Supplementary Data

Supplementary Table 1. Adverse events in patients with UC on placebo or ozanimod 0.92 mg in the phase 2 TOUCHSTONE study[1]

Event	Placebo (n = 65)	Ozanimod 0.92 mg (n = 67)
Any AE, n (%)	26 (40)	26 (39)
Serious AE, n (%)	6 (9)	3 (4)
AE leading to discontinuation, n (%)	4 (6)	1 (1)
AEs occurring in ≥2 patients receiving ozanimod, n (%)		
Ulcerative colitis flare	5 (8)	3 (4)
Increased ALT	0	3 (4)
Pyrexia	0	3 (4)
Nausea	2 (3)	2 (3)
Arthralgia	1 (2)	2 (3)
Rash	0	2 (3)
Headache	3 (5)	2 (3)
Vomiting	0	2 (3)
Abdominal pain	1 (2)	1 (1)
Back pain	1 (2)	1 (1)
Increased AST	0	1 (1)
Hyperbilirubinemia	0	1 (1)
Insomnia	0	1 (1)
Proctalgia	0	1 (1)
Anemia	4 (6)	0
Orthostatic hypotension	0	0
Nasopharyngitis	0	0

Adapted with permission from Sandborn WJ et al. *N Engl J Med*. 2016;374:1754-1762.[1]

Abbreviations: AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; UC, ulcerative colitis.

Supplementary Table 2. Pregnancies among patients with UC and MS in ozanimod clinical trials[2,3]

	UC	MS[a]
Pregnancies, n	9	47[b]
Live birth without congenital anomaly	2	24[b]
Live birth with congenital anomaly	0	1[c]
Premature live birth	0	3
Ongoing	2	2
Spontaneous early loss	2	7[b]
Elective termination[d]	3	9
No information	0	2

[a]Pregnancy numbers are higher for MS compared with UC due to a different patient population profile and longer study duration. [b]A total of 48 MS births resulted from 47 pregnancies because a twin pregnancy led to 1 live birth and 1 early loss. [c]Duplex kidney. [d]First trimester; none were due to known congenital anomaly.

Abbreviations: MS, multiple sclerosis; UC, ulcerative colitis.

Supplementary Table 3. Guidance on switching from other UC therapies to ozanimod

Current treatment	Event leading to treatment switch	Reason to switch to ozanimod
Any UC therapy	Loss of response	Ozanimod may be efficacious given its novel mechanism of action
	MS diagnosis	Ozanimod is also indicated for relapsing forms of MS
Anti-TNFs	Anti-TNF–induced lupoid reaction or anti-TNF–induced palmoplantar pustulosis[4-6]	Lupoid reaction and palmoplantar pustulosis not reported with non–anti-TNF drugs
Anti-TNFs, vedolizumab, or ustekinumab	Infusion/injection-related adverse reaction[4-8] or patient aversion to needles	Ozanimod is administered orally
JAK inhibitors	Risk of adverse events based on the boxed warning for serious infections, mortality, malignancy, MACE, and thrombosis[9,10]	Ozanimod's favorable safety profile with no boxed warnings

Abbreviations: JAK, Janus kinase; MACE, major adverse cardiovascular events; MS, multiple sclerosis; TNF, tumor necrosis factor; UC, ulcerative colitis.

References

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