OCEANIC-AF: Asundexian vs. Apixaban in Patients with Atrial Fibrillation

ESC Late-Breaking Trial Presentation
September 1st, 2024

Manesh R. Patel, MD on behalf of the OCEANIC-AF Executive Committee, Steering Committee, and Investigators

Disclosures

Research Grants: Bayer, Novartis, Janssen, Idorsia, NHLBI

Advisory Board/Consultancy: Bayer, Janssen, Esperion

Background: The Need for a Better Antithrombotic Therapy for Atrial Fibrillation

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- DOACs now accepted as first-line therapy over warfarin, with lower rates of stroke, mortality, and ICH
- Patients on DOACs still face a bleeding risk of 2.7–3.5%/year
- Bleeding and fear of bleeding remain a major challenge for DOAC therapy and adherence to treatment, resulting in:

Undertreatment
< 66% of patients with atrial fibrillation and CHA_2DS_2-VASc ≥ 2 are prescribed an OAC at all

Underdosing
Up to 25% of patients on DOACs are underdosed, which might result in higher rates of thromboembolic events

Poor treatment compliance
1 in 3 patients adhere to their DOAC < 80% of the time and the nonadherence is associated with poor clinical outcomes

January et al. JACC 2019;74:104–132.
Carnicelli et al. Circulation 2022;145:242–255.
Oldgren et al. Circulation 2014;129:1568–1576.
Camm et al. JACC 2020; 76:1425–1436.
Kakkar et al. PLoS One 2013;8:e63479.

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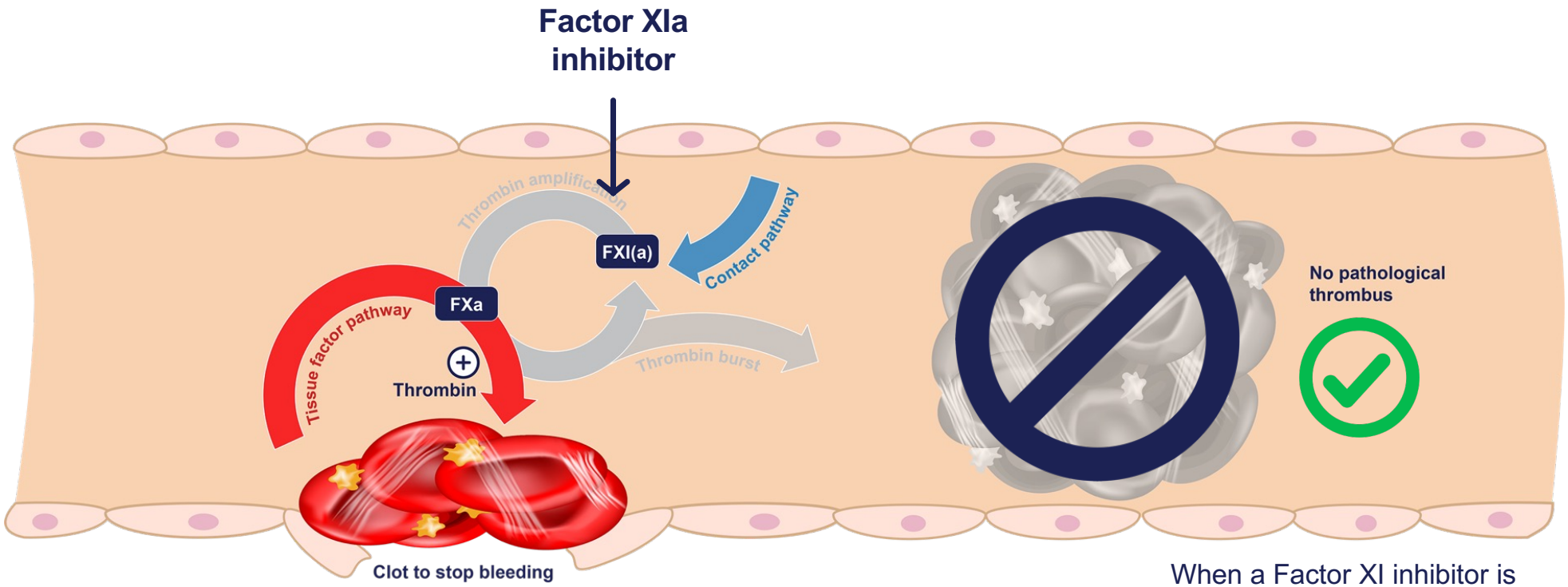
With a Factor XIa Inhibitor

Hypothesis: Uncoupling Hemostasis from Thrombosis



AND the tissue factor pathway still produces thrombin, which allows beneficial blood clots to form.

When a Factor XI inhibitor is used, thrombin amplification is inhibited, which prevents pathological thrombi—

