

# COLON-RELEASE PARNAPARIN SODIUM TABLETS (CB-01-05 MMX<sup>®</sup>) FOR ACTIVE LEFT-SIDED ULCERATIVE COLITIS. A RANDOMIZED, DOUBLE-BLIND, CONTROLLED STUDY VERSUS PLACEBO IN SUBJECTS TREATED WITH STABLE DOSES OF AMINOSALYCILATES

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## Background & Aims:

Parnaparin sodium as oral colon-release tablets formulated with MMX<sup>®</sup> technology (CB-01-05 MMX<sup>®</sup>) was proposed as a novel and safe treatment for ulcerative colitis (UC).

## Methods:

**Design:** randomized multicenter, double blind, controlled, add-on study.

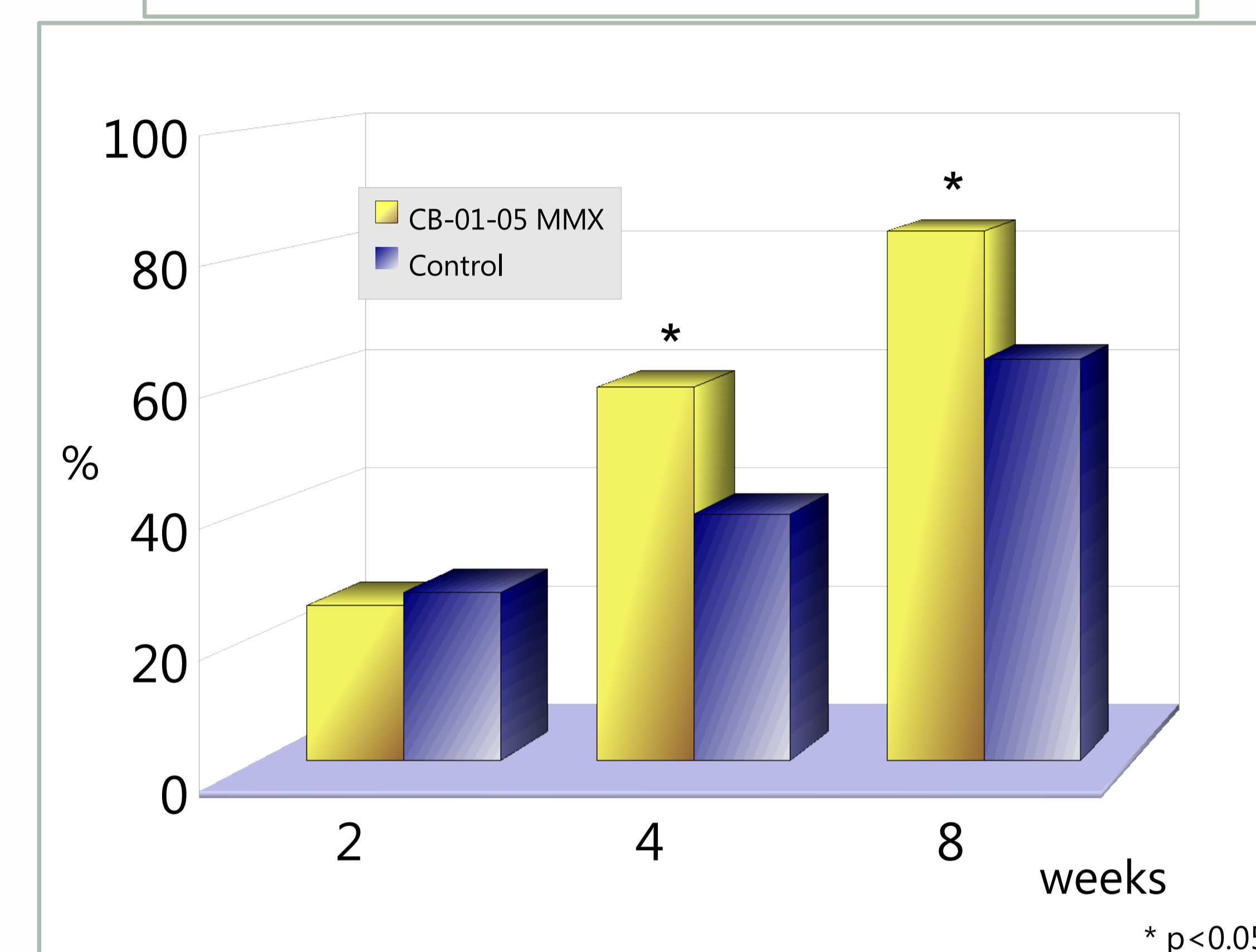
Efficacy of CB-01-05 MMX<sup>®</sup> 210 mg tablets was compared to placebo, in 141 subjects with mild to moderately active left-sided UC treated with stable doses of aminosallylates. Efficacy was assessed by clinical activity index (CAI), disease activity index (DAI), endoscopic index (EI) and histological score (HS). Primary end-point was the percentage of subjects in clinical remission (CAI < 4) at 8 weeks. Secondary end-points were percentages of subjects with CAI remission at 2-4 weeks, CAI improvement at 2-4-8 weeks, DAI improvement at 8 weeks, EI improvement and healing at 8 weeks, and HS improvement at 8 weeks.

