Study design

Key Inclusion Criteria

- ER+ (>10%) HER2- Early BC
- Intermediate-high or high risk of recurrence
  - T4, ≥ 2LN, T1c-T3 N0 or 1 LN and G3, high genomic risk or Ki-67 ≥ 20%
- Completed definitive locoregional therapy (surgery with or without radiotherapy), with or without (neo)adjuvant chemotherapy
- No evidence of invasive disease
- ECOG PS 0-1

Randomization 1:1

Arm A
Standard ET
(AI or TAM +/- OFS*)
+/- abemaciclib**
N=2,750

Arm B
Camizestrant 75 mg/daily
(+/- OFS)**
+/- abemaciclib**
N=2,750

Primary endpoint
IBCFS (STEEP)

Secondary endpoints
IDFS, DRFS, OS

**pre-peri-menopausal women and men will receive LHRH (for women mandatory in both arms, for men with AI only)*
*****Patients receiving Abemaciclib will be capped at a planned 30% of total population. Abemaciclib can only be prescribed in countries with regulatory approval for the broadened indication in High Risk Early Breast Cancer***

Stratification factors

• Risk of recurrence	High[a]	Intermediate-high[b]
• Menopausal status	Pre, Peri, Men	Post
• Planned use of abemaciclib	Yes	No

[a] **High-risk definition – LN affected**
- 1+N, pT1c-T3 with one of the following: Grade 3 or Ki67-high or high-risk genomic signature *or*
- 1+N, T4 *or*
- ≧ 2+N, any T

[b] **Intermediate-high risk definition – No LN affected**
- N0, pT1c-T3 with one of the following: Grade 3 or Ki67-high or high-risk genomic signature *or*
- N0, T4

CAMBRIA-2

Fortrea