Breast Cancer

MONALEESA Clinical Trial Program in Process: Ribociclib in HR+/HER2- Advanced Breast Cancer

*The MONALEESA (**M**ammary **ON**cology **A**ssessment of **LE**E011's **E**fficacy and **SA**fety) clinical trial program is designed to evaluate the safety and efficacy of ribociclib in combination with various endocrine agents and different patient populations of those with HR+/HER2- metastatic breast cancer[1].*

Metastatic breast cancer is the most serious form of the disease and occurs when the cancer has spread to other parts of the body, such as the brain, bone or liver[2].

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 ensure cancer cells do not grow and divide too quickly, becoming uncontrollable[3,4].

Trial Parameters	MONALEESA-3[1,5]	MONALEESA-7[1,5]
Purpose	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 in combination with endocrine therapy and goserelin compared to endocrine therapy and goserelin alone in premenopausal women with HR+/HER2- advanced breast cancer
Trial Design	Multicenter, randomized, double-blinded, placebo controlled	
Trial Participation	Approximately 660 participants from 233 clinical sites worldwide	Approximately 660 participants from 259 clinical sites worldwide
Primary Endpoints	To determine if there is a progression-free survival (PFS) improvement for ribociclib in combination with fulvestrant versus fulvestrant alone in this patient population	To determine if there is a PFS improvement for ribociclib in combination with endocrine therapy and goserelin compared to endocrine therapy and goserelin alone

Secondary Endpoints

- Overall survival
- Overall response rate
- Safety
- Clinical benefit rate
- Health-related QOL
- Time/duration to response

References:

1. Novartis Data on File.
2. American Cancer Society. Breast Cancer. Available at http://www.cancer.org/acs/groups/cid/documents/webcontent/003090-pdf.pdf.
3. 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.
4. O'Leary B, Finn RS, Turner NC. "Treating cancer with selective CDK4/6 inhibitors." *National Review of Clinical Oncology.* 13(7) (2016): 417-430.
5. ClinicalTrials.gov. U.S. National Institutes of Health, n.d. Web.

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