Effect of abelacimab vs. rivaroxaban on total bleeding events in patients with atrial fibrillation:

An Analysis from AZALEA–TIMI 71

Siddharth M. Patel, Robert P. Giugliano, David A. Morrow, Sabina A. Murphy, Sanobar Parkar, Shih-Ann Chen, Shaun G. Goodman, Boyoung Joung, Robert G. Kiss, Wojciech Wojakowski, Jeffrey I. Weitz, Daniel Bloomfield, Marc S. Sabatine, Christian T. Ruff

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Background

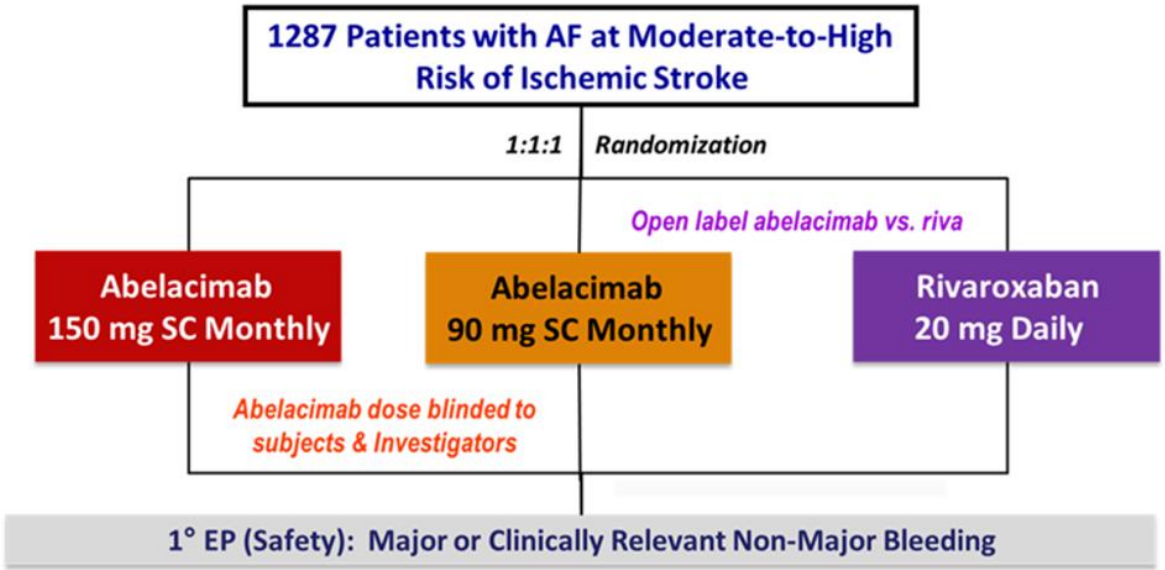
- In AZALEA-TIMI 71, **abelacimab**, a monoclonal antibody that inhibits factor XI, **substantially reduced the risk of first major or clinically relevant non-major (CRNM) bleeding** by >60% vs. rivaroxaban in patients with atrial fibrillation (AF).
- **Subsequent bleeding** episodes with ongoing anticoagulation are **common** and remain an **important safety concern** for patients and providers, often leading to **anticoagulation interruption** or even **discontinuation**.

Objective

- To examine the safety of abelacimab vs. rivaroxaban with respect to total bleeding events in patients with AF.

