Study ID: CLEE011G2301

Study Title: An Open Label Multi-center Protocol for U.S. Patients Enrolled in a Study of Ribociclib With Endocrine Therapy as an Adjuvant Treatment in Patients With Hormone Receptor-positive, HER2-negative, High Risk Early Breast Cancer

EudraCT Number: 2014-001795-53

ClinicalTrials.gov number: NCT03078751

Reason why study was not conducted (prematurely ended):

This study was originally designed as a randomized, Phase III, double-blind, placebo-controlled, multi-center, international study to evaluate the addition of ribociclib to standard adjuvant ET (letrozole, anastrozole, exemestane or tamoxifen) in patients with HR-positive, HER2-negative high risk EBC. A second study with a similar design to investigate intermediate risk EBC was also planned. However, following a review of the ribociclib development program strategy, a decision was taken to explore a different approach by initiating a single Phase III study (CLEE011012301C) for simplicity of trial logistics and for the purpose of analyzing the overall population through a single clinical trial. This clinical trial (CLEE011G2301) was then closed for recruitment on 12-Feb-2018 and the planned trial in the intermediate risk group was not initiated. CLEE011G2301 study was amended into an open-label, multi-center Phase II, conducted in US only.