

Functional Coronary Angiography to Indicate and Guide Revascularization in STEMI Patients with Multivessel Disease



The AIR-STEMI trial

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on behalf of the AIR-STEMI trial Investigators

Background



- **Complete revascularization is the gold standard in MI with MVD, but the best way to achieve it remains to be determined¹.**
- **Angiography may lead to overtreatment of nonculprit lesions with low risk of adverse events²**
- **Physiology can refine lesion selection, but wire-based physiology can be cumbersome in STEMI setting and previous trials showed conflicting results^{3,4}**

Research question

In patients with STEMI and multivessel disease after successful culprit-lesion PCI, does functional coronary angiography–guided complete revascularization reduce major cardiovascular events compared with conventional angiography-guided complete revascularization? ¹

Organization

Investigator-initiated, multicenter, prospective, superiority, randomized trial¹

Countries: Italy



Pakistan



21 centers

Study PI:

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Executive Committee: Abdul Hakeem, Giulia Bugani, Francesca Mantovani, Giampaolo Niccoli, Iginio Colaïori, Elisabetta Moscarella, Rocco Vergallo, Alberto Polimeni, Domenico D'Amario, Giulia Masiero

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Sponsor:



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Supporters:



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Study design

Inclusion criteria

- ✓ STEMI
- ✓ MVD
- ✓ Successful PPCI

Pts hospitalized for STEMI with indication to primary PCI

Multivessel disease at coronary artery angiography

Culprit lesion clearly identifiable and successfully treated

Exclusion criteria

- ✗ Culprit unclear
- ✗ Prior CABG
- ✗ LM as nonculprit
- ✗ Life exp <1 year

R

Physiology-guided Complete Revascularization

Angiography-guided Complete Revascularization

BP-SES Supraflex Cruz recommended

Primary endpoint: median follow-up 17.9 months (IQR 12-24 months)

Sample Size

We estimated that **9% of patients in the angiography group** would experience a primary outcome event. Assuming a **relative risk reduction of 35% with the physiology-guided strategy**, we calculated that a sample of 1718 patients would provide 80% power to detect a significant between-group difference at a two-sided alpha level of 0.05. To account for an anticipated 5% attrition rate, the **target sample size was increased to at least 1800 patients**

Functional Coronary Angiography¹

Angiography-guided

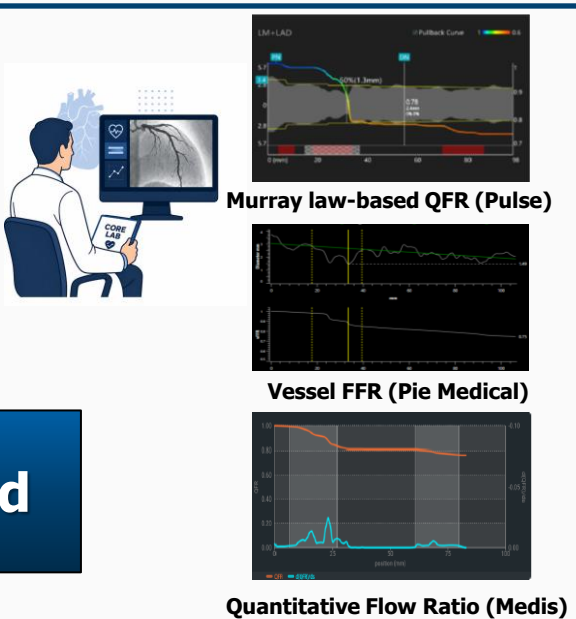
- PCI of all nonculprit lesions with %DS $\geq 50\%$
- During the index or staged procedure (index hospitalization)



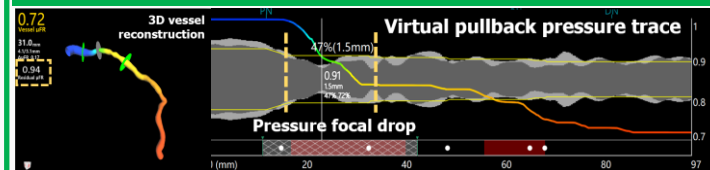
Nonculprit lesion

Physiology-guided

Central Core Lab – Functional Coronary Angiography



Positive angio-derived FFR $\rightarrow$ PCI



- Distal single point FFR value
- Longitudinal pattern of disease
- Procedural plan / treatment indication

