

Supplementary Appendix

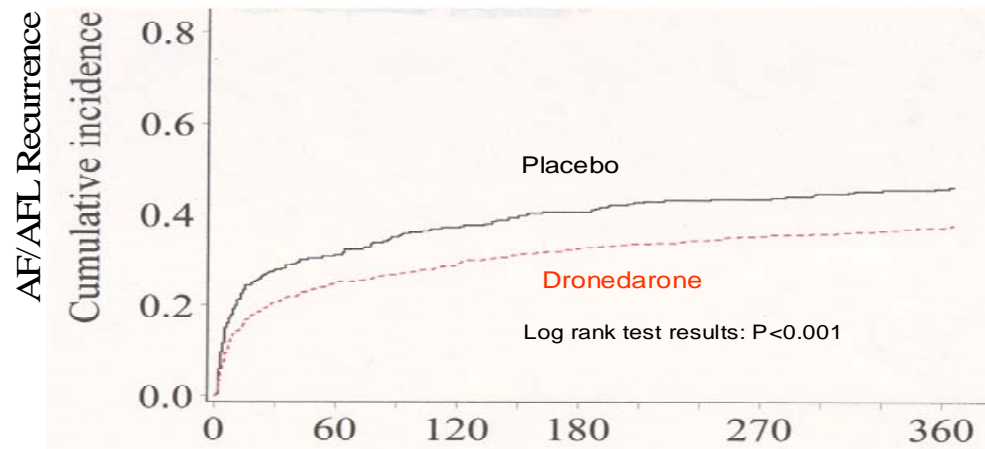
This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Singh BN, Connolly SJ, Crijns HJGM, et al. Dronedaronone for maintenance of sinus rhythm in atrial fibrillation or flutter. *N Engl J Med* 2007;357:987-99.

Online Supplementary Appendix (1). Effects of Dronedarone on Heart Rate and QT Intervals Compared to Placebo

Parameter	Criteria	EUROPEAN TRIAL		NON-EUROPEAN TRIAL		COMBINED	
		Placebo (N= 201)	Dronedarone 400 mg BID (N= 411)	Placebo (N= 208)	Dronedarone 400 mg BID (N= 417)	Placebo (N= 409)	Dronedarone 400 mg BID (N= 828)
Heart rate (bpm)	N	149	306	149	323	298	629
	Baseline : Mean (SD)	63.2 (10.5)	64.5 (10.4)	63.6 (11.1)	64.3 (10.5)	63.4 (10.8)	64.4 (10.5)
	D21 : Mean (SD)	63.5 (11.7)	60.7 (10.2)	64.1 (11.9)	59.1 (10.5)	63.8 (11.8)	59.9 (10.4)
	Change from baseline (a) Treatment effect (a) : p-value	-0.1	-3.5 0.0002	0.4	-5.1 <.0001	0.2	-4.4 <.0001
QRS interval (ms)	N	149	303	148	323	297	626
	Baseline : Mean (SD)	91.8 (17.7)	91.6 (16.3)	90.0 (18.0)	90.7 (18.2)	90.9 (17.9)	91.1 (17.3)
	D21 : Mean (SD)	92.5 (17.7)	91.7 (16.0)	90.1 (16.2)	91.3 (17.6)	91.3 (17.0)	91.5 (16.8)
	Change from baseline (a) Treatment effect(a) : p-value	0.7	0.1 0.579	-0.0	0.7 0.521	0.3	0.4 0.954
QT interval (ms)	N	133	278	132	283	265	561
	Baseline : Mean (SD)	395.6 (36.8)	398.8 (37.1)	406.4 (46.8)	402.1 (41.3)	401.0 (42.3)	400.5 (39.3)
	D21 : Mean (SD)	396.1 (34.4)	420.4 (38.5)	400.4 (38.3)	427.4 (42.5)	398.2 (36.4)	424.0 (40.7)
	Change from baseline (a) Treatment effect (a) : p-value	-0.3	22.0 <.0001	-4.9	24.8 <.0001	-2.6	23.4 <.0001
QTc Bazett (ms)	N	133	278	132	283	265	561
	Baseline : Mean (SD)	404.0 (33.7)	409.2 (33.3)	413.9 (36.6)	413.0 (34.6)	408.9 (35.5)	411.1 (34.0)
	D21 : Mean (SD)	404.8 (27.2)	419.6 (31.3)	409.6 (33.7)	419.6 (33.6)	407.2 (30.7)	419.6 (32.5)
	Change from baseline (a) Treatment effect (a) : p-value	-1.0	11.2 <.0001	-4.0	6.5 0.0002	-2.4	8.8 <.0001

*Plus-minus values are means \pm SD (standard deviation). AF = atrial fibrillation; AFL = atrial flutter; HR = hazard ratio; CI = confidence interval; TTM = transtelephonic monitoring; ms = milliseconds; (a) = change from baseline and treatment effect (difference between dronedarone 800 mg and placebo groups) are adjusted for baseline values.



No. at risk:

Placebo	409	192	156	133	112	90
Dronedaron 400mg BID	828	450	389	347	307	262

Online Supplementary Appendix (2). Prentice Incidence Curves for the Adjudicated First Symptomatic Atrial Fibrillation or Flutter Recurrence in Patients in the EUROPEAN and the NON-EUROPEAN TRIALS (Pooled data).

The time to recurrence of symptomatic atrial fibrillation or flutter is shown for the dronedaron and placebo groups in EURIDIS and ADONIS combined. AF/AFL denotes atrial fibrillation and atrial flutter respectively.