Study of ECI830 Single Agent or in Combination in Patients With Advanced HR+/HER2- Breast Cancer and Other Advanced Solid Tumors

Last Update: Apr 23, 2025

An Open-label, Multi-center, Phase I/II Study of ECI830 as a Single Agent and in Combination With Ribociclib and Endocrine Therapy in Patients With Advanced Hormone Receptor Positive, HER2-negative Breast Cancer and Advanced Solid Tumors

ClinicalTrials.gov Identifier:

NCT06726148

Novartis Reference Number:CECI830A12101

See if you Pre-qualify

All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

Phase I: Characterize safety and tolerability of ECI830 as a single agent and in combination with ribociclib and fulvestrant. Identify dose range for optimization/recommended dose for future studies.

Phase II: Assess the anti-tumor activity of ECI830 in combination with ribociclib and fulvestrant in patients with hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2-) advanced breast cancer. This is a first-in-human, open-label, phase I/II, multi-center study consisting of an ECI830 single agent treatment arm in patients with advanced HR+/HER2- breast cancer or other advanced solid tumors harboring CCNE1 amplification and a combination treatment arm of ECI830 with ribociclib and fulvestrant in patients with advanced breast cancer. Single agent escalation may be followed by an expansion part stratified by disease indication. The escalation of the combination arm may continue into a randomized, open label, Phase II with optional dose optimization in advanced breast cancer patients.

Condition

Advanced HR+/HER2- Breast Cancer, Advanced CCNE1-amplified Solid Tumors

Phase

Phase1, Phase2

Overall Status

Recruiting

Number of Participants

280

Start Date

Apr 03, 2025

Completion Date

Sep 25, 2028

Gender

All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

ECI830

Experimental
Drug

fulvestrant

Approved medication
Drug

ribociclib

Approved medication

Eligibility Criteria

Inclusion Criteria:

Age ≥ 18 years old.

Patients with one of the following indications:

Phase I:

HR+/HER2- aBC with disease progression on or following at least one line of hormone-based therapy in combination with a CDK4/6i and at least one additional line of systemic therapy for metastatic disease.

Histologically and/or cytologically confirmed diagnosis of locally advanced or metastatic cancer with a CCNE1 amplification. For dose expansion only: no more than 3 prior lines of therapy for advanced or metastatic disease.

Phase II:

HR+/HER2- aBC with disease progression on an aromatase inhibitor or tamoxifen in combination with a CDK4/6 inhibitor for unresectable/metastatic disease with no more than 2 lines of endocrine therapy.

Measurable disease as determined by RECIST v1.1.

BC only: If no measurable disease is present, then at least one predominantly lytic bone lesion must be present that can be accurately assessed at baseline and is suitable for repeated assessment.

Exclusion Criteria:

Previous treatment with a CDK2 inhibitor at any time.

Patients with inadequate bone marrow and/or organ functions with out-of-range laboratory values.

Clinically significant, uncontrolled heart disease and/or cardiac repolarization abnormality including MI, CABG, long QT syndrome, or risk factors for TdP.

Presence of symptomatic CNS metastases or CNS metastases that require local therapy or increasing doses of corticosteroids within 2 weeks prior to study entry.

For the combination treatment:

Patients with symptomatic visceral disease or any disease burden that makes the patient ineligible for endocrine-based therapy.

Patients who could not tolerate the prescribed dose of ribociclib during a previous course of treatment, requiring dose reduction or permanent discontinuation due to adverse events.

For patients with BC: Patient is concurrently using hormone replacement therapy.

WOCBP who are unwilling to use highly effective contraception methods, pregnant or nursing women.

Other protocol-defined inclusion/exclusion criteria may apply.

Israel

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Recruiting

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Recruiting

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Worldwide Contacts

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