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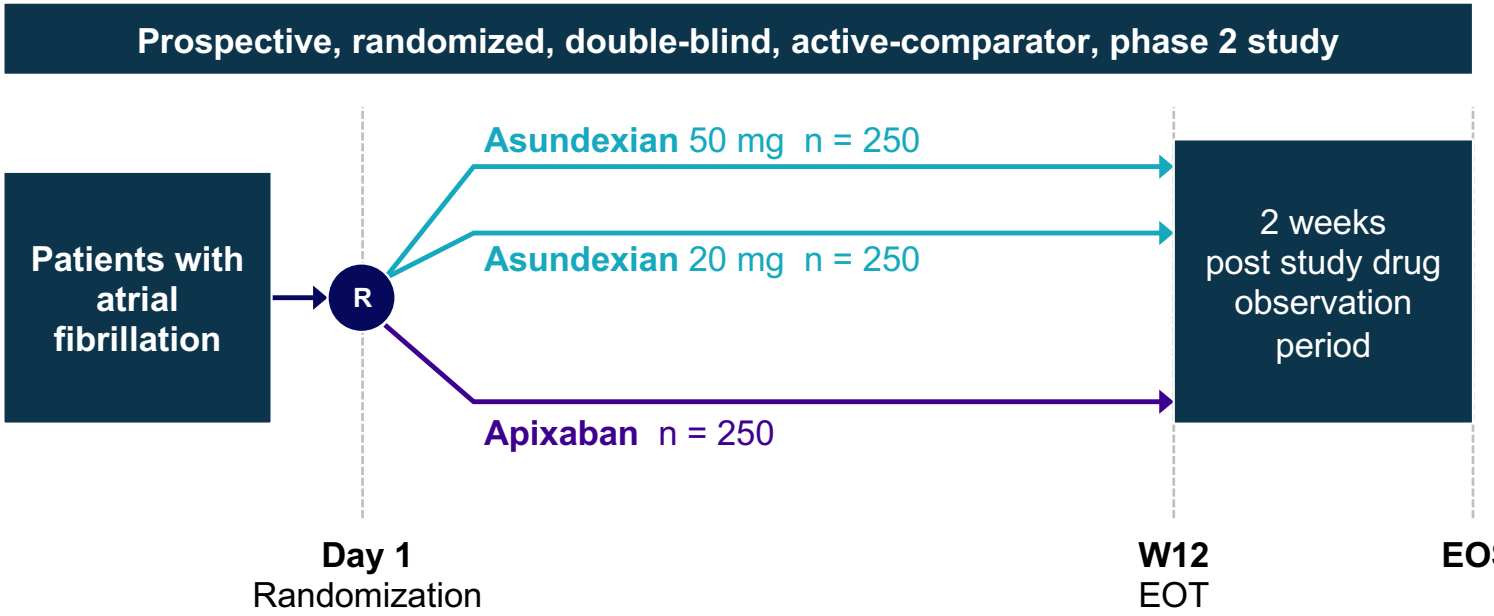
Randomized, Active Comparator-Controlled, Double-Blind, Double-Dummy, Parallel-Group, Dose-Finding Phase 2 Study to Compare the Safety of the Oral FXIa Inhibitor Asundexian with Apixaban in Patients with Atrial Fibrillation (PACIFIC-AF)



Primary safety endpoint: bleeding (ISTH major and non-major clinically relevant bleeding)

Quantification of Factor XI inhibition

Exploratory efficacy endpoint: stroke, systemic embolism, CV death, MI

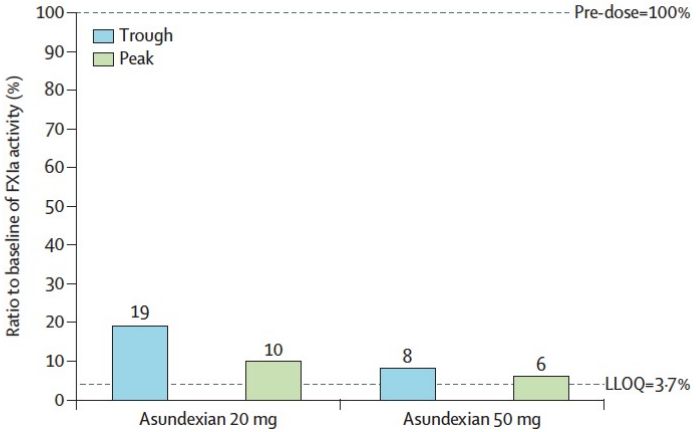
Primary Objective: to evaluate that the oral FXIa inhibitor Asundexian when compared with Apixaban leads to a **lower incidence of bleeding** in participants with atrial fibrillation

PACIFIC-AF: Phase 2 Study in Patients with Atrial Fibrillation

Safety of the oral factor XIa inhibitor asundexian compared with apixaban in patients with atrial fibrillation (PACIFIC-AF): a multicentre, randomised, double-blind, double-dummy, dose-finding phase 2 study

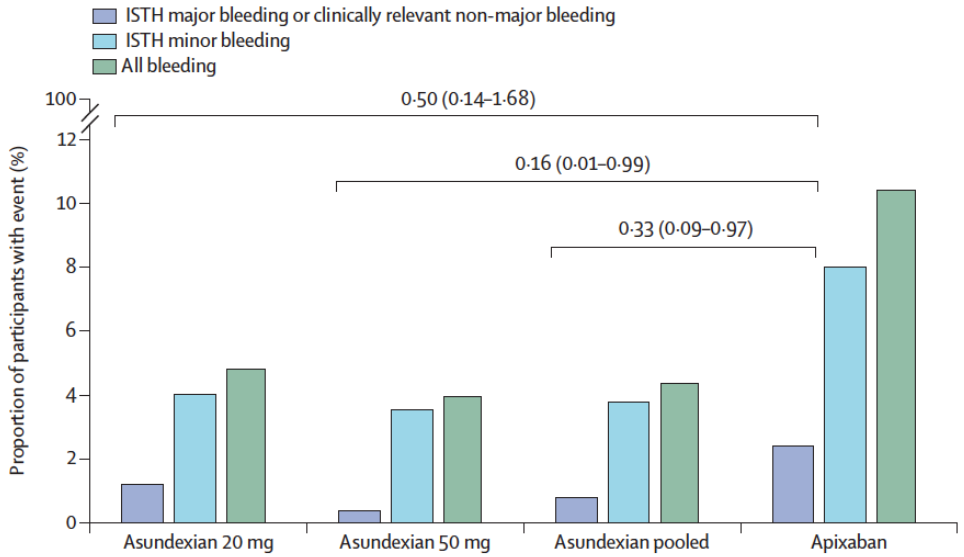
*Jonathan P Piccini, Valeria Caso, Stuart J Connolly, Keith A A Fox, Jonas Oldgren, W Schuyler Jones, Diana A Gorog, Václav Durdil, Thomas Viethen, Christoph Neumann, Hardi Mundl, Manesh R Patel, on behalf of the PACIFIC-AF Investigators**

FXIa Activity — Inhibition Data



	Asundexian 20 mg		Asundexian 50 mg	
n	224	222	228	228
Analysis value (95% CI)	14·82 (12·65–16·99)	7·42 (6·33–8·51)	6·59 (5·15–8·02)	4·32 (3·60–5·05)
Mean ratio to baseline (95% CI)	0·19 (0·16–0·22)	0·10 (0·08–0·12)	0·08 (0·07–0·10)	0·06 (0·05–0·07)

Primary Safety Outcome (ISTH bleeding classification)



