## Phase 3/5ASA/UC/ Maintain

Mesalazine in left-sided UC: Efficacy analyses from the PODIUM trial on maintenance of remission and mucosal healing

Randomised, double-controlled, investigator blinded trial. Left side UC patients were randomised to:

Once daily (OD) to a twice daily (BD) dosing regimen of a slow-release mesalazine (Pentasa®).

<u>Primary endpoint</u> of non-inferiority for 2 gr OD versus 1 gr BD dosing in terms of remission (UC-DAI score <2).

<u>Secondary endpoints:</u> endoscopic evaluation, time to relapse, severity of relapse, rectal bleeding & stool frequency, acceptability & compliance.

## **Results:**

- Mucosal healing w52: 84.4% once daily vs 78.8%twice daily.
- OD superior than BD with an 11.9% difference in remission rate (95% CI: 1.4-22.5).
- Kaplan-Meir demonstrated that 70.9% of the OD treatment and 58.9% of the BD group remained in remission at 12 months; p=0.02
- No differences in compliance.

## **Conclusions:**

Once daily slow-release mesalazine is similarly effective to the standard twice daily schedule in patients with left-sided ulcerative colitis for the maintenance of remission in mild-to-moderate disease. Once daily oral mesalazine superior to twice daily in terms of long time remission and mucosal healing.

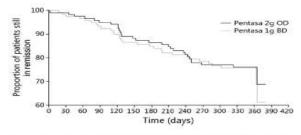


Figure 1 Kaplan-Meier estimated UC-DAI remission rates in patients with left-sided UC, where remission is defined as a UC-DAI total score < 2.

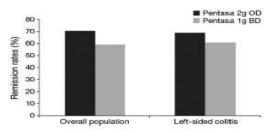


Figure 2 Twelve-month clinical and endoscopic remission rates for patients in the overall population and in the left-sided colitis subgroup.

