2021.OASIS-OLE

OLE/ Etrasimod/UC/ Efficacy/Safety

Long-term Safety and Efficacy of Etrasimod for Ulcerative Colitis: Results from the Open-label Extension of the OASIS Study

After completing OASIS (12weeks), patients could enroll in the open label extension and receive etrasimod 2 mg for up to week 52

Primary endpoint : long-term safety and tolerability of etrasimod.
Key efficacy endpoints included the proportion of patients with clinical response, clinical remission, or endoscopic improvement at w52, or sustained from Week 12 to w52

Results:
- Adverse events in 60% of patients mostly anemia or UC worsening.
- At the end of study, 64% clinical response, 33% clinical remission and 43% endoscopic improvement,

Conclusions:
In this long-term extension study, etrasimod 2 mg demonstrated a favourable safety profile. Most patients with clinical response, clinical remission, or endoscopic improvement at Week 12 maintained that status to end of treatment

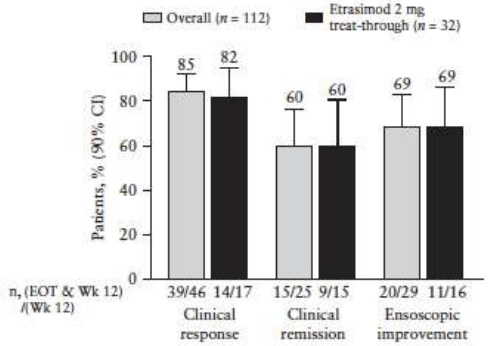

Figure 4. Proportion of patients with sustained response from Week 12 to EOT (ITT population). All patients received etrasimod 2 mg during the OLE. The overall group includes patients who received any treatment (placebo, etrasimod 1 mg, or etrasimod 2 mg) during the DB study. The etrasimod 2 mg treat-through group received etrasimod 2 mg during both the DB study and OLE. In these NRI analyses, data missing for any reason were imputed as non-response. CI, confidence interval; DB, double-blind; EOT, end of treatment; ITT, intention-to-treat; *n*, number of patients; NRI, non-responder imputation; OLE, open-label extension; Wk, week.

Table 2. Summary of treatment-emergent adverse events (safety population).*

Treatment in OLE:	Etrasimod 2 mg				Placebo
Treatment in DB study:	Placebo (*n* = 42)	Etrasimod 1 mg (*n* = 38)	Etrasimod 2 mg (*n* = 32)	Overall (*n* = 112)	Total (*n* = 6)†
Patients with ≥ 1 TEAE, *n* [%]	25 [59.5]	25 [65.8]	17 [53.1]	67 [59.8]	5 [83.3]
Number of TEAEs	111	85	56	252	22
Number of TEAEs, excluding TEAE of worsening UC‡	105	77	47	229	21
Patients with TEAEs leading to death, *n*	0	0	0	0	0
Patients with TEAEs leading to study discontinuation, *n* [%]	4 [9.5]	2 [5.3]	4 [12.5]	10 [8.9]	1 [16.7]
Ulcerative colitis—worsening§	2 [4.8]	2 [5.3]	4 [12.5]	8 [7.1]	1 [16.7]
Atrial fibrillation	1 [2.4]	0	0	1 [0.9]	0
Headache	1 [2.4]	0	0	1 [0.9]	0
Patients with serious TEAEs, *n* [%] [no. of events]¶	4 [9.5] [11]	0	3 [9.4]	7 [6.3] [14]	0
Gastrointestinal disorders	2 [4.8] [5]	0	1 [3.1]	3 [2.7] [6]	0
Ulcerative colitis—worsening§	2 [4.8]	0	1 [3.1]	3 [2.7]	0
Pancreatitis	1 [2.4]	0	0	1 [0.9]	0
Large intestine perforation	1 [2.4]	0	0	1 [0.9]	0
Blood and lymphatic system disorders	0	0	2 [6.3]	2 [1.8]	0
Iron-deficiency anaemia	0	0	2 [6.3]	2 [1.8]	0
Infections and infestations	1 [2.4] [2]	0	0	1 [0.9] [2]	0
Gastroenteritis	1 [2.4] [2]	0	0	1 [0.9] [2]	0
Renal and urinary disorders	1 [2.4]	0	0	1 [0.9]	0
Cystitis, haemorrhagic	1 [2.4]	0	0	1 [0.9]	0
Nervous system disorders	2 [4.8]	0	0	2 [1.8]	0
Fine motor skill dysfunction	1 [2.4]	0	0	1 [0.9]	0
Transient ischaemic attack	1 [2.4]	0	0	1 [0.9]	0
Cardiac disorders	1 [2.4]	0	0	1 [0.9]	0
Atrial fibrillation	1 [2.4]	0	0	1 [0.9]	0
Severity [all TEAEs], *n* [%] [no. of events]#¶					
Grade 1—mild	18 [42.9] [44]	17 [44.7] [46]	10 [31.3] [19]	45 [40.2] [109]	4 [66.7] [9]
Grade 2—moderate	20 [47.6] [59]	23 [60.5] [38]	12 [37.5] [32]	55 [49.1] [129]	5 [83.3] [13]
Grade 3—severe	5 [11.9] [8]	1 [2.6]	5 [15.6]	11 [9.8] [14]	0
Grade 4—life-threatening	0	0	0	0	0
Grade 5—death related to TEAE	0	0	0	0	0
Severity [treatment-related TEAEs], *n* [%] [no. of events]#¶					
Grade 1—mild	6 [14.3] [9]	3 [7.9]	1 [3.1] [2]	10 [8.9] [14]	0
Grade 2—moderate	8 [19.0] [12]	1 [2.6]	2 [6.3]	11 [9.8] [15]	1 [16.7]
Grade 3—severe	0	0	1 [3.1]	1 [0.9]	0
Grade 4—life-threatening	0	0	0	0	0
Grade 5—death related to TEAE	0	0	0	0	0
TEAE relation to study drug, *n* [%] [no. of events]#¶					
Not related	24 [57.1] [90]	25 [65.8] [81]	17 [53.1] [51]	66 [58.9] [222]	5 [83.3] [21]
Related	9 [21.4] [21]	3 [7.9] [4]	4 [12.5] [5]	16 [14.3] [30]	1 [16.7]
Treatment-related TEAEs of special					

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