Supplementary Table 1. Baseline demographics of patients enrolled in the treatment phase

Parameter	OTX-101 0.09% N = 371	Vehicle N = 373	Overall N = 744
Age			
Mean (SD)	58.4 (14.101)	59.5 (14.687)	59.0 (14.0)
min, max	18, 89	20, 90	18, 90
Sex, n (%)			
Female	315 (84.9)	311 (83.4)	626 (84.1)
Male	56 (15.1)	62 (16.6)	118 (15.9)
Race, n (%)			
White	310 (83.6)	305 (81.8)	615 (82.7)
Black	41 (11.1)	45 (12.1)	86 (11.6)
Asian	11 (3.0)	12 (3.2)	23 (3.1)
Other	9 (2.4)	11 (3.0)	20 (2.7)
Ethnicity, n (%)			
Not Hispanic/Latino	314 (84.6)	319 (85.5)	633 (85.1)
Hispanic/Latino	57 (15.4)	54 (14.5)	111 (14.9)

Notes: Intent-to-treat population. Reprinted from *Ophthalmology*. 126(9), Goldberg DF, Malhotra RP, Schechter BA, Justice A, Weiss SL, Sheppard JD. A Phase 3, Randomized, Double-Masked Study of OTX-101 Ophthalmic Solution 0.09% in the Treatment of Dry Eye Disease. 1230-1237, Copyright (2019), with permission from Elsevier.[1]

Abbreviations: max, maximum; min, minimum; SD, standard deviation.

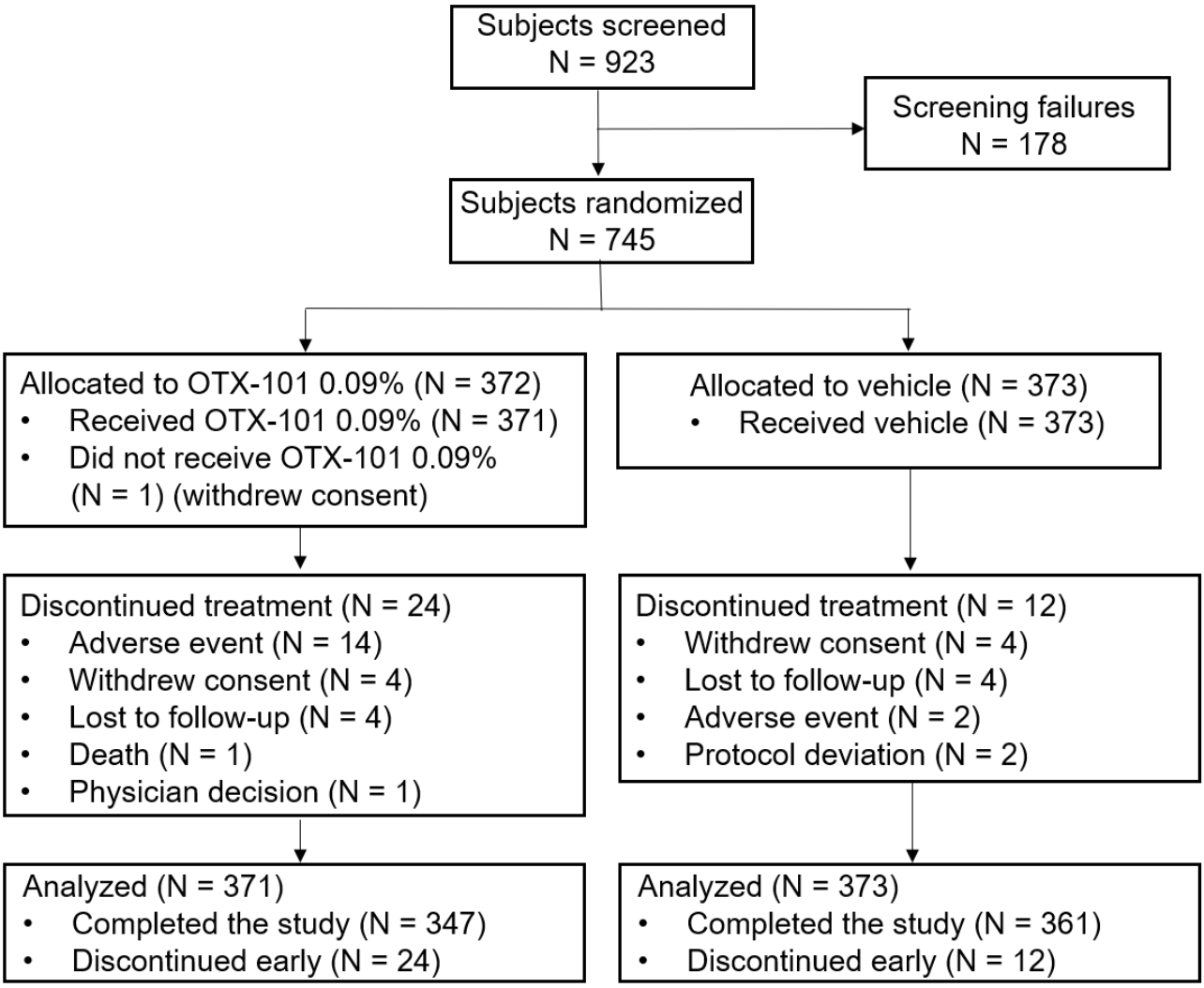
Supplemental Table 2. Snellen visual acuity and intraocular pressure during the long-term safety phase

