SUMMARY M15-913

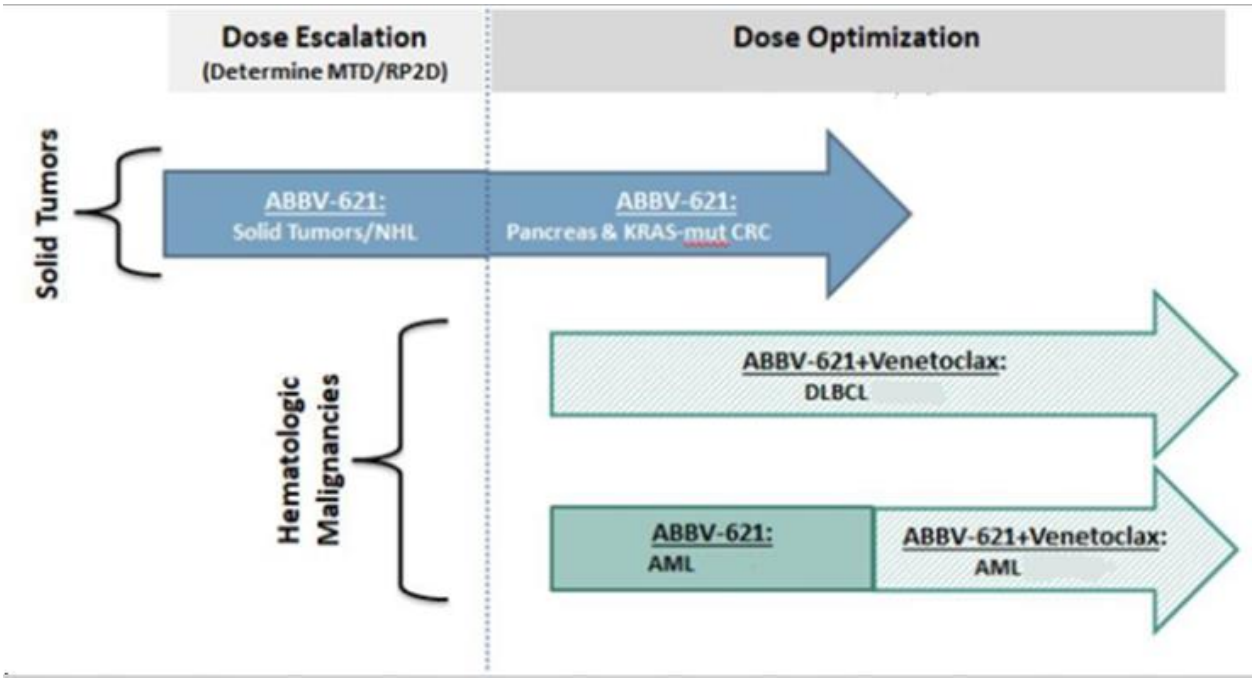
TITLE

An Open Label Phase 1, First-In-Human Study of TRAIL Receptor Agonist ABBV-621 in Subjects with Previously-Treated Solid Tumors and Hematologic Malignancies

INDICATION

Subjects with relapsed/refractory solid tumors and hematologic malignancies (AML and DLBCL)

STUDY DESIGN



MOST IMPORTANT INCLUSION CRITERIA

1. Subject must have a diagnosis of a solid tumor (except primary brain tumors), AML, or NHL. Subjects in the Dose Optimization solid tumor cohorts must have either colorectal cancer with documented KRAS mutations (as determined by local testing), or pancreatic cancer (irrespective of mutational status). NHL may be of any subtype for Dose Escalation but is limited to DLBCL for those enrolled to the cohort evaluating the combination of ABBV-621 and venetoclax.
2. Subject must have received at least one prior systemic therapy, and must have relapsed or progressed after, or failed to respond to any/all available effective therapy or therapies.

3. Subjects must have measurable disease (by RECIST 1.1 for those with solid tumors; by Lugano classification for those with NHL), except those with AML, who must have histologically confirmed relapsed or refractory disease (central review not required).
4. Subject must have an Eastern Cooperative Oncology Group (ECOG) Performance Score of 0 – 2.
5. Subject must have adequate hematologic, renal and hepatic function.

MOST IMPORTANT EXCLUSION CRITERIA

1. Presence of primary hepatobiliary malignancy, including cholangiocarcinoma or hepatocellular carcinoma, gallbladder carcinoma, cancer of ampulla of Vater.
2. Subjects with history of brain metastases who have not shown clinical and radiographic stable disease for at least 28 days after definitive therapy. In addition, any AML patient identified, through CSF analysis, as having active CNS disease, will be excluded from enrollment.
3. Receipt of any systemic anti-cancer agent, including investigational anti-cancer products, within 21 days prior to study drug administration or 3 half-lives, whichever is longer.
4. History of cirrhosis or other indication of significant possible hepatic dysfunction.
5. Subjects with a positive diagnosis of hepatitis A, B or C.