

# Chemotherapy Induced Peripheral Neuropathy Natural History Study (EPIPHANY)

**Status:** Recruiting

## Eligibility Criteria

**Age:** 18 years and over

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

### Inclusion Criteria:

All of the following criteria must be met in order to be enrolled in the study:

- Age  $\geq$  18 years
- Life expectancy  $\geq$  6 months
- Participants with Common Terminology Criteria for Adverse Events (CTCAE) Grade 0 CIPN (exception, patients with multiple myeloma treated with bortezomib, CTCAE Grade  $\leq$  1)
- Eastern Cooperative Oncology Group (ECOG) performance status of 0-2
- Breast cancer only:
  - Breast cancer beginning treatment with paclitaxel or docetaxel with curative intent (i.e., not metastatic disease beyond regional lymph nodes)
- Planned minimum of 6 cycles of chemotherapy
- Lymphoma only:
  - Incident lymphoma initiating treatment with vincristine
- Planned minimum of 4 cycles of chemotherapy
- Oxaliplatin-based regimens, Stage III colorectal cancer: Total of 6 months (planned minimum of 12 cycles). May consider Stage IV with minimal metastatic confirmed with Sponsor prior to enrollment
- Bortezomib use in untreated multiple myeloma: Total of 4 months (planned minimum of 9 cycles)
- Written informed consent given
- Enrollment must be completed prior to receiving the first dose of chemotherapy

### Exclusion Criteria:

Patients meeting ANY of the following criteria are not eligible for participation:

- Evidence of central nervous system metastases
- Evidence of clinically significant peripheral neuropathy (CTCAE  $>2$ ) as defined by patient report of frequent numbness or tingling in the hands or feet
- Any uncontrolled serious illness or medical condition that would impact the conduct of the current study
- Previous exposure to neurotoxic chemotherapy drugs
- Pre-existing neurodegenerative disease (Parkinson's, Alzheimer's, Huntington's, etc.), neuromuscular disorder (multiple sclerosis, ALS, polio, hereditary neuromuscular disease) or history of stroke or history of traumatic brain injury
- General anesthesia less than one month prior to the first dose of neurotoxic chemotherapy

## Conditions & Interventions

### Interventions:

drug: Vincristine, drug: Paclitaxel, drug: Oxaliplatin, drug: Docetaxel, drug: Bortezomib

### Conditions:

Chemotherapy-induced Peripheral Neuropathy

### Keywords:

CIPN

## More Information

**Contact(s):** There may be multiple sites in this clinical trial. 1-877-CTLILLY (1-877-285-4559) or - ClinicalTrials.gov@lilly.com

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**Phase:** N/A

**IRB**

**Number:** HM20016182

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