## Results:

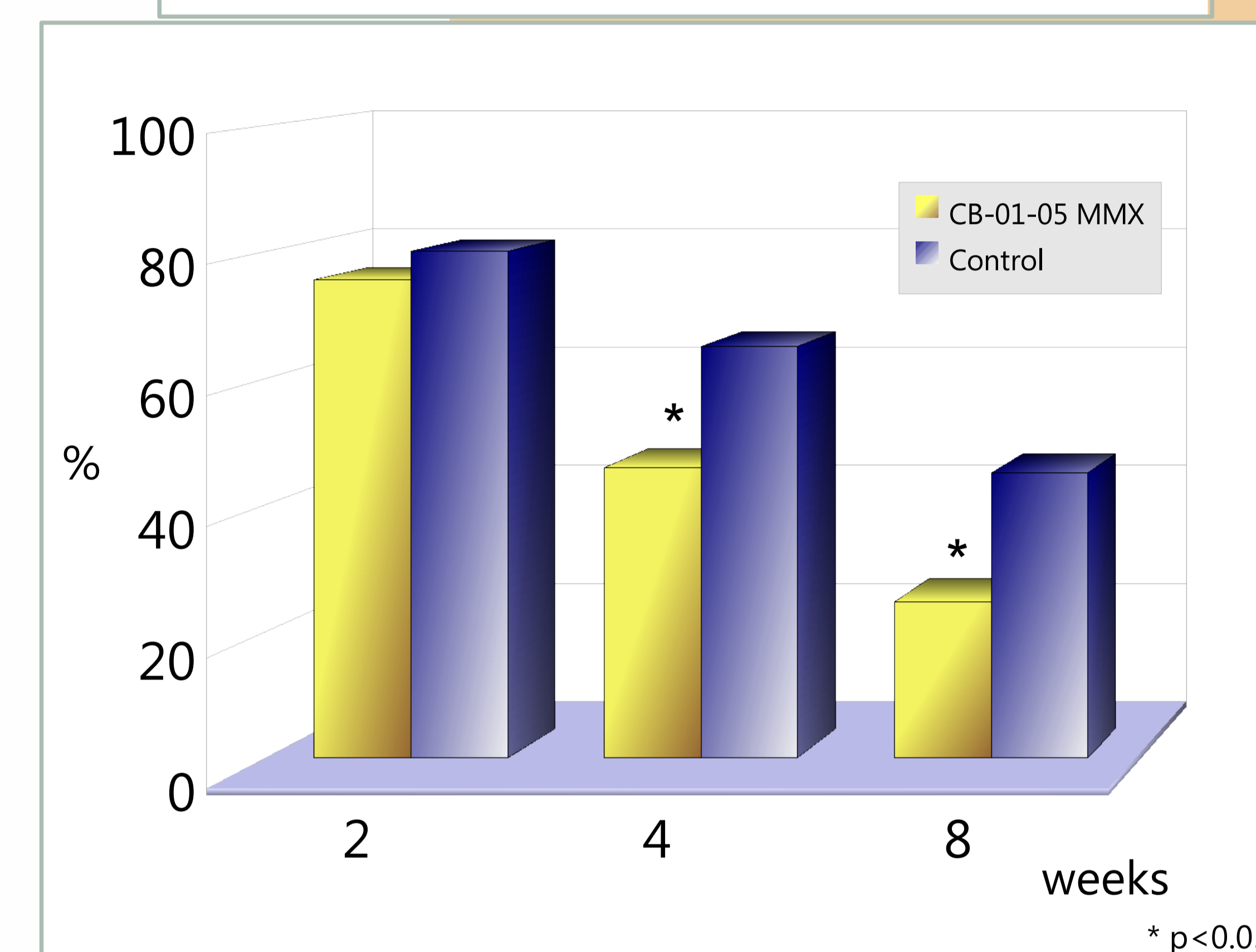
**Efficacy:** 61 subjects in CB-01-05 MMX<sup>®</sup> group and 60 in placebo group formed the per protocol (PP) population. Primary end-point was achieved after 8 weeks in 83.6% of subjects of CB-01-05 MMX<sup>®</sup> group vs. 63.3% in placebo group (P=.011). A similar significant difference was obtained after 4 weeks (59.0% vs. 38.9%, P=.028). Both CAI and DAI improved at 8 weeks in 91.8% of subjects receiving CB-01-05 MMX<sup>®</sup> (P=.012 and P=.022 respectively, compared to placebo). Significant differences between groups were also detected in rectal bleeding disappearance, after 4 (P=.034) and 8 (P=.018) weeks, in a higher proportion of subjects receiving CB-01-05 MMX<sup>®</sup>. Although no significant difference between groups was detected in EI improvement and healing, mucosal vulnerability recovered in a significantly higher proportion of subjects receiving CB-01-05 MMX<sup>®</sup> (80.3% vs. 56.7%, P=.005). HS improved in 51.7% of subjects receiving CB-01-05 MMX<sup>®</sup> vs. 50.0% placebo (P=.855). HS < 2 in patients with basal score ≥ 2 was observed in 42.5% in CB-01-05 MMX<sup>®</sup> group vs. 26.0% in placebo group (P=.085).

