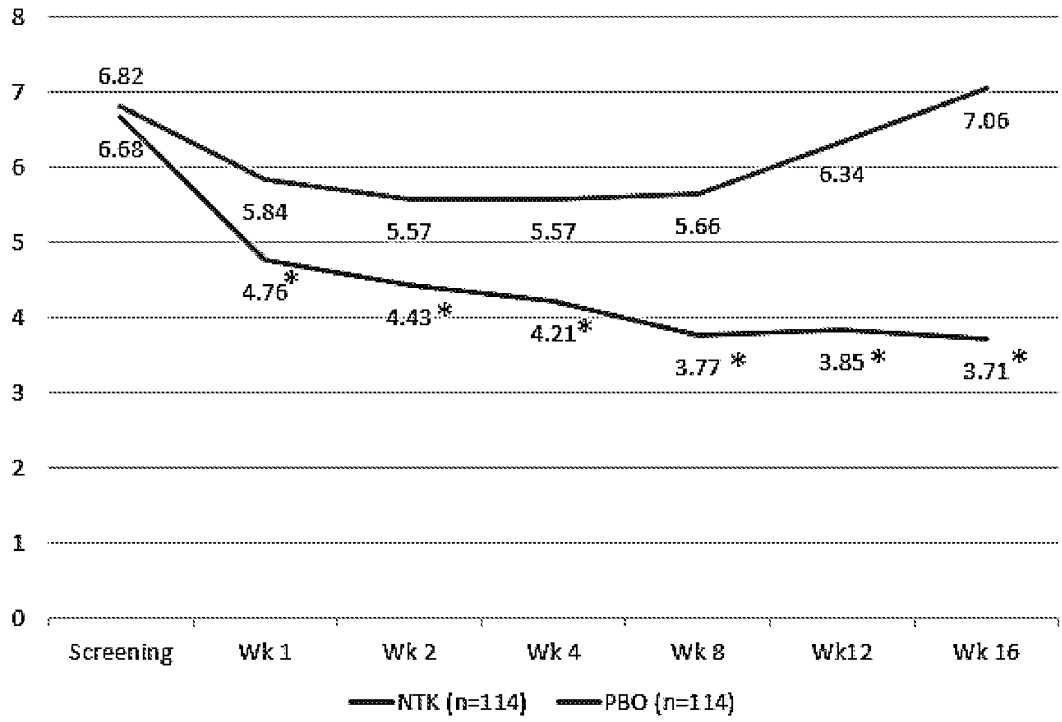

8
7
6
5
4
3
2
1
0
6.82
6.68
5.84
4.76*
5.57
4.43*
5.57
4.21*
5.66
3.77*
6.34
3.85*
7.06
3.71*
Screening
Wk 1
Wk 2
Wk 4
Wk 8
Wk12
Wk 16
NTK (n=114)
PBO (n=114)

Fig. 32

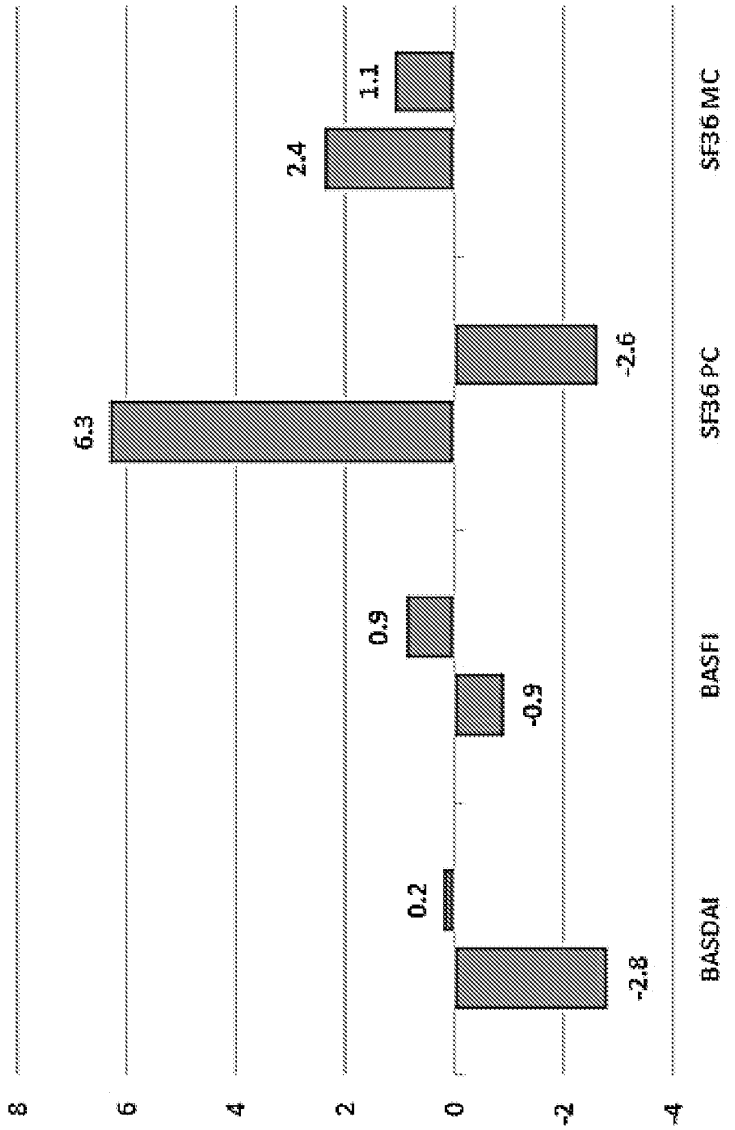

8
6
4
2
0
-2
-4
6.3
2.4
1.1
0.9
0.2
-2.6
-0.9
-2.8
BASDAI
BASFI
SF36 PC
SF36 MC
NTK (n=114)
PBO (n=114)

Fig. 33