

KARTA BADANIA
NAZWA BADANIA: A Phase 2 Study of Oral LOXO-305 in Patients with Previously Treated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) or Non-Hodgkin Lymphoma (NHL) (J2N-MC-JZNX)
NUMER PROTOKOŁU: J2N-MC-JZNX
WSKAZANIE- C91.1 - Przewlekła białaczka limfocytowa

Inclusion Criteria:

- Have confirmed diagnosis of CLL/SLL as defined by these iwCLL 2018 criteria.
- Have received prior CLL/SLL treatment
- Have received at least 1, but not more than 3 lines of prior treatment for CLL/SLL
- Have received a covalent BTK inhibitor
- Have a requirement for therapy consistent with iwCLL 2018 criteria for initiation of therapy
- Capable of swallowing oral study medication.
- Have an Eastern Cooperative Oncology Group Performance Status (ECOG) score of 0 to 2.

Exclusion Criteria:

- Have received prior treatment with a BTK degrader and a noncovalent BTK inhibitor
- Have a history of greater than or equal to ($\geq$) Grade 3 bleeding due to treatment with a BTK inhibitor
- Have known or suspected Richter's transformation
- Have known or suspected history of central nervous system involvement by CLL/SLL
- Previous or concurrent cancer distinct from CLL/SLL within 3 years before randomization.

Exceptions may occur with documented sponsor approval. Examples include:

- nonmelanoma skin cancer or lentigo maligna melanoma
 - cervical carcinoma in situ
 - localized prostate cancer undergoing active surveillance, and
 - localized (for example, lymph node negative) breast cancer with no evidence of active disease present for more than 3 years. Individual may be receiving adjuvant hormonal therapy
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