Supplementary Material I

TABLE S1 **Patients with the primary efficacy outcome or a major bleeding event within 3 months of enrolment**

Sex, Age (Years)	sPESI (points)	Type of Event	Dosage	Days from Enrolment	Length of Rehospitalisation (days)	Description	Management
Female, 46	0	Recurrent PE	20 mg once daily	29	4	Segmental recurrent PE occurring during rivaroxaban therapy. No haemodynamic decompensation.	Rivaroxaban discontinuation and switch to LMWH. No further complications.
Male, 46	≥ 1	Recurrent PE	15 mg twice daily	7	6	Segmental recurrent PE occurring during rivaroxaban therapy. No haemodynamic decompensation.	The therapy with rivaroxaban (15 mg twice daily) was continued. No further complications.
Female, 47	0	Recurrent PE	20 mg once daily	75	-	Segmental recurrent PE occurring during rivaroxaban therapy. No haemodynamic decompensation.	Rivaroxaban discontinuation and switch to LMWH; no further complications.
Female, 37	0	Major bleeding[a]	15 mg twice daily	12	1	Uterine bleeding.	Rivaroxaban discontinuation and switch to LMWH.

Male, 81	≥ 1	Major bleeding[a]	20 mg once daily	57	12	Haemorrhagic shock following acute bleeding from intestinal diverticula.	Red blood cell concentrates; rivaroxaban discontinuation and switch to LMWH. Subsequently, the patient suffered one further gastrointestinal major bleeding episode on heparin.
Female, 69	0	Major bleeding[a]	20 mg once daily	70	-	Gastrointestinal bleeding (onset 10 days before) and anaemia.	-
Female, 50	0	Major bleeding[a]	15 mg once daily	72	-	Uterine bleeding (onset 15 days before).	Rivaroxaban discontinuation.
Female, 49	0	Major bleeding[a]	20 mg once daily	57	6	Uterine bleeding (onset 20 days before).	Red blood cell concentrates; rivaroxaban discontinuation and switch to LMWH.
Male, 85	≥ 1	Major bleeding[a]	20 mg once daily	72	69	Intracranial haemorrhage.	After rivaroxaban discontinuation, the patient received prothrombin complex concentrate. He died 69 days later.

[a] As defined by the criteria of the International Society of Thrombosis and Haemostasis.[16]

LMWH: low-molecular-weight heparin; PE: pulmonary embolism; sPESI: simplified Pulmonary Embolism Severity Index.

TABLE S2 **Serious adverse events (n=68) in the safety population within 3 months of enrolment**

Adverse event	Time of Onset (Days After Enrolment)	Hospitalization Necessary
Progression of oedema (left leg)	49	Yes
Kidney stones	74	Yes
Retrosternal pain	5	Yes
Removal of external bone fixator and suspected recurrent pulmonary embolism	2	Yes
Gastritis	81	Yes
Suspected recurrent pulmonary embolism	7	Yes
Schizoaffective disorder (maniac phase)	64	Yes
Anaemia	55	Yes
Ankle fracture	49	Yes
Infarct pneumonia	2	Yes
Proximal tibial facture	71	Yes
Gastrointestinal bleeding	13	Yes
Chest pain	20	Yes
Exertional dyspnoea	37	Yes
Paradoxical septal motion	91	No
Upper gastrointestinal bleeding	5	Yes
Acute cytomegalovirus (momonucleosis-like) infection	2	Yes
Pleuritis	1	Yes
Reflux oesophagitis	2	Yes
Syncope	12	Yes
Hypermenorrhoea	12	Yes
Urosepsis and pyelonephritis	13	Yes
Allergic reaction (rivaroxaban)	2	Yes
Acute renal failure	53	Yes
Hypermenorrhoea	20	Yes
Pneumonia	2	Yes
Panic attack	57	Yes
Renal colic	1	Yes
Cancer	47	No
Infarction pneumonia	4	Yes
Dyspnoea	4	Yes

