Table A4. Summary of TEAEs Reported During the OLE

Category	OLE* (n = 115)	
	No.	%
Any TEAE	105	91.3
Any serious TEAE†	36	31.3
Study discontinuation as a result of TEAE‡	14	12.2
TEAE resulting in death§	8	7.0
Selected key AEs		
Any depression-related AE¶	17	15.0
Nausea	23	20.0
Increased gamma-glutamyl transferase	7	6.1
Increased alanine aminotransferase	4	3.5
Increased alkaline phosphatase	5	4.3

Abbreviations: AE, adverse event; OLE, open-label extension; TEAE, treatment-emergent adverse event.

*Patients were initiated at 500 mg telotristat ethyl three times per day. Mean treatment exposure was 11.3 weeks in the double-blind treatment period and 26.7 weeks in the OLE.

†AEs were considered serious if they involved death, a life-threatening AE, inpatient hospitalization, a persistent or significant incapacity, substantial disruption in the ability to conduct normal life function, or a congenital anomaly or birth defect.

‡TEAEs leading to study discontinuation in the OLE were supraventricular tachycardia, disease progression (five patients), abdominal distension, constipation, GI hemorrhage, hematemesis, large intestine perforation, asthenia, fatigue, general physical health deterioration, hepatomegaly, peritonitis, sepsis, increased liver enzymes, decreased weight, decreased appetite, dehydration, mental confusion, cognitive disorder, renal failure, and urticaria.

§None of the deaths occurring during the OLE were considered related to study drug. The deaths were generally attributable to the progression or complication of the underlying disease.

¶Depression-related AEs include depression, depressed mood, and decreased interest.

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