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REGULATORY · PHASE 3 DOSE SELECTION

One dose, two Phase 3 trials, two verdicts.

Asundexian 50 mg: approved in stroke, stopped in atrial fibrillation.

SWIPE →

Stroke: better than placebo, on top of antiplatelets.

6.2% vs 8.4%

ISCHEMIC STROKE, ASUNDEXIAN VS PLACEBO (OCEANIC-STROKE)

Hazard ratio 0.74. FDA approval 9 November 2026, 50 mg once daily. Major bleeding similar overall, higher above 75 years and in the first 90 days.

Atrial fibrillation: worse than apixaban.

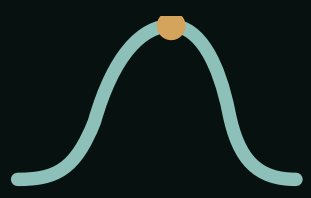
1.3% vs 0.4%

STROKE OR SYSTEMIC EMBOLISM, ASUNDEXIAN VS APIXABAN (OCEANIC-AF)

Same 50 mg once daily. The trial was stopped early on the data monitoring committee's advice. Major bleeding was lower: 0.2% vs 0.7%.

Hitting the target is not beating the comparator.

- Phase 2 in AF was a bleeding study: 50 mg gave 92% factor XIa inhibition at the lowest drug level, 94% at peak
- Phase 2 in stroke tested 10, 20 and 50 mg and showed no dose-response on its primary endpoint
- Against an active comparator, we would not take one dose into Phase 3 on target engagement and bleeding data alone



Find the model-informed path through drug development.

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