Negative angio-derived FFR $\rightarrow$ OMT



Endpoints¹

Primary

Death, any MI, CVA, or ID-revascularization

Key secondary

Cardiovascular death or MI

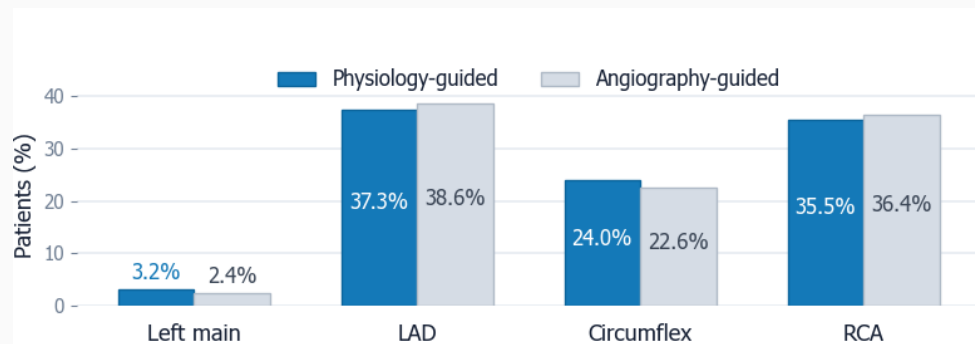
Safety

CA-AKI or BARC type 3-5 bleeding

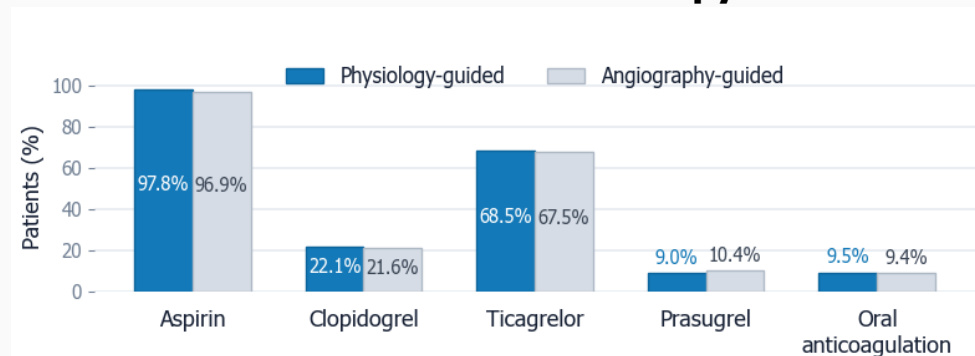
Baseline Characteristics*

Characteristic	Physiology (N=913)	Angiography (N=910)
Age (IQR) – yr	67 (58-76)	66 (57-75)
Female sex	223 (24.4)	208 (22.9)
Comorbidities		
Hypertension	638 (69.9)	614 (67.5)
Diabetes	195 (21.4)	205 (22.5)
Current smoker	292 (32.0)	278 (30.5)
Prior MI	87 (9.5)	98 (10.8)
eGFR <60 ml/min	116 (12.7)	127 (14.0)
PAD	100 (11.0)	106 (11.6)
Clinical presentation		
Cardiac arrest	34 (3.7)	32 (3.5)
Killip ≥2	192 (21.0)	171 (18.8)

Culprit vessel



Antithrombotic therapy



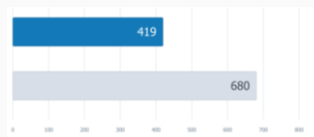
Procedural Data*

Characteristic	Physiology (N=913)	Angiography (N=910)
Index procedures	913	910
Staged procedures	419	680
Nonculprit vessel		
Total number	1147	1128
LAD	479 (41.7)	473 (41.9)
Circumflex	352 (30.6)	342 (30.3)
RCA	316 (27.5)	313 (27.7)
RVD (mm)	3.0 (2.7-3.3)	127 (2.7-3.3)
%DS	80 (72-87)	79 (72-86)
Functional evaluation		
Angio-derived FFR	1132 (98.7)	---
Wire-based FFR	15 (1.3)	---