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Hypothesis

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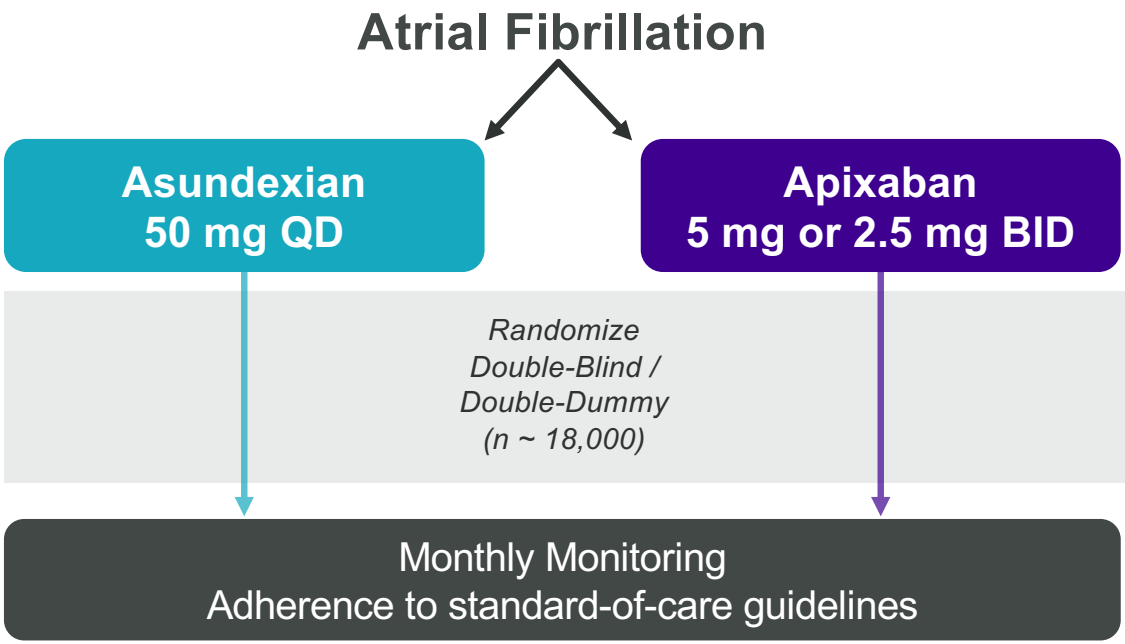
Hypothesis

Asundexian at 50 mg daily will be at least **non-inferior** to Apixaban for the prevention of stroke or systemic embolism in patients with atrial fibrillation at risk for stroke.

Also powered to determine if Asundexian is **superior** to Apixaban for reduction in ISTH major bleeding and net clinical benefit combining stroke, systemic embolism, and ISTH major bleeding.

OCEANIC-AF Study Design



Sample size of 18,000 (24 months randomization) allows for reaching **340 primary efficacy (90% power) events** within 33 months for incidence rate 1.5.

Primary Efficacy Endpoint: Stroke or Systemic Embolism

Primary Safety Endpoint: ISTH Major Bleeding

Primary Net Clinical Benefit Endpoint: Stroke or Systemic Embolism and ISTH Major Bleeding

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Inclusion Criteria

Patients will be eligible for the study if they have:

- Atrial fibrillation* with indication for indefinite treatment with an anticoagulant
- A CHA_2DS_2-VASc score ≥ 3 if male or ≥ 4 if female

OR

- A CHA_2DS_2-VASc score of 2 if male or 3 if female **AND at least 1 of the following:**
  - age ≥ 70 years
  - previous stroke, transient ischemic attack, or systemic embolism
  - renal dysfunction with CKD-EPI eGFR < 50 mL/min/1.73m^2 within 14 days prior to randomization
  - prior episode of non-traumatic major bleeding
  - current single agent antiplatelet therapy planned for at least the next 6 months
  - ≤ 6 consecutive weeks of treatment with oral anticoagulant prior to randomization (OAC Naïve)

** Documented on 6 (or more) lead EKG or as ≥ 30 seconds on continuous rhythm strip in last 12 months*

Key Exclusion Criteria

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Patients will be not eligible for the study:

- Mechanical heart valve prosthesis (not including transcatheter aortic valve replacement)
- Moderate-to-severe mitral stenosis at the time of inclusion into the study
- Atrial fibrillation only due to reversible cause (e.g., thyrotoxicosis, endocarditis, pneumonia, pulmonary embolism)
- Participants after successful ablation therapy without documented recurrent atrial fibrillation or participants after left atrial appendage (LAA) occlusion / exclusion or plan for ablation or LAA occlusion / exclusion within the next 6 months starting from randomization
- Recent ischemic stroke (within 7 days prior to randomization)
- eGFR < 25 mL/min/1.73m^2 within 14 days prior to randomization or on dialysis or expected to be started on dialysis within the next 12 months starting from randomization
- Requirement for chronic anticoagulation for a different indication than atrial fibrillation, e.g., mechanical heart valve or left ventricular cardiac thrombus (atrial thrombus is allowed), or dual antiplatelet therapy (single agent therapy is allowed)

Study Results

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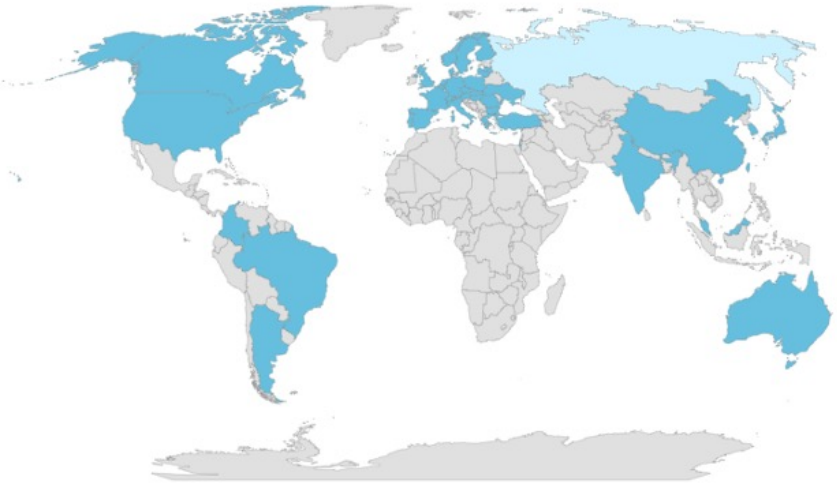
IDMC Recommends Stopping OCEANIC-AF

