M16-106:
A Phase 1 Dose Escalation, Open-Label Study of Venetoclax in Combination with Navitoclax and Chemotherapy in Subjects with Relapsed/Refractory Acute Lymphoblastic Leukemia or Lymphoblastic Lymphoma

Phase 1
R/R ALL/LL
N = ~42

Key Inclusion Criteria

- Relapsed or refractory acute lymphoblastic leukemia (ALL)
  - ≥ 4 years of age
  - Weight ≥ 20 kg
  - Able to swallow pills

Performance status:
- Subjects ≤ 16 years of age: Lansky ≥ 50
- Subjects > 16 years of age: Karnofsky ≥ 50 or ECOG < 3

Key Exclusion Criteria

- Overt CNS disease (CNS 3)
- < 100 days post-transplant, or > 100 days post-transplant with active GVHD
- Received any of the following prior to the first dose of study drug:
  - A biologic agent, Inotuzumab, CAR-T or other cellular therapy within 30 days
  - Chemotherapy, Blinatumomab, or other investigational agents within 14 days

Endpoints

Primary Endpoints:
- Safety of venetoclax & navitoclax
- Evaluate the safety of venetoclax & navitoclax and chemotherapy
- Determine dose limiting toxicities (DLT)
- Assess pharmacokinetics (PK)

Secondary Endpoints:
- Anti-tumor activity of venetoclax & navitoclax
- Anti-tumor activity of venetoclax, navitoclax and chemotherapy, after the first cycle of chemotherapy
- Determine the number of subjects who proceed to stem cell transplantation

Exploratory Endpoints:
- Evaluate biomarkers
- Minimal residual disease (MRD)

Venetoclax is being codeveloped by AbbVie and Genentech, a member of the Roche Group.


To learn more about our pipeline, please visit www.abbviescience.com/oncology

Venetoclax is being investigated for indications not approved by Regulatory Agencies. Safety and Efficacy has not been established in unapproved indications.

Navitoclax is an investigational agent not approved by FDA or any regulatory health agency. Safety and Efficacy has not been established.

To learn more about these studies, please visit https://ClinicalTrials.gov

or email abbvieclinicaltrials@abbvie.com

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