Staged procedures

Physio

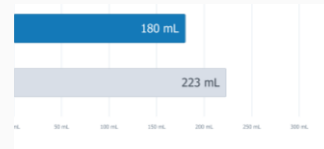
Angio



Contrast use

180 mL

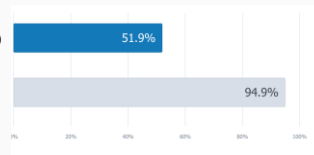
223 mL



NCV treated

Physio

Angio



Stent length

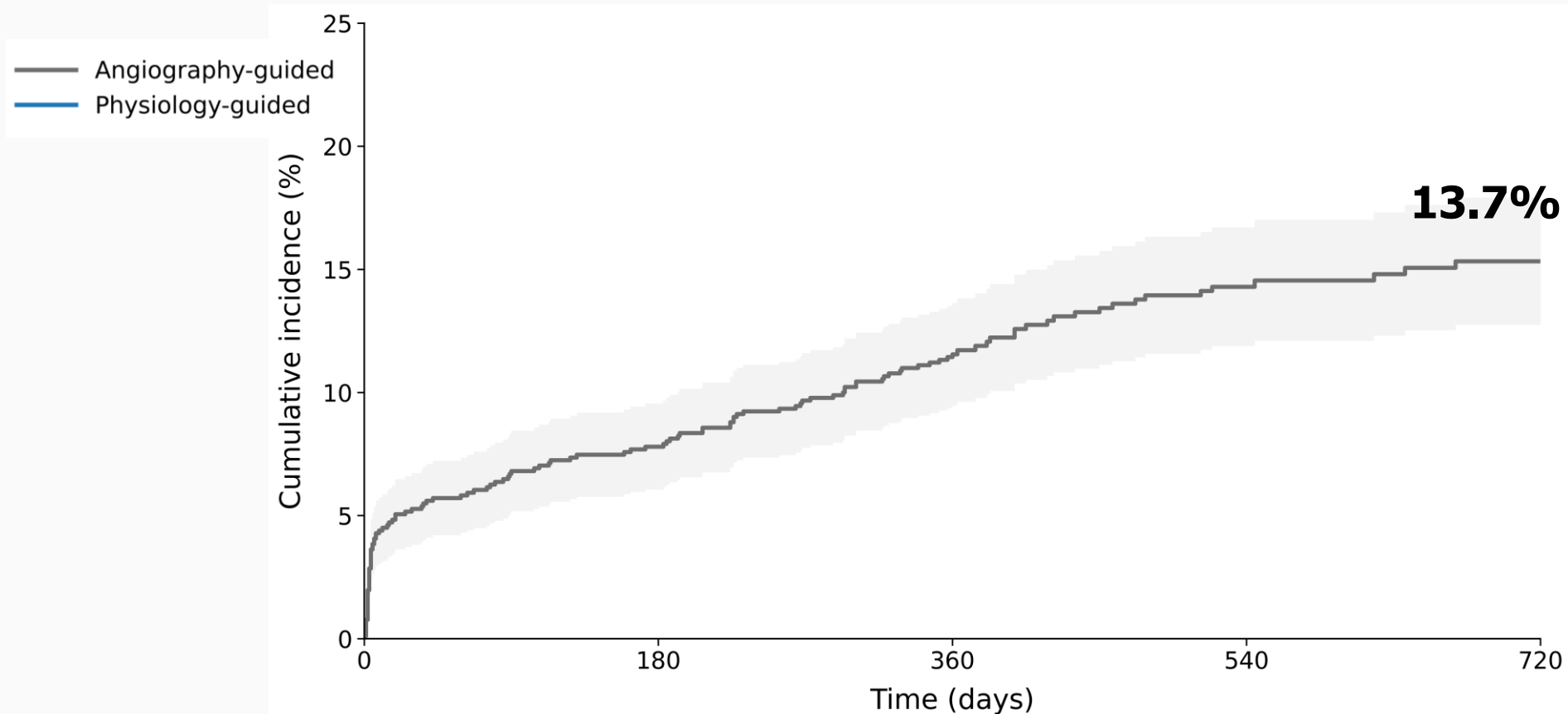
22 mm

32 mm

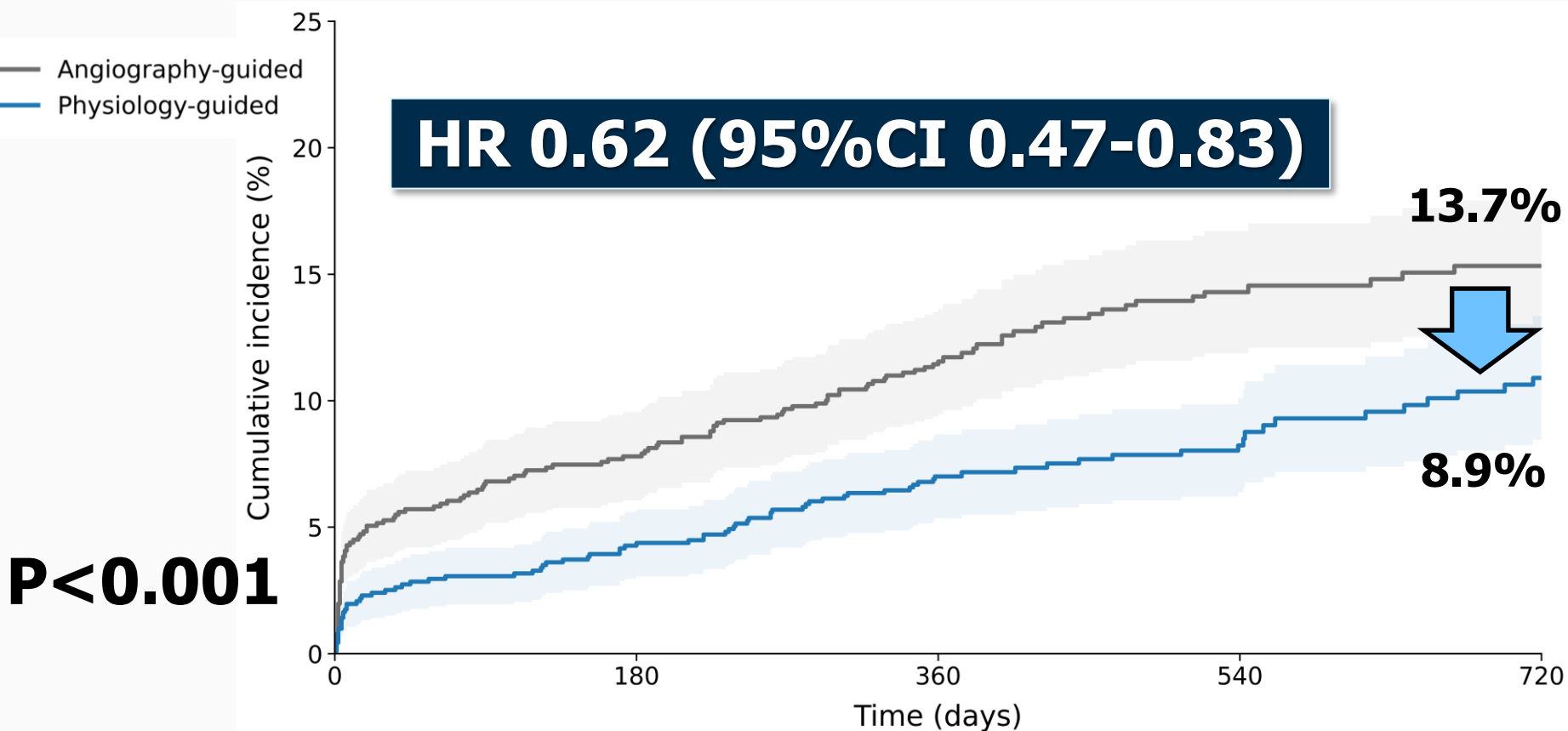