Gastrointestinal bleeding	57	Yes
Angina pectoris	57	Yes
Pancreatic cancer	1	Yes
Bronchial cancer	13	Yes
Suspected pancreatic cancer	2	Yes
Fever	3	Yes
Pneumonia	2	Yes
Chronic obstructive pulmonary disease	33	Yes
Bleeding	57	Yes
Bronchial asthma	35	Yes
Pneumonia	4	Yes
Elevation of troponin	1	Yes
Thoracic pain	32	Yes
Anxious disorder	4	Yes
Suspected deep vein thrombosis	63	No
Prostate cancer	55	No
Chronic inflammatory demyelinating polyneurophathy	4	Yes
Advanced mesothelioma	34	Yes
Bladder-bowel fistula	33	Yes
Lobar pneumonia	70	Yes
Elevation of troponin	1	Yes
Diarrhea	85	Yes
Chest pain	36	Yes
Sepsis	22	Yes
Suspected recurrent pulmonary embolism	75	No
Exacerbation of chronic obsctructive pulmonary disease	7	Yes
Pneumonia	12	Yes
Suspected esophagus cancer	13	Yes
Pneumonia	26	Yes
Pneumonia	34	Yes
Chest pain	5	Yes
Hypotension	29	Yes
Non-ST elevation myocardial infarction	3	Yes
Suspected deep vein thrombosis	2	Yes
Stroke	53	Yes
Chest pain	2	Yes

Advanced endometrial cancer	26	Yes

TABLE S3 **Answers to Dimension 2 of PEmb-QoL "At what time of day are your lung symptoms most intense?"**

	Week 3	**Month 3**
When waking up	8.2%	6.1%
At mid-day	8.7%	6.4%
In the evening	16.0%	12.2%
During the night	5.7%	4.0%
At any time of the day	20.0%	14.8%
Never	38.1%	53.9%
Not available	3.3%	2.6%

TABLE S4 **Answers to Dimension 3 of PEmb-QoL "Compared to one year ago, how would you rate the condition of your lungs in general now?"**

		Week 3	**Month 3**
Much better		4.0%	14.1%
Slightly better		6.4%	8.5%
About the same		19.1%	30.8%
Slightly worse		27.3%	22.6%
Much worse		13.2%	6.8%
No problems		28.2%	15.8%
Not available		1.9%	1.4%

TABLE S5. Baseline characteristics of the patients who completed the Pulmonary Embolism Quality of Life questionnaire at both visits (week 3 and month 3) versus those who did not (at either or both visits)

Variable	**PEmb-QoL assessed at 3 weeks and 3 months (N=425)**	**PEmb-QoL not assessed at either visit (N=151)**
Patient Demographics		
Age (years), mean (SD; range)	57.0 (16.0; 19-90)	55.2 (18.2; 18-87)
Women, n/N (%)	192/425 (45.2)	74/151 (49.0)
Education Level, n/N (%)		
Elementary school	14/384 (3.6)	6/135 (4.4)
Basic primary school	42/384 (10.9)	16/135 (11.9)
Secondary general school	97/384 (25.3)	26/135 (19.3)
Intermediate secondary school	95/384 (24.7)	37/135 (27.4)
A-level	68/384 (17.7)	27/135 (20.0)
University degree	67/384 (17.4)	23/135 (17.0)
Doctorate	1/384 (0.3)	0
Functional Parameters and Biochemical Markers		
Body mass index (kg/m²), median (Q1-Q3)	27.1 (24.3-30.5)	27.0 (24.4-30.6)
Systolic / diastolic blood pressure (mm Hg), mean (SD)	137 (19) / 80 (12)	136 (19) / 80 (12)
Heart rate (beats per minute), mean (SD)	78 (13)	77 (13)
Oxygen saturation (%), median (Q1-Q3)	97 (96-98)	97 (95-98)