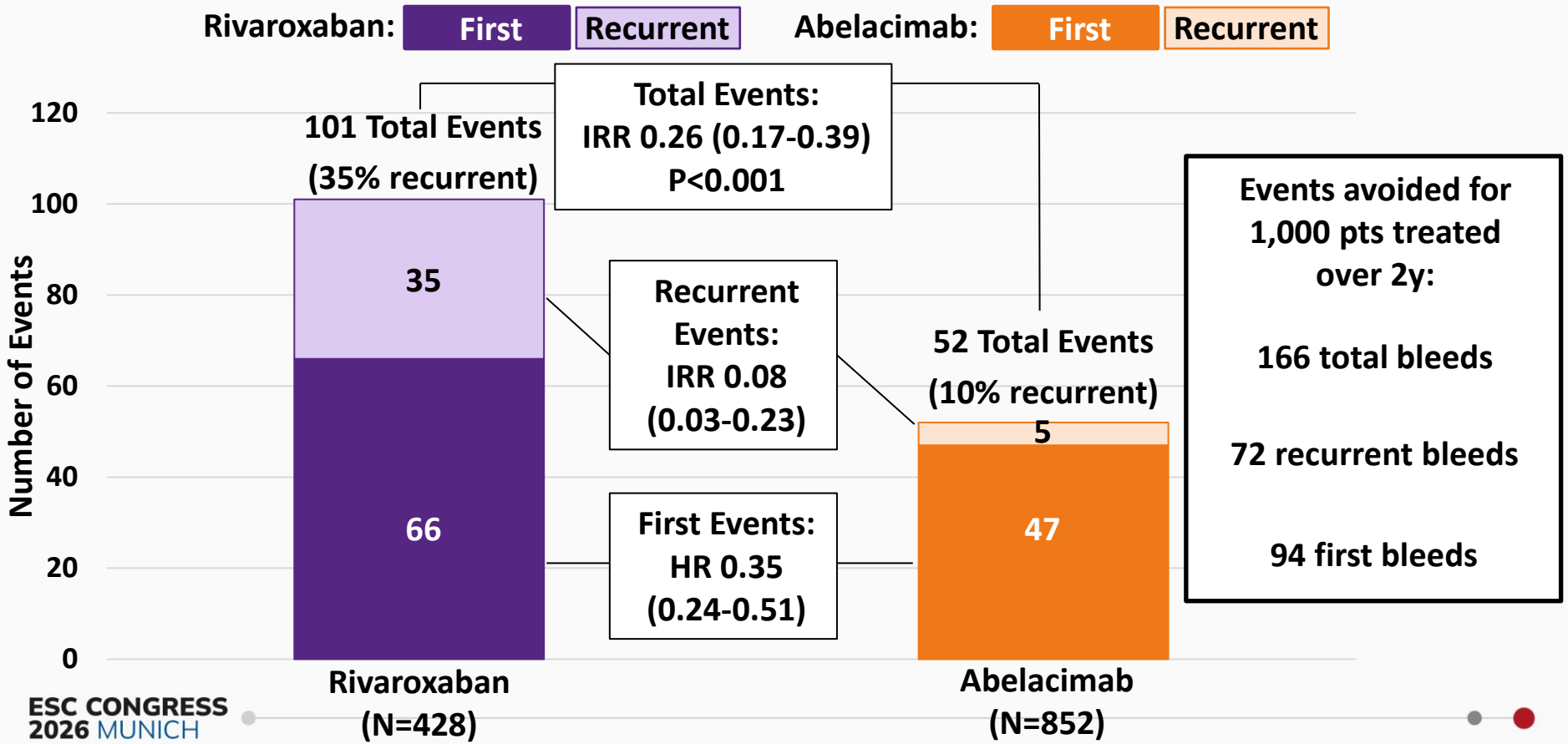
Methods

AZALEA Trial Design

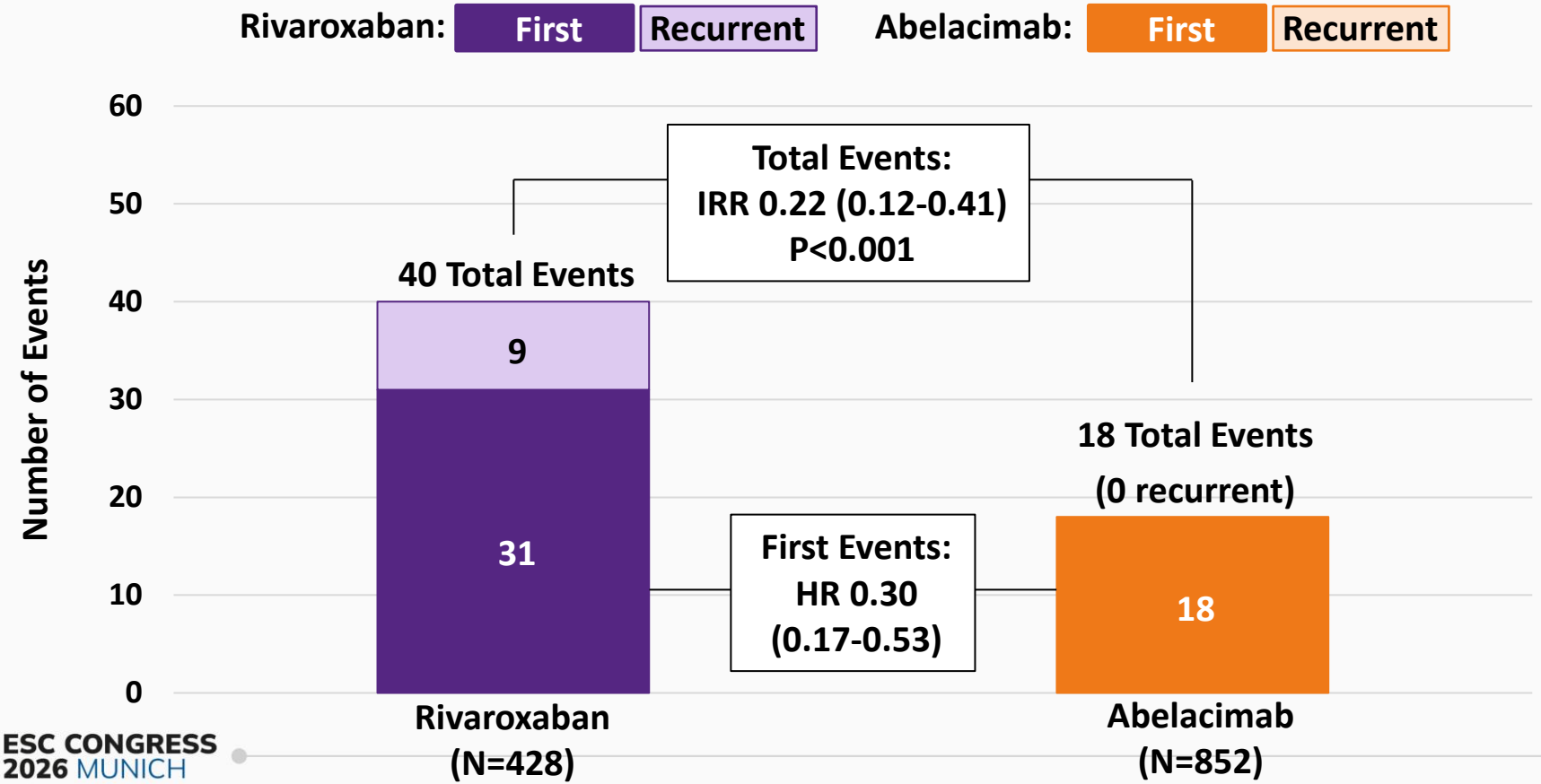


- Bleeding events adjudicated by independent CEC.
- Analyses are **on-treatment**, including events within 60d of study drug dosing.
  - Abelacimab arms pooled.
- Negative binomial regression to examine safety of abelacimab vs. rivaroxaban for total bleeding events.
  - Estimates summarized by incidence rate ratio (IRR).

