ZYNLONTA® (loncastuximab-tesirine-lpyl) – Infection Prophylaxis

Summary

- LOTIS-2 was a pivotal Phase 2, multicenter, open-label single-arm study that evaluated the efficacy and safety of ZYNLONTA used as monotherapy in 145 adult patients with relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL) following ≥2 lines of prior systemic therapy.[1]
    - Patients with known seropositive and requiring antiviral therapy for human immunodeficiency virus (HIV), hepatitis B virus, or hepatitis C were excluded from the study.[1]
- ADC Therapeutics does not make recommendations regarding infection prophylaxis while on treatment with ZYNLONTA. Please defer to your clinical judgment and institutional guidelines for infection prophylaxis. See **Relevant Prescribing Information** for additional information.

Clinical Data

LOTIS-2 (Phase 2)[1]

- LOTIS-2 was a Phase 2, open-label, single-arm, multicenter study which evaluated the efficacy and safety of ZYNLONTA monotherapy in patients (≥18 years of age) with R/R diffuse large B-cell lymphoma (DLBCL) following >2 lines of prior systemic therapy.
    - Patients with known seropositive and requiring antiviral therapy for human immunodeficiency virus, hepatitis B virus, or hepatitis C were excluded from the study.[1]

Literature Search

- A PubMed biomedical literature search conducted on April 16, 2025, yielded no relevant data regarding ZYNLONTA and infection prophylaxis.

Relevant Prescribing Information

Section 2: Dosage and Administration[2]

2.2 Recommended Premedication

- Unless contraindicated, administer dexamethasone 4 mg orally or intravenously twice daily for 3 days beginning the day before administering ZYNLONTA. If dexamethasone administration does not begin the day before ZYNLONTA, dexamethasone should begin at least 2 hours prior to administration of ZYNLONTA.

Section 5: Warnings and Precautions[2]

5.3 Infections

- Fatal and serious infections, including opportunistic infections, occurred in patients treated with ZYNLONTA. Grade 3 or higher infections occurred in 10% of patients, with fatal infections occurring in 2%. The most frequent Grade ≥3 infections included sepsis and pneumonia [see Adverse Reactions (6.1)].
- Monitor for any new or worsening signs or symptoms consistent with infection. For Grade 3 or 4 infection, withhold ZYNLONTA until infection has resolved [see Dosage and Administration (2.3)].

Section 6: Adverse Reactions[2]

6.1 Clinical Trials Experience

- Serious adverse reactions occurred in 28% of patients receiving ZYNLONTA. The most common serious adverse reactions that occurred in ≥2% receiving ZYNLONTA were febrile neutropenia, pneumonia, edema, pleural effusion, and sepsis. Fatal adverse reactions occurred in 1%, due to infection.
- Clinically relevant adverse reactions in <10% of patients (all grades) who received ZYNLONTA included infections: Pneumonia (5%), sepsis (2%).

Table 1: Adverse Reactions (≥10%) in Patients with R/R DLBCL who received ZYNLONTA in LOTIS-2. Adopted from Prescribing Information.[2]

	ZYNLONTA (N=145)	
Adverse Reaction	**All Grades (%)**	**Grades 3 or 4 (%)**
Infection		
Upper respiratory tract infection[h]	10	<1[a]

a=No Grade 4 adverse reactions occurred

h=Upper respiratory tract infection includes upper respiratory tract infection, upper respiratory tract congestion, nasopharyngitis, rhinitis, rhinovirus infection, and sinusitis

References

[1] Data on File. LOTIS-2 Clinical Study Report. ADC Therapeutics.
[2] ZYNLONTA® (loncastuximab tesirine-lpyl) FDA-approved Prescribing Information. October 2022.

ADC Therapeutics encourages all health care professionals to report any adverse events and product quality complaints to medical information at 855-690-0340. Please consult the ZYNLONTA Prescribing Information.