- **Staged procedures** **-38.4%**
- **Contrast use** **-19.3%**
- **NCVs treated** **-45.3%**
- **Total stent length** **-31.2%**

Primary Endpoint (death, CVA, MI, id-revasc)

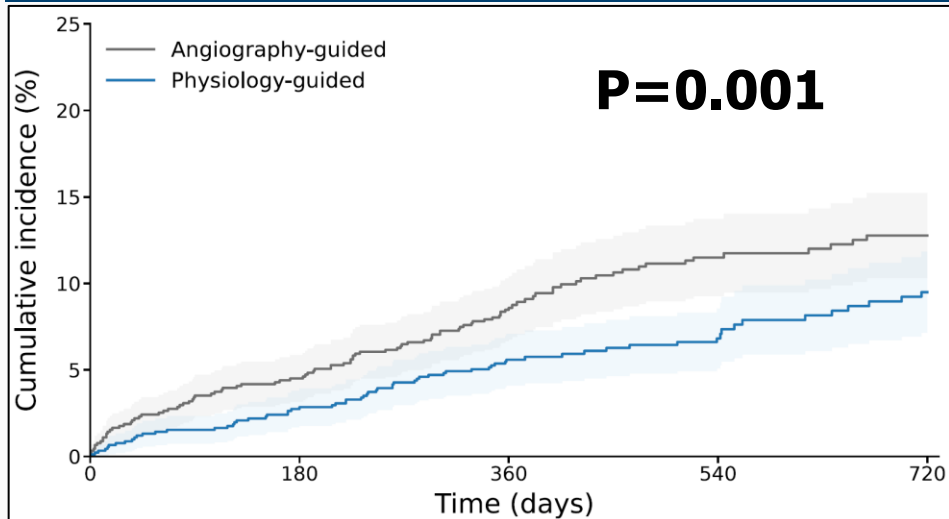


Primary Endpoint (death, CVA, MI, id-revasc)



