Novartis Clinical Trial Programs: Ribociclib in HR+/HER2- Advanced Breast Cancer

Breast Cancer Franchise

What is Ribociclib?

Ribociclib is a cyclin-dependent kinase inhibitor, a class of drugs that may help slow the progression of cancer by inhibiting two proteins called cyclin-dependent kinase 4 and 6 (CDK4/6). Targeting of CDK4/6 can help prevent cancer cells from growing and dividing too quickly, becoming uncontrollable[1,2].

	MONALEESA-2[3,4]	MONALEESA-7[3,4]	MONALEESA-3[3,4]	COMPLEEMENT-1[3,4]
Purpose	To evaluate ribociclib plus letrozole compared to letrozole alone in postmenopausal women with HR+/HER2- advanced breast cancer who received no prior therapy	To evaluate ribociclib in combination with endocrine therapy and goserelin compared to endocrine therapy and goserelin alone in premenopausal women with HR+/HER2- advanced breast cancer who received no prior therapy	To evaluate ribociclib plus fulvestrant compared to fulvestrant alone in men and postmenopausal women with HR+/HER2- advanced breast cancer that have received no or a maximum of one prior endocrine therapy	To evaluate ribociclib plus letrozole for the treatment of men and pre/postmenopausal women with HR+/HER2- advanced breast cancer with no prior hormonal therapy
	*Hormone receptor-positive, human epidermal growth factor receptor-2 negative (HR+/HER2-)			
Trial Design	Phase III, multicenter, randomized, double-blinded, placebo-controlled			Phase IIIb, open-label, multicenter
Trial Participation	Ongoing, not recruiting (668 patients enrolled globally)	Ongoing, not recruiting (672 patients enrolled globally)	Ongoing, not recruiting (672 patients enrolled globally)	Currently recruiting (estimated enrollment: 3000 patients)
Primary Endpoints	To determine if there is a progression-free survival (PFS) improvement for ribociclib in combination with letrozole compared to letrozole alone in this patient population	To determine if there is a PFS improvement for ribociclib in combination with endocrine therapy (NSAI, tamoxifen, letrozole or anastrozole) and goserelin compared to endocrine therapy and goserelin alone	To determine if there is a PFS improvement for ribociclib in combination with fulvestrant versus fulvestrant alone in this patient population	Assess the number of participants with adverse events as a measure of safety and tolerability during treatment on ribociclib plus letrozole
Secondary Endpoints	Overall survival, Safety, Health-related quality of life, Overall response rate, Clinical benefit rate, Time/duration to response			• Time-to-progression • Overall response rate • Clinical benefit rate • Patient reported outcome

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. Neganova, Irina, and Majlinda Lako. "G1 to S Phase Cell Cycle Transition in Somatic and Embryonic Stem Cells." *Journal of Anatomy* 213.1 (2008): 30–44. 2. O'Leary B, Finn RS, Turner NC. "Treating cancer with selective CDK4/6 inhibitors." *National Review of Clinical Oncology.* 13(7) (2016): 417-430. 3. Novartis Data on File. 4. ClinicalTrials.gov. U.S. National Institutes of Health, n.d. Web.

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