A PHASE 2A STUDY TO EVALUATE SAFETY, PHARMACOKINETICS AND CLINICAL EFFICACY OF ORAL TREATMENT WITH MBF-118 IN PATIENTS WITH FIBROSTENOSING CROHN'S DISEASE

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MBF-118, an oral PPARγ partial agonist, was well tolerated in a 10-patient phase 2a open-label trial in fibrostenosing Crohn's disease, with no serious or treatment-related adverse events and signals of symptom improvement.

KEY POINTS

- Ten patients with imaging-confirmed stenotic CD on stable biologic therapy and in clinical remission (CDAI mean 32±23) received MBF-118 100 mg or 200 mg daily for 28 days, with some continuing to 90 days.
- No serious adverse events or treatment-related AEs leading to discontinuation were reported during observation periods up to 132 days; almost all AEs were mild (grade 1) and none were deemed drug-related.
- Pharmacokinetic analysis confirmed therapeutically relevant MBF-118 levels in colonic and ileal biopsy tissue, and plasma adiponectin increases confirmed pharmacodynamic effect at both doses.
- Improvement in abdominal pain and stool frequency (PRO-2) was observed in 50% of patients and in abdominal pain score (NRS-11) in 40% of patients.
- By imaging, 3 patients showed reduction in pre-stenotic dilation, 3 showed increased lumen diameter, and 2 showed reduced stenotic length; other clinical measures remained stable.
- All patients were on stable biologics (anti-TNFα, anti-integrin, or anti-IL-12/23) at enrollment, and 60% had prior surgical resection for CD.

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