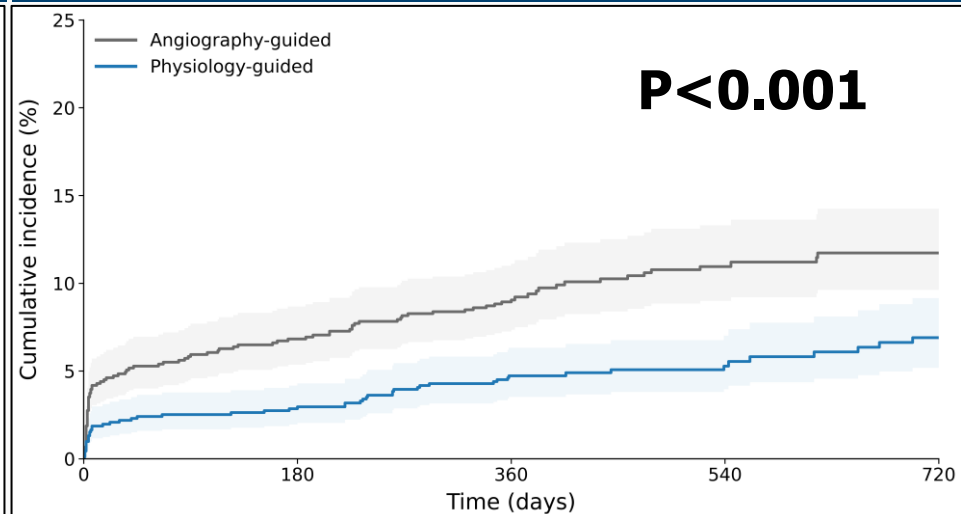
Secondary Endpoints

EP1 excluding MI type 4a



HR 0.67 (95%CI 0.50-0.92)

CV death or MI



HR 0.52 (95%CI 0.37-0.73)

Secondary Endpoints



Outcome	Physiology (N=913)	Angiography (N=910)	HR (95% CI)	P value
	no. (%)	no. (%)		
Death	36 (3.9)	46 (5.1)	0.77 (0.50-1.20)	0.250
Cardiovascular death	20 (2.2)	31 (3.4)	0.64 (0.36-1.12)	0.120
Myocardial infarction	35 (3.8)	73 (8.0)	0.47 (0.31-0.70)	<0.001
Procedure-related	15 (1.6)	33 (3.6)	0.45 (0.24-0.83)	0.010
Spontaneous	21 (2.3)	45 (5.0)	0.46 (0.27-0.77)	0.003
ID-revascularization	29 (3.2)	47 (5.2)	0.61 (0.38-0.97)	0.037
Cerebrovascular accident	3 (0.3)	4 (0.4)	0.75 (0.17-3.35)	0.710
Safety outcome*	42 (4.6)	65 (7.1)	0.63 (0.43-0.93)	0.020
Contrast-associated acute kidney injury	20 (2.2)	36 (4.0)	0.55 (0.32-0.94)	0.031
BARC 3-5 bleeding	23 (2.5)	33 (3.6)	0.69 (0.41-1.18)	0.170

Limitations

- **Open-label design**
- **ID-revascularization in the primary endpoint**
- **Relative contribution of each component to the observed benefit cannot be determined**
- **Central core laboratory assessment might limit generalizability**

Among patients with STEMI and multivessel coronary artery disease, a strategy of complete revascularization guided by functional coronary angiography reduced:

- **a composite of death, MI, CVA, or ID-revasc**
- **cardiovascular death or MI**



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ORIGINAL ARTICLE

Complete Revascularization Guided by Functional Coronary Angiography in STEMI

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*From FIRE to AIR-STEMI: an extraordinary scientific journey and, above all, an
adventure of friendship. Our deepest gratitude to all the patients, investigators, and
colleagues who made it possible.*

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