**Safety:** no serious adverse events occurred. CB-01-05 MMX<sup>®</sup> did not affect haemocoagulative parameters, nor induced laboratory abnormalities of clinical importance.

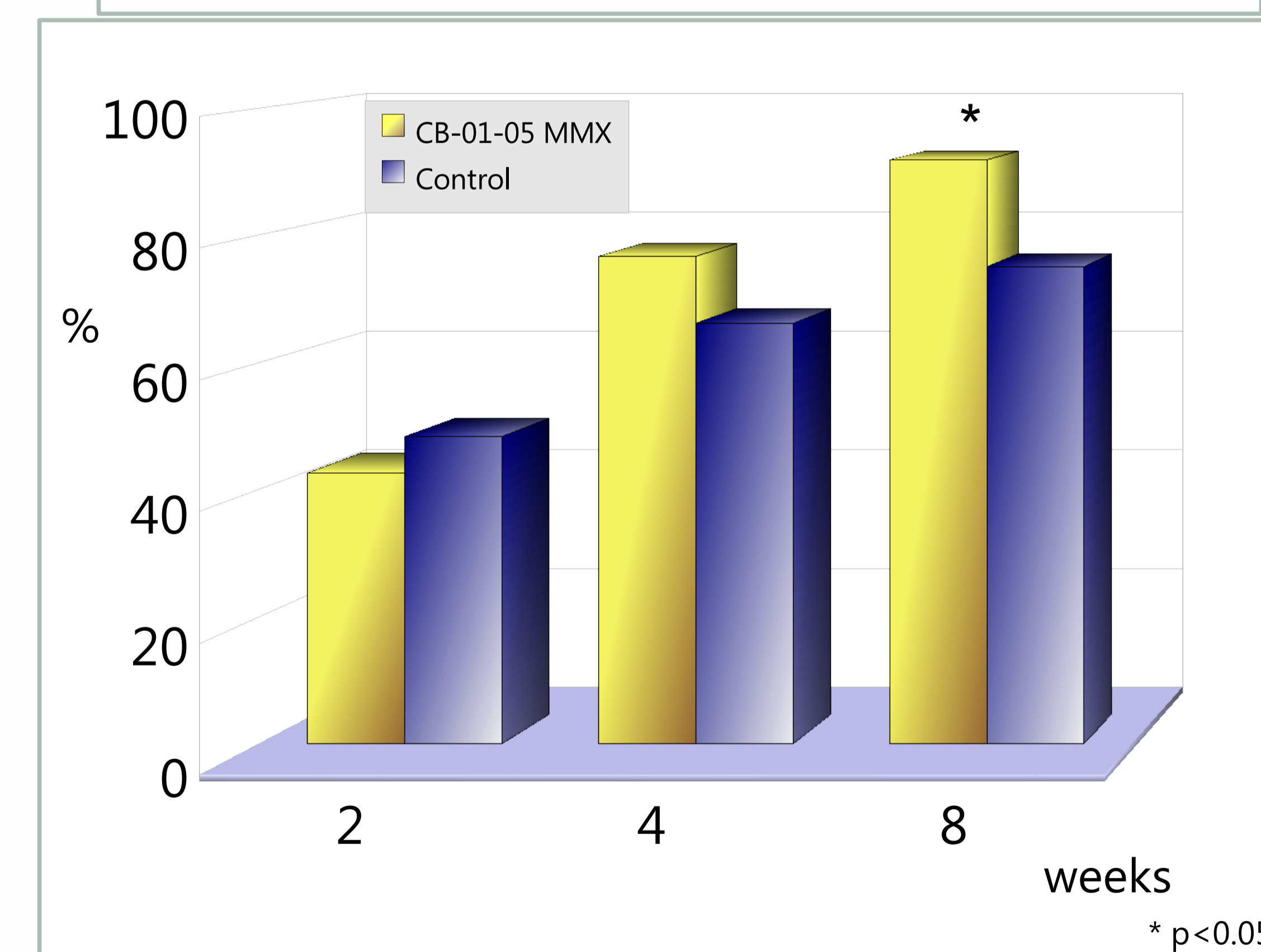
Percentage of subjects in clinical remission



Percentage of subjects with rectal bleeding



Percentage of subjects with clinical improvement



Other parameters after 8 weeks of treatment

Parameter	CB-01-05 MMX <sup>®</sup> (%)	Comparator (%)	P value
DAI improvement (≥2)	91.8	76.7	<b>0.022</b>
EI improvement (≥1)	88.5	76.7	0.085
Absent mucosal vulnerability	80.3	56.7	<b>0.005</b>
HS <2 (basal ≥ 2)	42.5	26.0	0.085

## Conclusions:

CB-01-05 MMX<sup>®</sup>, administered together with aminosallylates, was safe, significantly more effective and fast-acting than aminosallylates plus placebo in subjects with mild to moderate left-sided UC.