

ERRATA SHEET TO THE ARTHRITIS ADVISORY COMMITTEE BRIEFING MATERIALS

NINTEDANIB SOFT CAPSULES

INDICATION: Treatment of systemic sclerosis-associated interstitial lung disease

DATE: JULY 11, 2019

AVAILABLE FOR PUBLIC RELEASE

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Figure 14 of the briefing materials contains errors. The graphical display of the point estimates and 95% confidence intervals for the subgroups of age \geq 65 years and male gender was incorrect. These errors have been corrected in Figure 1 below.

Pla	acebo Adi.	Ninteda	nib								
	Adi.		edanib								
	Adj. Mean Rate	n	Adj. Mean Rate							Difference (95% CI)	p-value
n											
288	-93.3	287								41.0 (2.9, 79.0)	
						ii				, , ,	
229	-97.5	224	-53.1			H	-			44.4 (1.4, 87.4)	0.730
59	-77.8	63	-49.7			_				28.1 (-54.2, 110.4)	
						-¦ ;					
212	-82.0	220	-47.4			-	_			34.6 (-9.3, 78.4)	0.594
76	-126.8	67	-68.3			+	•			58.6 (-18.0, 135.1)	
						-					
186	-98.1	200	-52.2				_			45.8 (-0.8, 92.5)	0.725
81	-99.5	62	-55.0			+	_			44.5 (-32.9, 121.9)	
16	-54.1	20	-74.4	-		• •				-20.4 (-176.7, 136.0)	
126	-106.6	139	-66.9			-	_			39.7 (-16.6, 95.9)	0.277
73	-52.0	69	-41.7		-	- - 	_			10.3 (-65.6, 86.1)	
71	-91.7	59	-48.3							43.4 (-37.0, 123.8)	
18	-176.2	20	2.2							178.4 (28.1, 328.7)	
						i i					
140	-66.5	138	-40.2			-	-			26.3 (-27.9, 80.6)	0.452
148	-119.3	149	-63.9			\dashv	-			55.4 (2.3, 108.5)	
						: i					
177	-93.5	173	-63.6			+	_			29.9 (-19.1, 78.8)	0.491
111	-93.1	114	-35.9			_	-			57.2 (-3.5, 118.0)	
						-					
146	-112.0	153	-55.4				-			56.6 (3.2, 110.0)	0.420
142	-74.5	134	-49.1			+++				25.3 (-28.9, 79.6)	
						1 !					
127	-117.1	127	-84.5			+4				32.6 (-25.2, 90.5)	0.762
161	-73.4	160	-29.0			4				44.5 (-5.93, 94.9)	
						1 !				,	
74	-85.5	57	-69.3		_	به ب				16.2 (-64.1, 96.5)	0.496
214		230	-48.2								
		_					_				
		-400	-300	-200	-100	0	100	200	300	400	
	288 229 59 212 76 186 81 16 126 73 71 18 140 148 177 111 146 142 127 161	n Rate 288 -93.3 229 -97.5 59 -77.8 212 -82.0 76 -126.8 186 -98.1 81 -99.5 16 -54.1 126 -106.6 73 -52.0 71 -91.7 18 -176.2 140 -66.5 148 -119.3 177 -93.5 111 -93.1 146 -112.0 142 -74.5 127 -117.1 161 -73.4	n Rate n 288 -93.3 287 229 -97.5 224 59 -77.8 63 212 -82.0 220 76 -126.8 67 186 -98.1 200 81 -99.5 62 16 -54.1 20 126 -106.6 139 73 -52.0 69 71 -91.7 59 18 -176.2 20 140 -66.5 138 148 -119.3 149 177 -93.5 173 111 -93.1 114 146 -112.0 153 142 -74.5 134 127 -117.1 127 161 -73.4 160 74 -85.5 57 214 -96.1 230	n Rate n Rate 288 -93.3 287 -52.4 229 -97.5 224 -53.1 59 -77.8 63 -49.7 212 -82.0 220 -47.4 76 -126.8 67 -68.3 186 -98.1 200 -52.2 81 -99.5 62 -55.0 16 -54.1 20 -74.4 126 -106.6 139 -66.9 73 -52.0 69 -41.7 71 -91.7 59 -48.3 18 -176.2 20 2.2 140 -66.5 138 -40.2 148 -119.3 149 -63.9 177 -93.5 173 -63.6 111 -93.1 114 -35.9 146 -112.0 153 -55.4 142 -74.5 134 -49.1 127 <td>n Rate n Rate 288 -93.3 287 -52.4 229 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-176.2 20 2.2 140 -66.5 138 -40.2 148 -119.3 149 -63.9 177 -93.5 173 -63.6 111 -93.1 114 -35.9 146 -112.0 153 -55.4 142 -74.5 134 -49.1 127 -117.1 127 -84.5 161 -73.4 160</td><td>n Rate 288 -93.3 287 -52.4 229 -97.5 224 -53.1 59 -77.8 63 -49.7 212 -82.0 220 -47.4 76 -126.8 67 -68.3 186 -98.1 200 -52.2 81 -99.5 62 -55.0 16 -54.1 20 -74.4 126 -106.6 139 -66.9 73 -52.0 69 -41.7 71 -91.7 59 -48.3 18 -176.2 