- From December 2022 to November 2023, 14,830 of the planned 18,000 patients had been randomized
- IDMC recommended stopping OCEANIC-AF to the EC and study team due to inferiority of Asundexian to Apixaban for the prevention of stroke and systemic embolism
- November 19th, 2023: Sites notified worldwide
  - // Patients transition to open-label therapy and close-out visits conducted across the world



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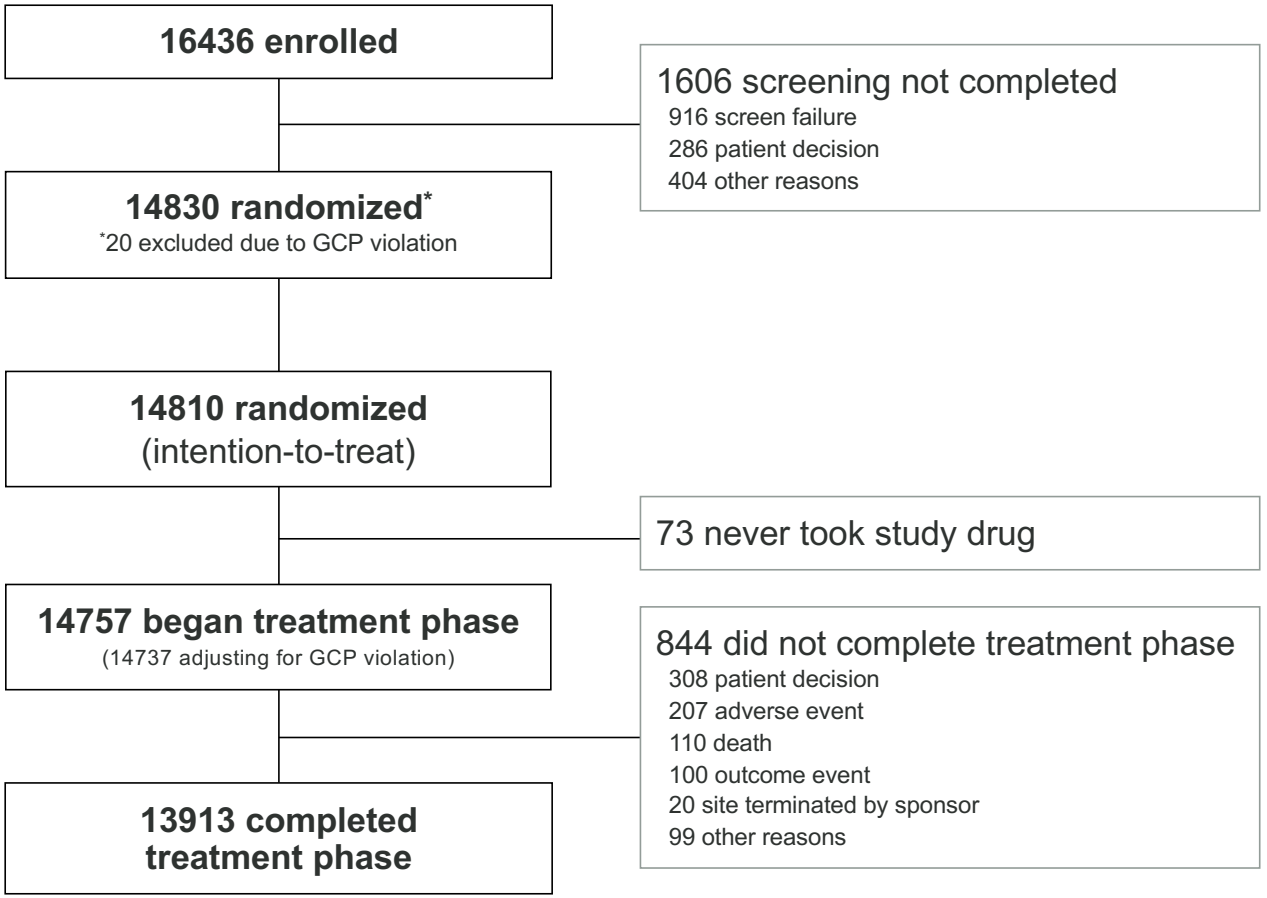
Patient Disposition



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Patient Demographics

	Asundexian 50 mg (N=7415)	Apixaban (N=7395)	Total (N=14,810)
Age, mean (SD), yrs	73.9 (7.7)	73.9 (7.7)	73.9 (7.7)
Female	2656 (35.8%)	2558 (34.6%)	5214 (35.2%)
Race, White	5216 (70%)	5211 (70%)	10,427 (70%)
Region			
Eastern Europe	1520 (20.5%)	1515 (20.5%)	3035 (20.5%)
North America	1405 (18.9%)	1406 (19.0%)	2811 (19.0%)
South America	400 (5.4%)	401 (5.4%)	801 (5.4%)
Asia	2114 (28.5%)	2108 (28.5%)	4222 (28.5%)
Western EU, Australia, Israel	1976 (26.6%)	1965 (26.6%)	3941 (26.6%)
≤6 weeks of prior OAC use (DOAC or warfarin)	1238 (16.7%)	1255 (17.0%)	2493 (16.8%)
SAPT for >6 months	742 (10.0%)	743 (10.0%)	1485 (10.0%)
CHA_2DS_2-VASc score mean (SD)	4.3 (1.3)	4.3 (1.3)	4.3 (1.3)
Type of AF			
First detected	118 (1.6%)	134 (1.8%)	252 (1.7%)
Paroxysmal	2760 (37%)	2641 (36%)	5401 (36%)
Persistent	1773 (24%)	1805 (24%)	3578 (24%)
Long-standing persistent	436 (5.9%)	428 (5.8%)	864 (5.8%)
Permanent	2327 (31%)	2384 (32%)	4711 (32%)

