Breast Cancer Franchise

EarLEE Clinical Trial Program: Ribociclib Plus Endocrine Therapy for HR+/HER2- Early Breast Cancer

The EarLEE clinical trial program is designed to evaluate the safety and efficacy of ribociclib with endocrine therapy as an adjuvant treatment versus endocrine therapy alone in patients with HR+/HER2- breast cancer at intermediate or high-risk of progressing to advanced breast cancer[1].

	EarLEE-1[1,2]	EarLEE-2[1,2]
Purpose	To evaluate ribociclib in combination with endocrine therapy (tamoxifen, letrozole, anastrazole or exemestane) as an adjuvant treatment in men and women with HR+/HER2- high-risk early breast cancer	To evaluate ribociclib in combination with endocrine therapy (tamoxifen, letrozole, anastrazole or exemestane) as an adjuvant treatment in men and women with HR+/HER2- intermediate-risk early breast cancer
Trial Design	Multicenter, randomized, double-blind, placebo-controlled	
Trial Participation	Enrolling (estimated enrollment: 2,000)	Enrolling (estimated enrollment: 4,000)
Primary Endpoints	To determine the impact on invasive disease-free survival (iDFS) in high-risk patients treated with ribociclib plus endocrine therapy	To determine the impact on invasive disease-free survival (iDFS) in intermediate-risk patients treated with ribociclib plus endocrine therapy

Secondary Endpoints

• Recurrence-free survival • Distant disease-free survival • Overall survival • Quality of life

Novartis Clinical Development

Novartis is currently conducting clinical trials around the world for a number of diseases, including early and advanced breast cancer.

To learn more about all of Novartis clinical development programs, please visit **www.novartisclinicaltrials.com**.

These trials are evaluating ribociclib for investigational use. This is not a comprehensive list of ribociclib clinical trials. For more information, please go to ClinicalTrials.gov.

References:
1. ClinicalTrials.gov. U.S. National Institutes of Health, n.d. Web.
2. Novartis Data on File.

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