JOHN WAYNE CANCER INSTITUTE
at Providence Saint John's Health Center

CLINICAL TRIAL ANNOUNCEMENT

A Phase 2 Study of **Abemaciclib** in Brain Metastases

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This is a multicenter, open-label, Phase 2 trial of **abemaciclib** in patients with brain metastases secondary to HR+ breast cancer, NSCLC, or melanoma. This study will evaluate the safety and efficacy of abemaciclib in patients with HR+ metastatic breast cancer, NSCLC, or melanoma and new or not previously irradiated brain lesions as well as previously irradiated progressive brain lesions.

Abemaciclib (LY2835219) is an oral, selective, and potent small molecule inhibitor of cyclin-dependent kinase (CDK) 4 and 6 (CDK4 and CDK6) with acceptable physical characteristics, pharmacokinetic (PK) properties, and safety profile in nonclinical species.

Inclusion Criteria:

- Have brain metastases secondary to hormone receptor positive breast cancer, NSCLC, or melanoma.
- Have either human epidermal growth factor receptor 2 positive (HER2+) (Study Part A) or HER2- (Study Part B) breast cancer.
- Participants in Study Part C must have HR+ breast cancer, NSCLC, or melanoma with brain lesions clinically indicated for surgical resection as well as consent to provide tissue for drug concentration determination after 5 to 14 days of study drug dosing.
- Participants in Part D must have NSCLC of any subtype.
- Participants in Part E must have melanoma of any subtype.
- For Parts A, B, D, and E: Must have at least 1 measurable brain lesion ≥10 millimeters (mm) in the longest diameter (LD).
- For Part C (surgical): Have metastatic brain lesion(s) for which surgical resection is clinically indicated.
- Have completed local therapy (surgical resection, WBRT, or SRS) ≥14 days prior to initiating abemaciclib and recovered from all acute effects.
- If receiving concomitant corticosteroids, must be on a stable or decreasing dose for at least 7 days prior to the baseline Gd-MRI.
- Have a Karnofsky performance status of ≥70.
- Have a life expectancy ≥12 weeks.
- For HR+ breast cancer participants in part A, B, and C, If currently receiving endocrine therapy, a participant may continue to receive the same endocrine therapy provided that extracranial disease is stable for at least 3 months and central nervous system (CNS) disease progression has occurred while on this endocrine therapy. If these conditions are not met, participants must discontinue endocrine therapy prior to initiation of abemaciclib.