Patient Demographics

Comorbidities	Asundexian 50 mg (N=7415)	Apixaban (N=7395)	Total (N=14,810)
Hypertension	6558 (88.4%)	6565 (88.8%)	13123 (88.6%)
Hyperlipidemia	4747 (64.0%)	4719 (63.8%)	9466 (63.9%)
Heart failure	3456 (46.6%)	3473 (47.0%)	6929 (46.8%)
Coronary artery disease	2496 (33.7%)	2452 (33.2%)	4948 (33.4%)
Diabetes mellitus	2722 (36.7%)	2748 (37.2%)	5470 (36.9%)
Chronic kidney disease	1399 (18.9%)	1357 (18.4%)	2756 (18.6%)
Obstructive sleep apnea	786 (10.6%)	744 (10.1%)	1530 (10.3%)
Peripheral artery disease	442 (6.0%)	485 (6.6%)	927 (6.3%)
Deep venous thrombosis	170 (2.3%)	162 (2.2%)	332 (2.2%)
Gastrointestinal bleed	276 (3.7%)	214 (2.9%)	490 (3.3%)
Hyperuricemia	841 (11.3%)	763 (10.3%)	1604 (10.8%)
Osteoarthritis	951 (12.8%)	984 (13.3%)	1935 (13.1%)
Gastroesophageal reflux disease	775 (10.5%)	766 (10.4%)	1541 (10.4%)
Anemia	1432 (19.3%)	1346 (18.2%)	2778 (18.8%)
Stroke or TIA	1389 (18.7%)	1305 (17.6%)	2694 (18.2%)

Primary Results

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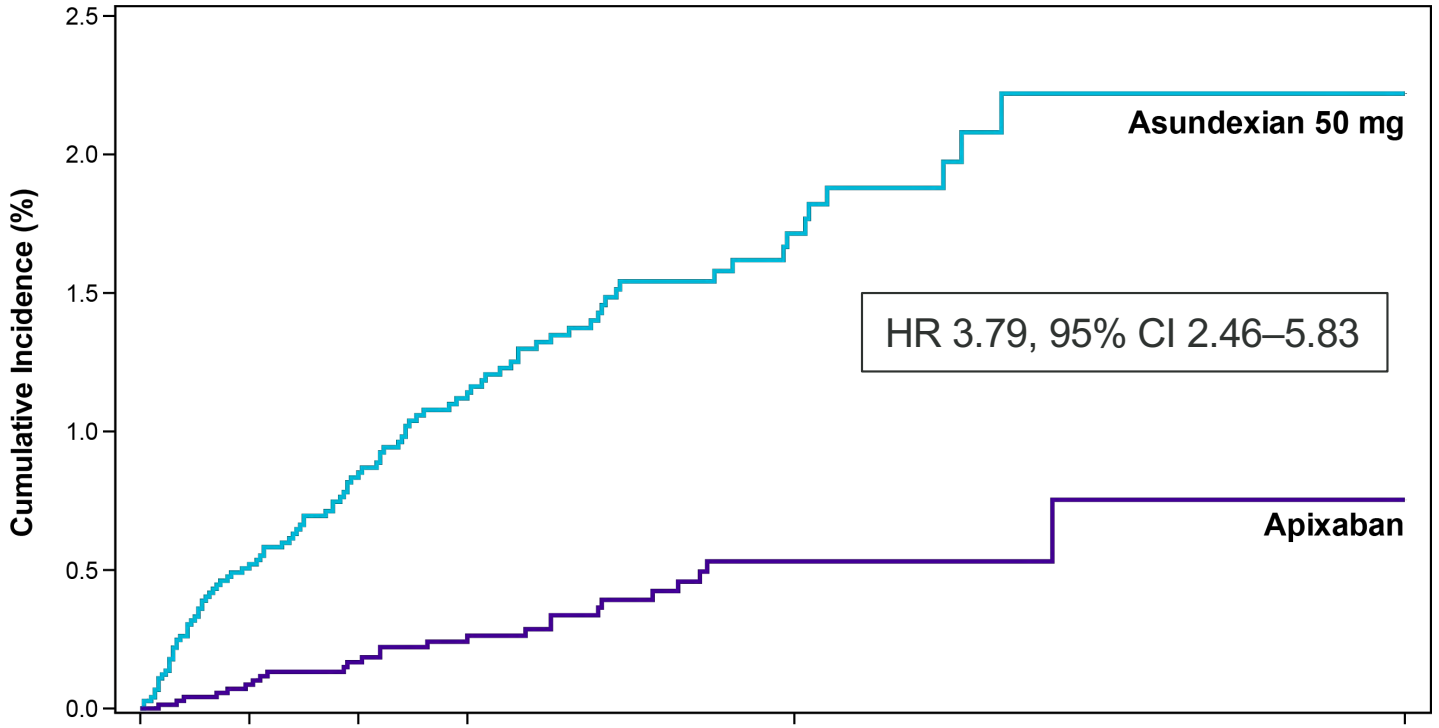
Cumulative Event Rate for the Primary Efficacy Endpoint



Median follow-up: 160 days

Number of participants at risk

Asundexian 50 mg	7415	6564	5574	4622	1958	1
Apixaban	7395	6596	5624	4657	1979	0

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Efficacy Events

Efficacy Events According to ITT	Asundexian (N=7415)	Apixaban (N=7395)	Total (N=14,810)	csHR (95% CI)*
Stroke or SE	98 (1.3%)	26 (0.4%)	124 (0.8%)	3.79 (2.46–5.83)
Ischemic stroke or SE	96 (1.3%)	22 (0.3%)	118 (0.8%)	4.38 (2.76–6.96)
All-cause mortality	60 (0.8%)	71 (1.0%)	131 (0.9%)	0.84 (0.60–1.19)
Ischemic stroke	85 (1.1%)	21 (0.3%)	106 (0.7%)	4.06 (2.52–6.54)
CV death	48 (0.6%)	44 (0.6%)	92 (0.6%)	1.09 (0.72–1.64)
CV death, MI, or stroke	155 (2.1%)	77 (1.0%)	232 (1.6%)	2.02 (1.54–2.66)

*Derived from a stratified cause-specific Cox proportional hazards regression model. Cumulative Incidence Rates provided
CI indicates confidence interval; csHR, cause-specific hazard ratio; CV, cardiovascular; ITT, intention to treat; MI, myocardial infarction; SE, systemic embolism.

