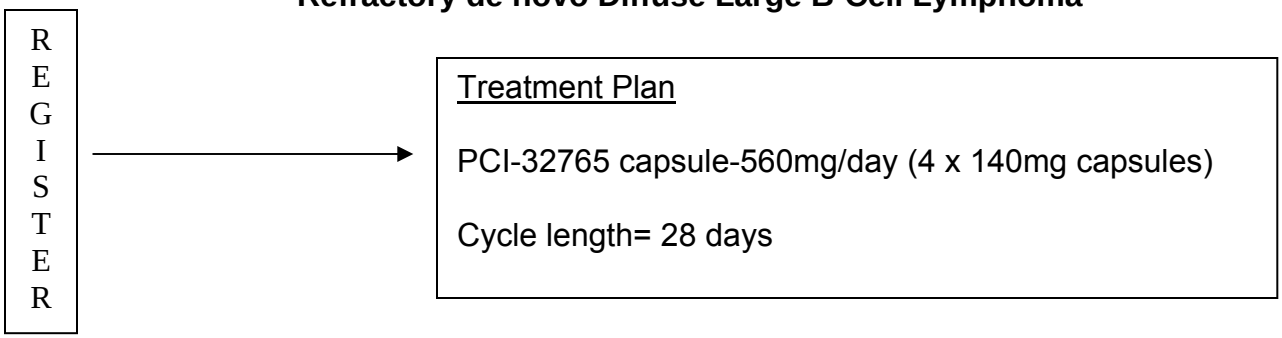
FAST FACTS

HO11403: A Multicenter, Open-Label Phase 2, Safety and Efficacy Study of Bruton's Tyrosine Kinase (Btk) Inhibitor, PCI-32765, in Subjects with Relapsed or Refractory de novo Diffuse Large B-Cell Lymphoma



INCLUSION CRITERIA

- ECOG performance status of ≤ 2
- Biopsy confirmed DLBCL (from either initial diagnosis or relapsed/ refractory disease).
  - Archival tissue must be available for central pathology review
- Relapsed or refractory disease, defined as: recurrence of disease after a complete remission (CR) or partial response (PR), stable disease (SD) or progressive disease (PD) at completion of the treatment regimen preceeding entry into the study (residual disease)
- Must have received appropriate first line therapy
- Must be ineligible for HDT/ASCT by one of the following: Age ≥ 70 years, DLCO < 50%, LVEF < 50% by MUGA or echo, Other organ dysfunction or comorbidities precluding the use of HDT/ASCT, or subject refusal
- Must have ≥ 1 measurable lesion on CT scan > 2cm in longest dimension

EXCLUSION CRITERIA

- Prior treatment with chemotherapy, external beam radiation therapy or anticancer antibodies within 3 weeks of the first dose of study drug, or Radio-or toxic immunoconjugates within 10 weeks of the first dose of study drug
- Transformed DLBCL or DLBCL with co-existing histologies (FL or MALT)
- Primary mediastinal (thymic) large B-cell lymphoma or known CNS lymphoma
- Prior malignancy, except for adequately treated basal cell or squamous cell skin cancer, in situ cervical cancer, or other cancer from which the subject has been disease free for at least 2 years or which will limit survival to less than 2 years.
- Clinically significant cardiovascular disease within 6 months of screening, or any Class 3 (moderate) or 4 (severe) cardiac disease
- Significant screening ECG abnormalities, including LBBB, 2nd degree AV block type II, 3rd degree block, bradycardia, or QTc ≥ 500 msec
- Unable to swallow capsules or malabsorption syndrome affecting GI function
- Known history of HIV, or active infection with hepatitis C virus (HCV) or hepatitis B virus (HBV)
- Any of the following lab abnormalities:
  - ANC < 750 cells/mm3, unless there is bone marrow involvement
  - Platelet count < 50,000 cells/mm3, unless there is bone marrow involvement
  - AST or ALT ≥ 3 x ULN
  - Creatinine > 2 x ULN

PRE-STUDY LABS AND TESTS: within ≤ 21 days prior to THERAPY
Physical exam, ECG x 3, BM Biopsy (within 30 days),
CT chest/ abdomen/pelvis (neck if applicable) and PET or PET/CT (within 30 days),
CBC with differential, platelets, electrolytes, glucose, BUN, creatinine, calcium, phosphorous, total protein, albumin, AST, ALT, total bilirubin, alkaline phoshatase, LDH, magnesium, uric acid, urinalysis, HCG

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