PACIFIC NEUROSCIENCE INSTITUTE℠

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

# CLINICAL TRIAL ANNOUNCEMENT

## Phase I Trial to Evaluate **Belinostat** in Patients with **Refractory Solid Tumors**


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Sponsor

Spectrum Pharmaceuticals,

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PROVIDENCE Health & Services

Official Title:
An Open-label, Nonrandomized, Phase 1 Study to Evaluate the Safety and Pharmacokinetics of Belinostat in Patients with Relapsed/Refractory Solid Tumors or Hematological Malignancies Who Have Wild-Type, Heterozygous, and Homozygous UGT1A1*28 Genotypes

The purpose of this research study is to determine the pharmacokinetic profile and safety of belinostat in patients with wild-type, heterozygous, and homozygous UGT1A1*28 genotypes. Inhibition of HDAC is expected to have utility in the treatment of diseases characterized by aberrant cellular division such as cancer.

**Belinostat** is a histone deacetylase (HDAC) inhibitor that regulates the activity of cellular pathways through modification of non-histone proteins. It is currently approved for treatment of relapsed or refractory peripheral T-cell lymphoma.

UGT1A1 is the major UGT1 gene product that catalyzes the glucuronidation of bilirubin, a breakdown product of heme, which needs to be removed from the body. Historically, genetic defects in the UGT1 gene complex have been found to have a profound impact on the health of affected individuals, especially those that modify UGT1A1 enzyme activities. The UGT1A1*28 genetic polymorphism is characterized by the presence of an additional TA repeat in the TATA sequence in the UGT1A1 promoter, resulting in a decrease in bilirubin glucuronidation activity and an increase in the level of unconjugated bilirubin. UGT1A1 activity is reduced in individuals with genetic polymorphisms that lead to reduced enzyme activity, such as UGT1A1*28 polymorphism.

Enrolled patients will be assigned to 1 of 3 cohorts (A, B, or C) based on their UGT1A1 genotype

Key Inclusion Criteria:

- Diagnosis of advanced solid tumors or advanced hematological malignancy that is relapsed/refractory, for which no standard salvage therapy exists
- Must have received at least 1 prior systemic therapy for the current malignancy

Key Exclusion Criteria:

- Patient has acute or progressive hepatic disease