# Ribociclib in HR+/HER2- Advanced Breast Cancer

**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**

<table>
<thead>
<tr>
<th>Purpose</th>
<th>To evaluate ribociclib plus letrozole compared to letrozole alone in postmenopausal women with HR+/HER2- advanced breast cancer who received no prior therapy</th>
</tr>
</thead>
</table>

**MONALEESA-7\(^3\)^4**

| Purpose | 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 |

**MONALEESA-3\(^3\)^4**

| Purpose | To evaluate ribociclib plus fulvestrant compared to fulvestrant alone in men and postmenopausal women with HR+/HER2- advanced breast cancer who have received no or a maximum of one prior endocrine therapy |

**COMPLEMENT-1\(^3\)^4**

| Purpose | 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 |

---

**Purpose**
To evaluate ribociclib plus letrozole compared to letrozole alone in postmenopausal women with HR+/HER2- advanced breast cancer who received no prior therapy

**Purpose**
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

**Purpose**
To evaluate ribociclib plus fulvestrant compared to fulvestrant alone in men and postmenopausal women with HR+/HER2- advanced breast cancer who have received no or a maximum of one prior endocrine therapy

**Purpose**
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

---

**Trial Design**
Phase III, multicenter, randomized, double-blinded, placebo-controlled

**Trial Design**
Phase IIIb, open-label, multicenter

---

**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

**Primary Endpoints**
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

**Primary Endpoints**
To determine if there is a PFS improvement for ribociclib in combination with fulvestrant versus fulvestrant alone in this patient population

**Primary Endpoints**
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

**Secondary Endpoints**
• 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:**