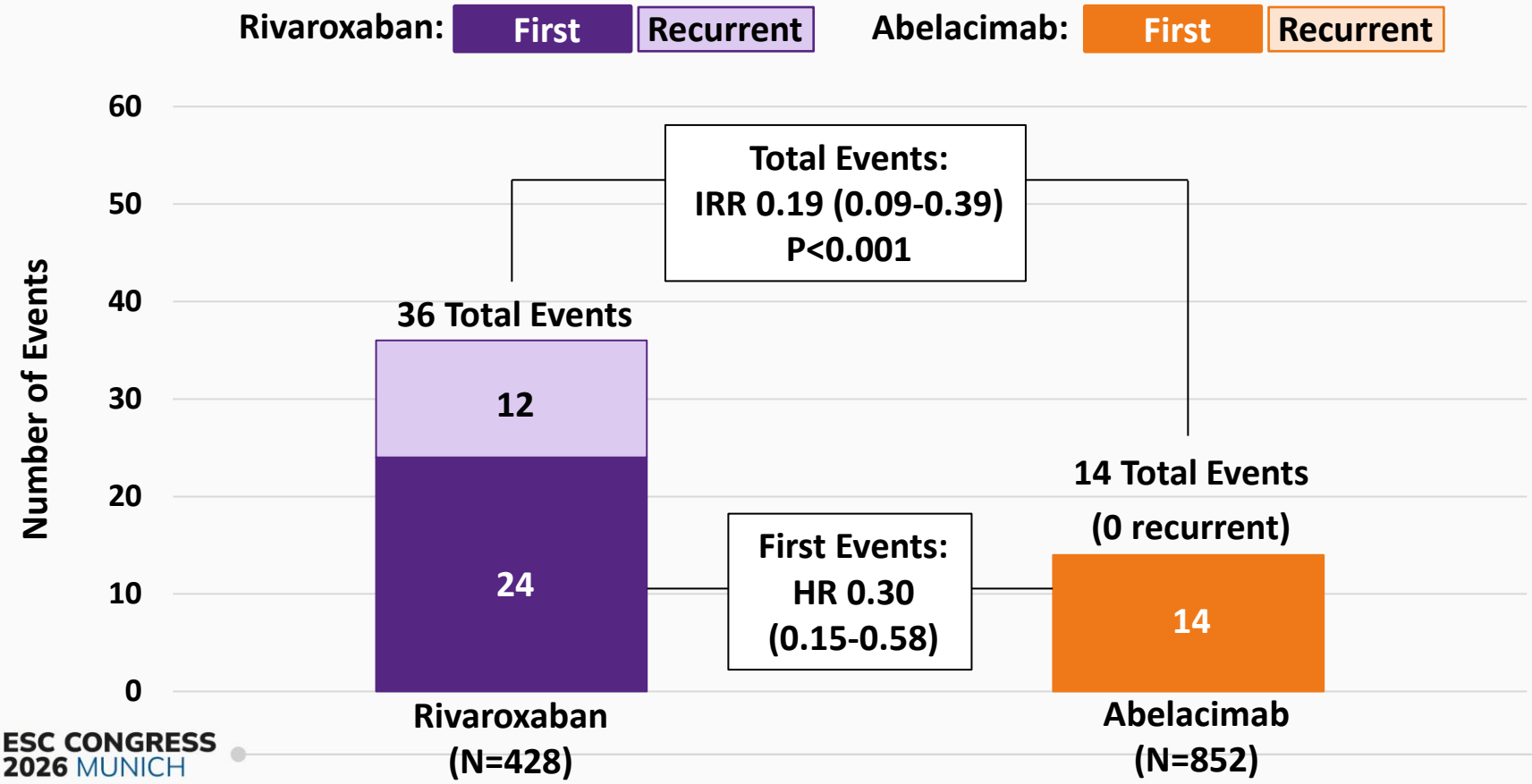
ISTH Major or CRNM Bleeding



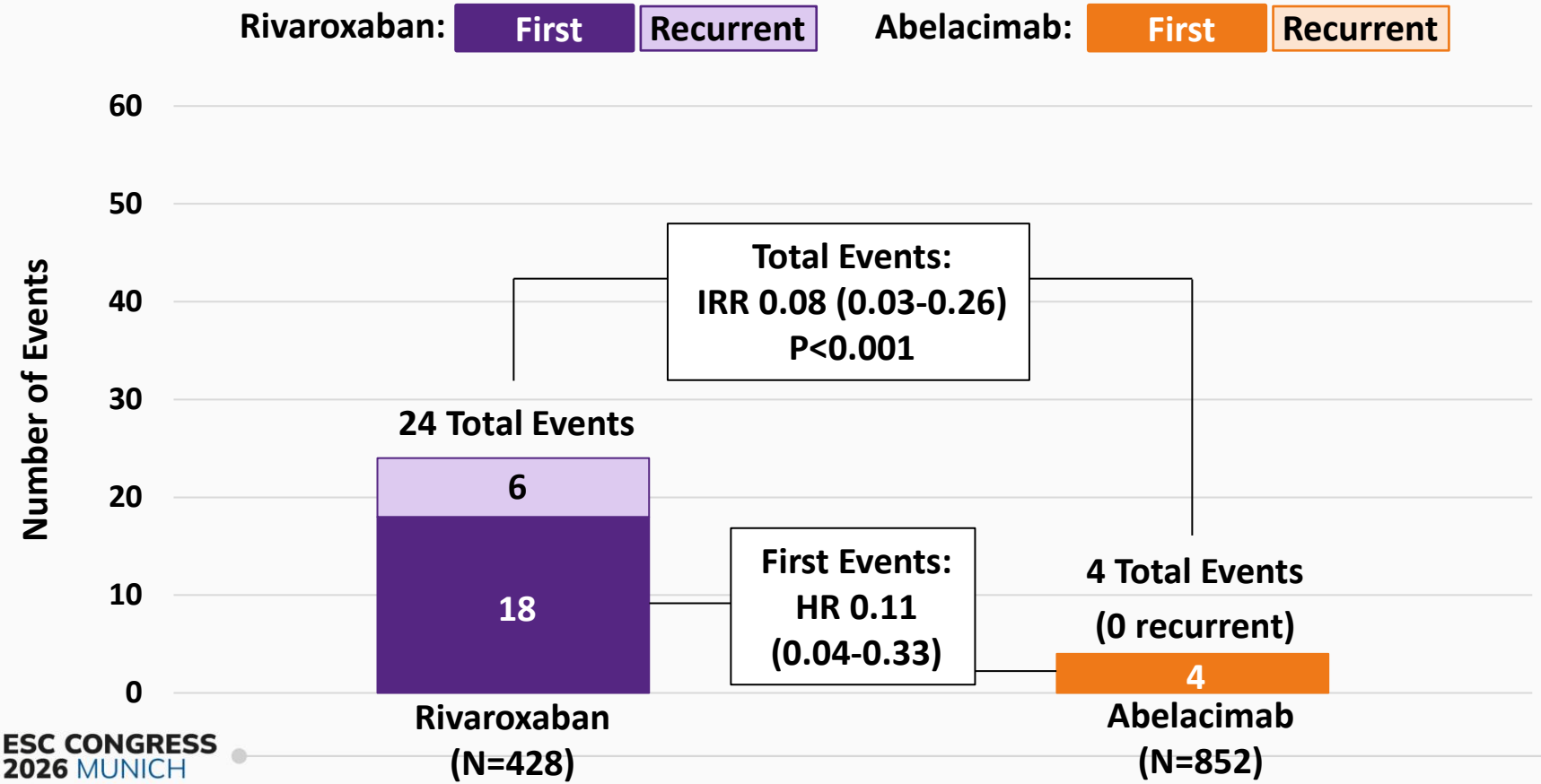
ISTH Major Bleeding



ISTH Major or CRNM GI Bleeding



ISTH Major GI Bleeding



Summary

- **Compared with rivaroxaban, abelacimab substantially reduced the totality of bleeding across a range of bleeding severity (major and major/CRNM bleeding)**
  - Safety benefit consistent for total GI bleeding, which accounts for majority (~60-70%) of bleeding events with direct oral anticoagulants (DOACs)
  - 166 major/CRNM total bleeds avoided with abelacimab vs. rivaroxaban for 1,000 patients treated over 2 years
- **These data further support the safety of FXI inhibition with abelacimab in minimizing the total burden of anticoagulation-related bleeding in AF patients**