	Prior OTX-101[a] n = 129			Prior vehicle[a] n = 129			Overall N = 258		
	n	OS	OD	n	OS	OD	n	OS	OD
Snellen VA (logMAR equivalent)									
Baseline[b]	129	0.061 (0.101)	0.065 (0.107)	129	0.065 (0.098)	0.066 (0.088)	258	0.063 (0.099)	0.065 (0.098)
Week 26	116	0.061 (0.098)	0.064 (0.121)	111	0.064 (0.086)	0.060 (0.081)	227	0.062 (0.092)	0.062 (0.103)
Week 39	115	0.063 (0.096)	0.065 (0.107)	107	0.060 (0.077)	0.061 (0.080)	222	0.062 (0.087)	0.063 (0.095)
Week 52	111	0.065 (0.097)	0.070 (0.100)	105	0.060 (0.095)	0.059 (0.090)	216	0.063 (0.096)	0.065 (0.095)
Week 64	2	0.048 (0.069)	0.048 (0.069)	30	0.070 (0.074)	0.059 (0.083)	32	0.068 (0.073)	0.058 (0.081)
Early discontinuation	11	0.044 (0.051)	0.070 (0.098)	27	0.057 (0.095)	0.054 (0.075)	38	0.053 (0.084)	0.058 (0.081)
IOP, mmHg									
Baseline[b]	129	15.1 (2.6)	14.8 (2.5)	129	15.1 (2.7)	14.9 (2.7)	258	15.1 (2.6)	14.9 (2.6)
Week 26	116	15.4 (3.0)	15.3 (3.1)	111	15.5 (2.5)	15.4 (2.6)	227	15.5 (2.7)	15.4 (2.9)
Week 39	115	15.2 (2.9)	15.1 (3.0)	107	15.2 (2.6)	15.3 (2.8)	222	15.2 (2.8)	15.2 (2.9)
Week 52	111	15.1 (2.9)	15.0 (2.9)	105	15.4 (2.6)	15.3 (2.7)	216	15.2 (2.7)	15.1 (2.8)
Week 64	2	15.0 (4.2)	15.0 (4.2)	30	16.5 (2.4)	16.4 (2.5)	32	16.4 (2.5)	16.3 (2.6)
Early discontinuation	10	14.6 (3.0)	13.2 (1.9)	27	15.1 (2.9)	15.0 (2.7)	37	14.9 (2.9)	14.5 (2.6)

Notes: [a]During the treatment phase, patients administered 1 drop in each eye twice daily of OTX-101 0.09% or vehicle. All patients administered 1 drop of OTX-101 0.09% in each eye twice daily during the long-term safety phase. [b]Baseline refers to treatment phase baseline (week 0) for prior OTX-101 and to the week 12 visit for prior vehicle. Data presented for the safety population as mean (SD).

Abbreviations: IOP, intraocular pressure; logMAR, logarithm of the minimum angle of resolution; OD, right eye; OS, left eye; SD, standard deviation; VA, visual acuity.

Supplemental Figure 1. Patient disposition of the treatment phase



Notes: One patient randomized to OTX-101 0.09% who withdrew consent prior to receiving any study medication was excluded from the analysis. One patient randomized to vehicle inadvertently received OTX-101 0.09% and was included in the vehicle group for the purpose of efficacy analysis. Reprinted from *Ophthalmology*. 126(9), Goldberg DF, Malhotra RP, Schechter BA, Justice A, Weiss SL, Sheppard JD. A Phase 3, Randomized, Double-Masked Study of OTX-101 Ophthalmic Solution 0.09% in the Treatment of Dry Eye Disease. 1230-1237, Copyright (2019), with permission from Elsevier.[1]

Reference

1. Goldberg DF, Malhotra RP, Schechter BA, Justice A, Weiss SL, Sheppard JD. A Phase 3, Randomized, Double-Masked Study of OTX-101 Ophthalmic Solution 0.09% in the Treatment of Dry Eye Disease. *Ophthalmology*. 2019;126(9):1230-1237.