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Safety Events

	Asundexian 50 mg (N=7373)	Apixaban (N=7364)	Total (N=14,737)	csHR (95% CI)†
ISTH major bleeding	17 (0.2%)	53 (0.7%)	70 (0.5%)	0.32 (0.18–0.55)
ISTH major and CRNM bleeding	83 (1.1%)	188 (2.6%)	271 (1.8%)	0.44 (0.34–0.57)
ISTH CRNM bleeding	67 (0.9%)	140 (1.9%)	207 (1.4%)	0.48 (0.36–0.64)
Hemorrhagic stroke	1 (<0.1%)	6 (0.1%)	7 (<0.1%)	0.17 (0.02–1.42)
Symptomatic intracranial hemorrhage	3 (<0.1%)	18 (0.2%)	21 (0.1%)	0.16 (0.05–0.55)
Fatal bleeding	0 (0%)	4 (0.1%)	4 (<0.1%)	Not calculated
ISTH minor bleeding	187 (2.5%)	317 (4.3%)	504 (3.4%)	0.59 (0.49–0.70)
Stroke, SE, or ISTH major bleeding (net clinical benefit endpoint)	120 (1.6%)	75 (1.0%)	195 (1.3%)	1.61 (1.21–2.15)

*The primary safety estimand is the cause-specific hazard ratio of ISTH major bleeding when treatment with Asundexian is compared with treatment with Apixaban in adult patients with atrial fibrillation at risk for stroke who have taken at least one dose of Asundexian or Apixaban while alive and while exposed to Asundexian or Apixaban.
†Cause-specific hazard ratios and their associated 95% confidence intervals were derived from a stratified cause-specific Cox proportional hazards regression model.
CI indicates confidence interval; CRNM, clinically relevant non-major; csHR, cause-specific hazard ratio; ISTH, International Society on Thrombosis and Haemostasis; SE, systemic embolism.

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Adverse Events

	Asundexian 50 mg (N=7373)	Apixaban (N=7364)	Total (N=14,737)
Any treatment-emergent adverse event (TEAE)	2573 (35%)	2569 (35%)	5142 (35%)
Any study intervention-related TEAE	385 (5.2%)	502 (6.8%)	887 (6.0%)
Any TEAE leading to discontinuation of study intervention	147 (2.0%)	118 (1.6%)	265 (1.8%)
Any serious TEAE	582 (7.9%)	599 (8.1%)	1181 (8.0%)
Any study intervention-related serious TEAE	27 (0.4%)	47 (0.6%)	74 (0.5%)
Any serious TEAE leading to discontinuation of study intervention	38 (0.5%)	35 (0.5%)	73 (0.5%)
TEAE with outcome death	29 (0.4%)	43 (0.6%)	72 (0.5%)

Key Data and Subgroup Evaluation

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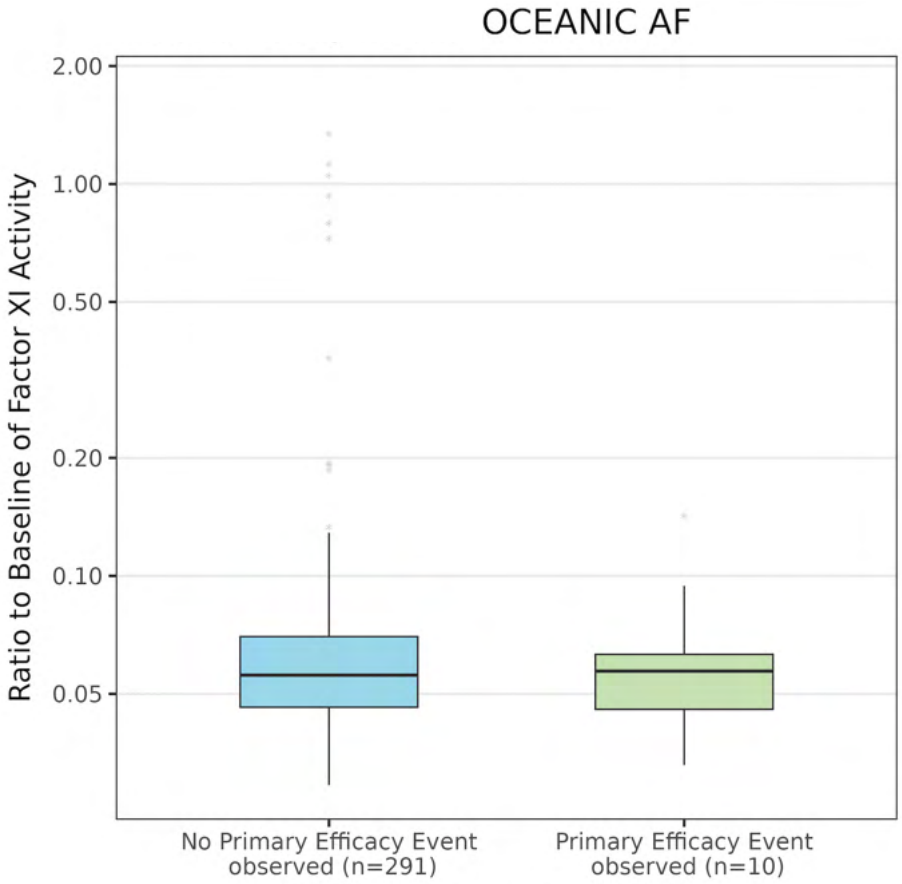
Factor XI Activity

- Planned PK/PD substudy in OCEANIC-AF patients with evaluation at 4 weeks post-randomization
- PK (not shown) was similar between OCEANIC-AF and PACIFIC-AF
- Factor XI activity at trough was similar between OCEANIC-AF (8.1%) and PACIFIC-AF (8.0%)
- Limited number of patients with primary efficacy events but no observed differences in Factor XI activity



