

Electronic Appendix

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TABLE E-I Surgical Details of the Efficacy Population

Characteristic	Ximelagatran (N = 982)	Warfarin (N = 967)
Type of surgery*		
Unilateral total knee arthroplasty	940 (95.7)	921 (95.2)
Bilateral total knee arthroplasty	42 (4.3)	46 (4.8)
Reason for total knee arthroplasty*		
Osteoarthritis	925 (94.2)	923 (95.4)
Rheumatoid arthritis	46 (4.7)	35 (3.6)
Other	11 (1.1)	9 (0.9)
Type of anesthesia*		
General	373 (38)	336 (34.7)
Regional	518 (52.7)	536 (55.4)
General and regional	91 (9.3%)	95 (9.8)
Type of prosthesis*		
Cemented	891 (90.7)	895 (92.6)
Noncemented	22 (2.2)	21 (2.2)
Hybrid	69 (7.0)	51 (5.3)
Duration of surgery† (<i>min</i>)	99.6 ± 36.1	97.3 ± 33.1
Time to first dose†‡ (<i>h</i>)	20.2 ± 3.5	20.2 ± 3.3
Tourniquet duration† (<i>min</i>)	77.8 ± 26.7	75.6 ± 25.7
Time to walking† (<i>d</i>)	1.9 ± 1.9	1.9 ± 1.6
Duration of hospital stay† (<i>d</i>)	5.6 ± 3.0	5.5 ± 2.7

*Values are given as the number of patients with the percentage in parentheses. †Values are given as the mean and the standard deviation. ‡Time to first morning dose of ximelagatran or ximelagatran placebo.

TABLE E-II Evaluation of the Surgical Wound*

Characteristic	Ximelagatran	Warfarin
Wound bleeding		
Unusual bruising and/or hematoma	63/1142 (5.5%)	51/1142 (4.5%)
Intra-articular bleeding	13/322 (4.0%)	11/314 (3.5%)
Wound appearance		
Swelling	54/1142 (4.7%)	52/1141 (4.6%)
Drainage	48/1142 (4.2%)	29/1141 (2.5%)
Erythema	50/1142 (4.4%)	41/1141 (3.6%)
Bleeding	23/1142 (2.0%)	14/1141 (1.2%)
Treatment-emergent postoperative complications†		
Wound site erythema	1/1151 (0.1%)	6/1148 (0.5%)
Wound seroma	4/1151 (0.3%)	0/1148 (0.0%)
Wound hematoma	3/1151 (0.3%)	5/1148 (0.4%)
Stitch abscess	3/1151 (0.3%)	4/1148 (0.3%)
Wound infection	31/1151 (2.7%)	26/1148 (2.3%)
Abscess	1/1151 (0.1%)	0/1148 (0.0%)
Wound dehiscence	3/1151 (0.3%)	5/1148 (0.4%)
Wound necrosis	1/1151 (0.1%)	2/1148 (0.2%)

*The values are given as the number of patients with each bleeding complication or those for whom the particular wound characteristic was “worse than expected” at any scheduled visit, including the follow-up visit. The denominators refer to the number of patients with data available. †According to terminology in an adverse event dictionary.

Fig. E-1. Cumulative Proportion of Bleeding Events (Major and Minor) Over Time for the Entire Study Period. Ximelagatran was not Administered until Day 1.

