Studie

Novartis – REPOWER

Real-world Evaluation of Patient Outcomes and Experinces with Ribociclib Early Adopters: A Hybrid Study with Prospective Patient-reported Outcomes and Retrospective Clinical Chart Review

Study overview

REPOWER: "Real-world Evaluation of Patient Outcomes and Experiences with Ribociclib Early Adopters: A Hybrid Study with Prospective Patient-reported Outcomes and Retrospective Clinical Chart Review"

The overall goal of this non-interventional study (NIS) is to evaluate effectiveness, persistence, treatment patterns, adverse events (AEs), and patient-reported experience (including adherence, treatment satisfaction, health-related quality of life [HRQoL], work productivity, and etc.), among HR+/HER2- stage II and III eBC patients treated with ribociclib + ET and to evaluate AEs and patients-reported experience among HR+/HER2- stage II and III eBC patients treated with abemaciclib + ET, as per local label. https://www.Novartis.com/clinicaltrials/study/nct07243002

No visits or procedures are mandated; patients are to be treated following typical standard of care (SOC). This protocol does not recommend the use of any specific treatment, and no study medication is provided as part of participation.

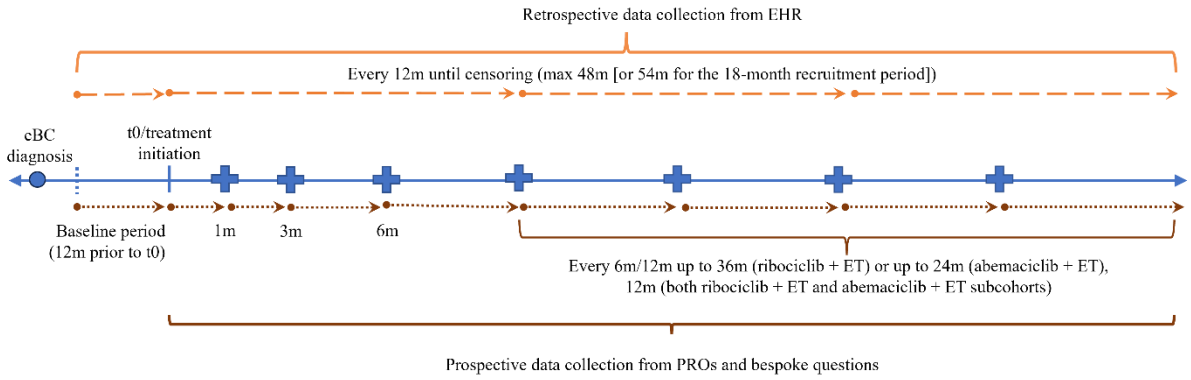
Inclusion Criteria

- Males or females.
- Diagnosed with breast cancer, as defined by the International Classification of Diseases, 9th or 10th Revision, Clinical Modification (ICD-9-CM 174.xx, 175.xx/ICD 10-CM C50.xx).
- Aged ≥18 years (or local legal age of consent) at the date of initial breast cancer diagnosis.
- Patients with anatomic staging II and III as determined using American Joint Committee on Cancer (AJCC) Criteria
- Have initiated adjuvant therapy with ribociclib or abemaciclib, per the approved local label, in combination with ET (within 14 days prior to enrollment).
- Have HR+ status, as determined by the closest biomarker test on or before the adjuvant therapy initiation date:
- Tested positive for estrogen receptor (ER+), or
- Tested positive for progesterone receptor (PR+), or
- Tested positive for both.
- Tested negative for HER2 (HER2-) using the closest biomarker test on or before the adjuvant therapy initiation date.
- Written informed consent

Exclusion Criteria

- Patients with local or distant breast cancer recurrence before the ribociclib/abemaciclib initiation date.
- Patients enrolled in clinical trials (receiving treatment with clinical study drugs in any setting, i.e., neoadjuvant, adjuvant, local/regional, metastatic) during the 12-month baseline period.
- Patients physically/mentally incapable of understanding the study requirements or fulfilling data collection instruments and require support of a legally authorized representative.

Schedule of Assessment & Visit Schedule



Time of visit	**Baseline period**	**Period between t0[1] + 14 days (Week 1)**	**1 month post-t0 (-7 days /+14 days)**	**3 months post-t0 (±14 days)**	**6 months post-t0 (±14 days)**	**Every 6 months post-t0 (±14 days) up to 36 months[2]**	**Every 12 months post-t0[3]**
Evaluation number	**0**	**1**	**2**	**3**	**4**	**NA**	**NA**
Inclusion/ Exclusion criteria	X		-	-	-	-	-
Informed consent		X	-	-	-	-	-
Physical examination		X	-	-	-	-	-
Primary and other clinical outcomes from EHR							
Effectiveness (STEEP criteria)4	-	-	-	-	-	-	X
Persistence[4]	-	-	-	-	-	-	X
Baseline characteristics – including tumor characteristics recurrence	X	-	-	-	-	-	-
Treatment patterns	-	-	-	-	-	-	X
AEs and treatment for AEs[5]	-	-	-	-	-	-	X