20 2.2 140 -66.5 138 -40.2 148 -119.3 149 -63.9 177 -93.5 173 -63.6 111 -93.1 114 -35.9 146 -112.0 153 -55.4 142 -74.5 134 -49.1 127 -117.1 127 -84.5 161 -73.4 160 -29.0</td><td>n Rate n Rate 288 -93.3 287 -52.4 229 -97.5 224 -53.1 59 -77.8 63 -49.7 212 -82.0 220 -47.4 76 -126.8 67 -68.3 186 -98.1 200 -52.2 81 -99.5 62 -55.0 16 -54.1 20 -74.4 126 -106.6 139 -66.9 73 -52.0 69 -41.7 71 -91.7 59 -48.3 18 -176.2 20 2.2 140 -66.5 138 -40.2 148 -119.3 149 -63.9 177 -93.5 173 -63.6 111 -93.1 114 -35.9 146 -112.0 153 -55.4 142 -74.5 134 -49.1 127 -117.1 127 -84.5 161 -73.4 160</td><td>n Rate n 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-47.4 76 -126.8 67 -68.3 186 -98.1 200 -52.2 81 -99.5 62 -55.0 16 -54.1 20 -74.4 - 126 -106.6 139 -66.9 -66.9 73 -52.0 69 -41.7 -48.3 -48.3 -48.3 -48.3 -48.3 -48.3 -48.3 -48.2 -48.3 -48.2 -48.3 -49.2 -48.3 -49.2 -48.3 -49.2 -48.3 -49.2 -48.3 -49.2 -48.4 -49.1 -49.1 -49.1 -49.1 -49.1 -49.1 -49.1 -49.1 -49.1 -49.1 -49.1 -49.1 -49.1 -49.1 -49.1 -49.1 <td>n Rate n Rate 288 -93.3 287 -52.4 229 -97.5 224 -53.1 59 -77.8 63 -49.7 212 -82.0 220 -47.4 76 -126.8 67 -68.3 186 -98.1 200 -52.2 81 -99.5 62 -55.0 16 -54.1 20 -74.4 126 -106.6 139 -66.9 73 -52.0 69 -41.7 71 -91.7 59 -48.3 18 -176.2 20 2.2 140 -66.5 138 -40.2 148 -119.3 149 -63.9 177 -93.5 173 -63.6 111 -93.1 114 -35.9 146 -112.0 153 -55.4 142 -74.5 134 -49.1 127<td>n Rate n Rate 288 -93.3 287 -52.4 229 -97.5 224 -53.1 59 -77.8 63 -49.7 212 -82.0 220 -47.4 76 -126.8 67 -68.3 186 -98.1 200 -52.2 81 -99.5 62 -55.0 16 -54.1 20 -74.4 126 -106.6 139 -66.9 73 -52.0 69 -41.7 71 -91.7 59 -48.3 18 -176.2 20 2.2 140 -66.5 138 -40.2 148 -119.3 149 -63.9 177 -93.5 173 -63.6 111 -93.1 114 -35.9 146 -112.0 153 -55.4 142 -74.5 134 -49.1 127 -117.1 127 -84.5 161 -73.4 160</td><td>n Rate 288 -93.3 287 -52.4 229 -97.5 224 -53.1 59 -77.8 63 -49.7 212 -82.0 220 -47.4 76 -126.8 67 -68.3 186 -98.1 200 -52.2 81 -99.5 62 -55.0 16 -54.1 20 -74.4 126 -106.6 139 -66.9 73 -52.0 69 -41.7 71 -91.7 59 -48.3 18 -176.2 20 2.2 140 -66.5 138 -40.2 148 -119.3 149 -63.9 177 -93.5 173 -63.6 111 -93.1 114 -35.9 146 -112.0 153 -55.4 142 -74.5 134 -49.1 127 -117.1 127 -84.5 161 -73.4 160 -29.0</td><td>n Rate n Rate 288 -93.3 287 -52.4 229 -97.5 224 -53.1 59 -77.8 63 -49.7 212 -82.0 220 -47.4 76 -126.8 67 -68.3 186 -98.1 200 -52.2 81 -99.5 62 -55.0 16 -54.1 20 -74.4 126 -106.6 139 -66.9 73 -52.0 69 -41.7 71 -91.7 59 -48.3 18 -176.2 20 2.2 140 -66.5 138 -40.2 148 -119.3 149 -63.9 177 -93.5 173 -63.6 111 -93.1 114 -35.9 146 -112.0 153 -55.4 142 -74.5 134 -49.1 127 -117.1 127 -84.5 161 -73.4 160</td><td>n Rate n Rate 288 -93.3 287 -52.4 229 -97.5 224 -53.1 59 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-93.5 173 -63.6 2

^a treatment-by-time-by-subgroup interaction

The subgroup of patients with mycophenolate use at baseline comprised patients who took mycophenolate mofetil and sodium; however, 3 patients who took mycophenolic acid were allocated to the subgroup of patients without concomitant mycophenolate use at baseline, based on an incomplete specification in the trial statistical analysis plan detected only after database lock. This was later confirmed as not having an influence on the interpretation of the results of this subgroup.

Figure 1 Forest plot of the rate of decline in FVC [mL/year] over 52 weeks in subgroups in the SENSCIS trial (corrected) - TS