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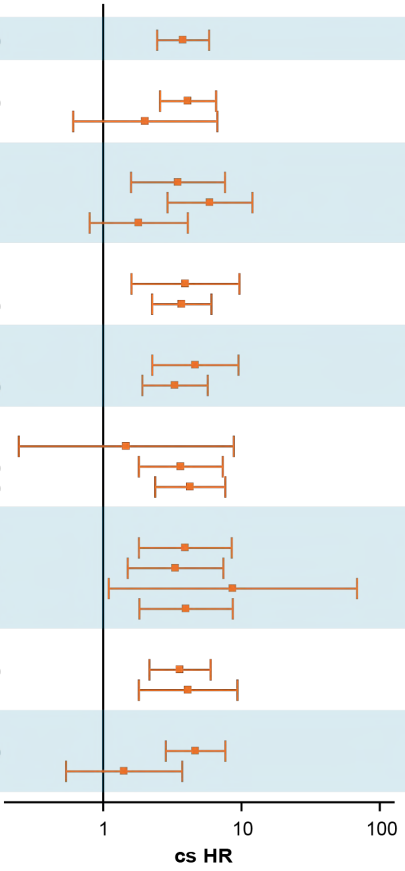
Subgroup Evaluation

	Asundexian 50mg n/N (%)	Apixaban n/N (%)	CoxPH model csHR (95% CI)
Overall	98/7415 (1.3%)	26/7395 (0.4%)	3.79 (2.46, 5.83)
Single agent antiplatelet therapy planned to continue for ≥6 months after randomization			
No	90/6673 (1.3%)	22/6652 (0.3%)	4.11 (2.58, 6.55)
Yes	8/742 (1.1%)	4/743 (0.5%)	2.01 (0.61, 6.69)
eGFR group (mL/min/1.73m²)			
<50	29/1347 (2.2%)	8/1289 (0.6%)	3.48 (1.59, 7.60)
50 to 80	53/3854 (1.4%)	9/3854 (0.2%)	5.92 (2.92, 11.99)
>80	16/2133 (0.8%)	9/2162 (0.4%)	1.81 (0.80, 4.09)
Pooled CHA_2DS_2-VASc score Group 1			
≤3 for males and ≤4 for females	23/3077 (0.7%)	6/3132 (0.2%)	3.93 (1.60, 9.66)
>3 for males and >4 for females	75/4338 (1.7%)	20/4263 (0.5%)	3.70 (2.26, 6.06)
Sex			
Female	43/2656 (1.6%)	9/2558 (0.4%)	4.64 (2.26, 9.52)
Male	55/4759 (1.2%)	17/4837 (0.4%)	3.31 (1.92, 5.70)
Age group			
<65 years	3/730 (0.4%)	2/715 (0.3%)	1.47 (0.25, 8.80)
65–75 years	37/3455 (1.1%)	10/3403 (0.3%)	3.64 (1.81, 7.32)
>75 years	58/3230 (1.8%)	14/3277 (0.4%)	4.26 (2.38, 7.64)
Atrial fibrillation pattern			
Paroxysmal	33/2760 (1.2%)	8/2641 (0.3%)	3.93 (1.81, 8.50)
Persistent	25/1773 (1.4%)	8/1805 (0.4%)	3.34 (1.50, 7.40)
Long-standing persistent	9/436 (2.1%)	1/428 (0.2%)	8.67 (1.10, 68.48)
Permanent	31/2327 (1.3%)	8/2384 (0.3%)	3.97 (1.83, 8.65)
History of stroke or TIA			
No	67/6026 (1.1%)	19/6090 (0.3%)	3.59 (2.16, 5.98)
Yes	31/1389 (2.2%)	7/1305 (0.5%)	4.11 (1.81, 9.34)
≤6 consecutive weeks of treatment with oral anticoagulant prior to randomization			
No	88/6177 (1.4%)	19/6140 (0.3%)	4.66 (2.84, 7.65)
Yes	10/1238 (0.8%)	7/1255 (0.6%)	1.42 (0.54, 3.73)



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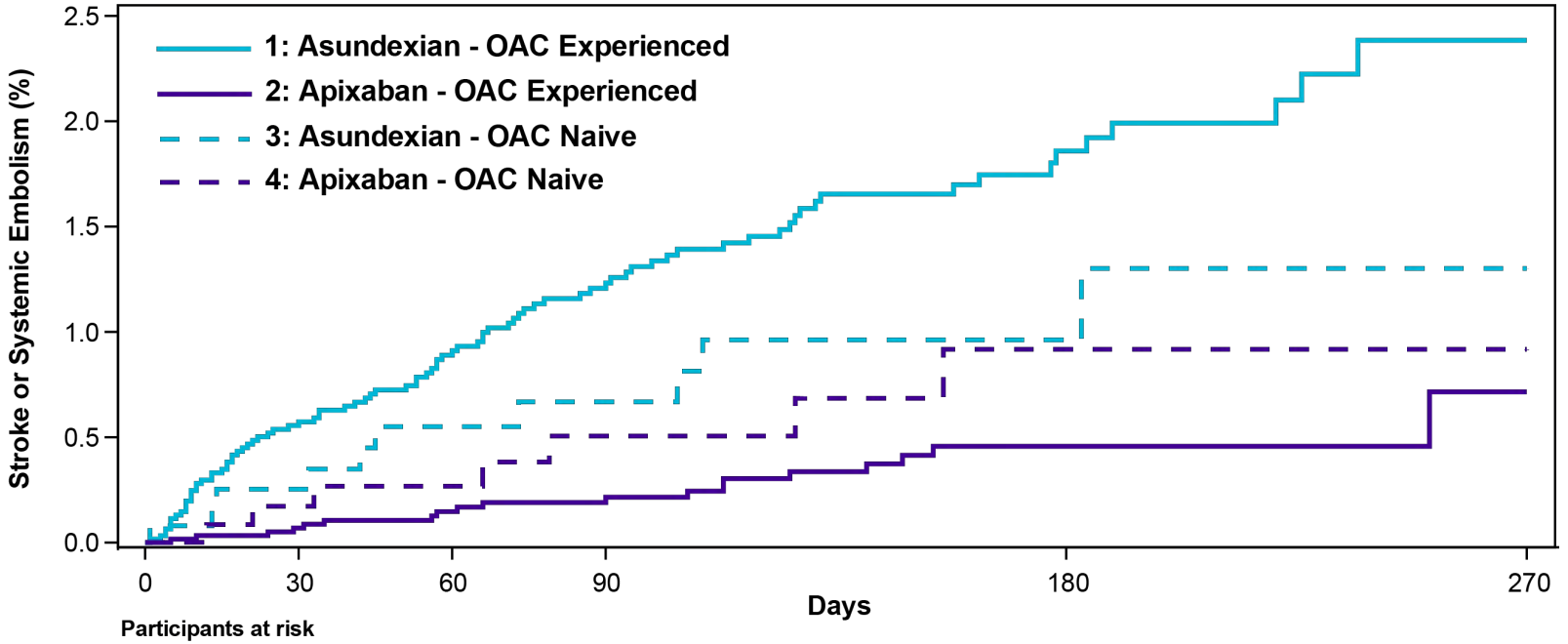
Pre-specified Exploratory Hypothesis Generating: OAC Naïve or OAC Experienced Assigned to Asundexian or Apixaban