Respiratory rate (breaths per minute), median (Q1-Q3)	16 (15-18)	16 (14-18)
Risk Factors for Pulmonary Embolism and Comorbidities, n/N (%)		
Oestrogen use	70/422 (16.6)	22/149 (14.8)
Immobilisation (for at least 3 days)	46/420 (11.0)	12/150 (8.0)
Previous deep vein thrombosis	63/416 (15.1)	24/150 (16.0%)
Previous pulmonary embolism	35/421 (8.3)	9/151 (6.0)
Recent major surgery (past 30 days)	27/424 (6.4)	11/150 (7.3)
Recent major trauma (past 30 days)	17/425 (4.0)	8/150 (5.3)
Long travel (> 4 hours, past 30 days)	54/418 (12.9)	16/149 (10.7)
Active cancer	29/420 (6.9)	9/147 (6.1)
Chronic obstructive pulmonary disease	21/420 (5.0)	7/149 (4.7)
Chronic heart failure	4/425 (0.9)	3/150 (2.0)
Coronary artery disease	31/422 (7.3)	10/148 (6.8)
Arterial hypertension	172/425 (40.5)	69/149 (46.3)
Diabetes mellitus	26/425 (6.1)	12/151 (7.9)
Simplified Pulmonary Embolism Severity Index (sPESI) ≥ 1	94/412 (22.8)	33/144 (22.9)

PEmb-QoL: Pulmonary Embolism Quality of Life questionnaire.

TABLE S6 Baseline characteristics of the patients who completed the EQ-5D-5L questionnaire at both visits (week 3 and month 3) versus those who did not (at either or both visits)

Variable	**EQ-5D-5L assessed at both 3 weeks and 3 months (N=473)**	**EQ-5D-5L not assessed at either visit (N=103)**
Patient Demographics		
Age (years), mean (SD; range)	56.9 (16.1; 18-90)	55.1 (18.7; 20-86)
Women, n/N (%)	217/473 (45.9)	49/103 (47.6)
Education Level, n/N (%)		
Elementary school	15/429 (3.5)	5/90 (5.6)
Basic primary school	46/429 (10.7)	12/90 (13.3)
Secondary general school	102/429 (23.8)	21/90 (23.3)
Intermediate secondary school	113/429 (26.3)	19/90 (21.1)
A-level	78/429 (18.2)	17/90 (18.9)
University degree	74/429 (17.2)	16/90 (17.8)
Doctorate	1/429 (0.2)	0
Functional Parameters and Biochemical Markers		
Body mass index (kg/m²), median (Q1-Q3)	27.2 (24.4-30.5)	26.5 (24.0-29.5)
Systolic / diastolic blood pressure (mm Hg), mean (SD)	136 (19) / 80 (12)	136 (19) / 81 (12)
Heart rate (beats per minute), mean (SD)	78 (13)	78 (12)
Oxygen saturation (%), median (Q1-Q3)	97 (96-98)	97 (95-98)

Respiratory rate (breaths per minute), median (Q1-Q3)	16 (15-18)	16 (15-18)
Risk Factors for Pulmonary Embolism and Comorbidities, n/N (%)		
Oestrogen use	76/470 (16.2)	16/101 (15.8)
Immobilisation (for at least 3 days)	49/467 (10.5)	9/103 (8.7)
Previous deep vein thrombosis	69/464 (14.9)	18/102 (17.6)
Previous pulmonary embolism	36/469 (7.7)	8/103 (7.8)
Recent major surgery (past 30 days)	31/471 (6.6)	7/103 (6.8)
Recent major trauma (past 30 days)	21/472 (4.4)	4/103 (3.9)
Long travel (> 4 hours, past 30 days)	59/464 (12.7)	11/103 (10.7)
Active cancer	29/467 (6.2)	9/100 (9.0)
Chronic obstructive pulmonary disease	22/469 (4.7)	6/100 (6.0)
Chronic heart failure	4/473 (0.8)	3/102 (2.9)
Coronary artery disease	30/469 (6.4)	11/101 (10.9)
Arterial hypertension	194/471 (41.2)	47/103 (45.6)
Diabetes mellitus	33/473 (7.0)	5/103 (4.9)
Simplified Pulmonary Embolism Severity Index (sPESI) ≥ 1	97/457 (21.2)	30/99 (30.3)