OAC Experienced
HR 95% C.I.
4.66 (2.84–7.65)

OAC Naïve*
HR 95% C.I.
1.42 (0.54–3.73)

Participants at risk						
1	6177	5500	4683	3874	1648	192
2	6140	5519	4734	3924	1682	182
3	1238	1064	891	748	310	26
4	1255	1077	890	733	297	30

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* ≤ 6 consecutive weeks of treatment with oral anticoagulant prior to randomization (OAC Naïve)

OAC Naïve vs. OAC Experienced

	OAC Naïve* (N=2493)			OAC Experienced (N=12,317)			
	Asundexian (N=1238) n (%) Events/100 pt-yrs (95% CI)	Apixaban (N=1255) n (%) Events/100 pt-yrs (95% CI)	HR (95% CI)	Asundexian (N=6177) n (%) Events/100 pt-yrs (95% CI)	Apixaban (N=6140) n (%) Events/100 pt-yrs (95% CI)	HR (95% CI)	P value Interaction
Stroke or systemic embolism	10/1238 (0.8%) 2.45 (1.18–4.19)	7/1255 (0.6%) 1.73 (0.70–3.23)	1.42 (0.54–3.73)	88/6177 (1.4%) 4.12 (3.31–5.03)	19/6140 (0.3%) 0.88 (0.53–1.32)	4.66 (2.84–7.65)	0.03
Ischemic stroke or systemic embolism	10/1238 (0.8%) 2.45 (1.18–4.19)	5/1255 (0.4%) 1.24 (0.40–2.53)	2.00 (0.68–5.85)	86/6177 (1.4%) 4.03 (3.22–4.92)	17/6140 (0.3%) 0.79 (0.46–1.21)	5.09 (3.02–8.56)	0.12
Ischemic stroke	9/1238 (0.7%) 2.21 (1.01–3.86)	5/1255 (0.4%) 1.24 (0.40–2.53)	1.80 (0.60–5.39)	76/6177 (1.2%) 3.55 (2.80–4.40)	16/6140 (0.3%) 0.74 (0.43–1.15)	4.77 (2.78–8.18)	0.12
Cardiovascular death	8/1238 (0.6%) 1.95 (0.84–3.52)	11/1255 (0.9%) 2.71 (1.35–4.53)	0.77 (0.31–1.92)	40/6177 (0.6%) 1.86 (1.33–2.47)	33/6140 (0.5%) 1.53 (1.05–2.10)	1.21 (0.76–1.92)	0.33
CV death, MI, or stroke	25/1238 (2.0%) 6.17 (3.99–8.81)	20/1255 (1.6%) 4.95 (3.02–7.34)	1.31 (0.72–2.35)	130/6177 (2.1%) 6.10 (5.09–7.19)	57/6140 (0.9%) 2.65 (2.01–3.38)	2.29 (1.68–3.13)	0.08
All-cause death	9/1238 (0.7%) 2.19 (1.00–3.84)	17/1255 (1.4%) 4.19 (2.44–6.40)	0.56 (0.25–1.26)	51/6177 (0.8%) 2.37 (1.76–3.06)	54/6140 (0.9%) 2.51 (1.88–3.22)	0.94 (0.64–1.38)	0.22

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* ≤ 6 consecutive weeks of treatment with oral anticoagulant prior to randomization (OAC Naïve)

Conclusions and Implications

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Conclusions

- Over 14,810 patients with atrial fibrillation at risk for stroke were enrolled over 11 months worldwide.
- Asundexian 50 mg once daily was inferior for prevention of stroke and systemic embolism compared with Apixaban in patients with atrial fibrillation at high risk for stroke.
  - // The majority of patients (83%) had previously been treated with OAC.
  - // Observed rate of stroke and systemic embolism on Apixaban in this high-risk population was lower than previously observed.

Implications

- More research is needed to determine the correct amount of FXIa inhibition for atrial fibrillation stroke prevention.
  - Ongoing patient risk adjusted analyses of PK/PD, FXI activity, and stroke rates.
  - Near total suppression of FXIa activity may be required for this indication.
- Prior use of oral anticoagulants without clinical issues and current medical therapies may lead to lower rates of stroke and systemic embolism and bleeding compared with historical data based on patient risk.
- Multiple ongoing studies with Factor XI inhibition in different indications are ongoing with IDMC oversight. These will be informative to the effect of targeting Factor XI on patient care.

Thank You

Executive Committee

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ORIGINAL ARTICLE

Asundexian versus Apixaban in Patients with Atrial Fibrillation

J.P. Piccini, M.R. Patel, J. Steffel, K. Ferdinand, I.C. Van Gelder, A.M. Russo, C.-S. Ma, S.G. Goodman, J. Oldgren, C. Hammett, R.D. Lopes, M. Akao, R. De Caterina, P. Kirchhof, D.A. Gorog, M. Hemels, M. Rienstra, W.S. Jones, J. Harrington, G.Y.H. Lip, S.J. Ellis, F.W. Rockhold, C. Neumann, J.H. Alexander, T. Viethen, J. Hung, R. Coppolecchia, H. Mundl, and V. Caso, for the OCEANIC-AF Steering Committee and Investigators*

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