LOTIS

Loncastuximab Tesirine Clinical Assessments

For information about the LOTIS Clinical Trial Program, email ADC Therapeutics at medicalinformation@ADCTherapeutics.com.

To learn more about ADC Therapeutics, please visit www.ADCTherapeutics.com.

ADC THERAPEUTICS

Innovating Science. Inspiring Hope.

Loncastuximab tesirine (ADCT-402) is an investigational agent, and safety and efficacy have not yet been established.

Ibrutinib is supplied by Pharmacyclics LLC.

The LOTIS Clinical Development Program

LOTIS·1
LOncastuximab Tesirine ClinIcal AsSessment

[402-101] - A Phase 1 Dose-escalation Study to Evaluate the Tolerability, Safety, Pharmacokinetics, and Antitumor Activity of ADCT-402 in Patients With Relapsed or Refractory B-cell Lineage Non Hodgkin Lymphoma (B-NHL)

NCT02669017

COMPLETED

LOTIS·2
LOncastuximab Tesirine ClinIcal AsSessment

[402-201] - A Phase 2 Open-Label Single-Arm Study to Evaluate the Efficacy and Safety of Loncastuximab Tesirine in Patients With Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL)

NCT03589469

ACTIVE, NOT RECRUITING

LOTIS·3
LOncastuximab Tesirine ClinIcal AsSessment

[402-103] - A Phase 1/2 Open-Label Study to Evaluate the Safety and Efficacy of Loncastuximab Tesirine and Ibrutinib in Patients With Advanced Diffuse Large B-Cell Lymphoma or Mantle Cell Lymphoma

NCT03684694

RECRUITING

LOTIS·4
LOncastuximab Tesirine ClinIcal AsSessment

[402-104] - A Phase 1 Open-Label Study to Evaluate the Safety and Antitumor Activity of Loncastuximab Tesirine and Durvalumab in Patients With Advanced Diffuse Large B-Cell Lymphoma, Mantle Cell Lymphoma, or Follicular Lymphoma

NCT03685344

ACTIVE, NOT RECRUITING

LOTIS·5
LOncastuximab Tesirine ClinIcal AsSessment

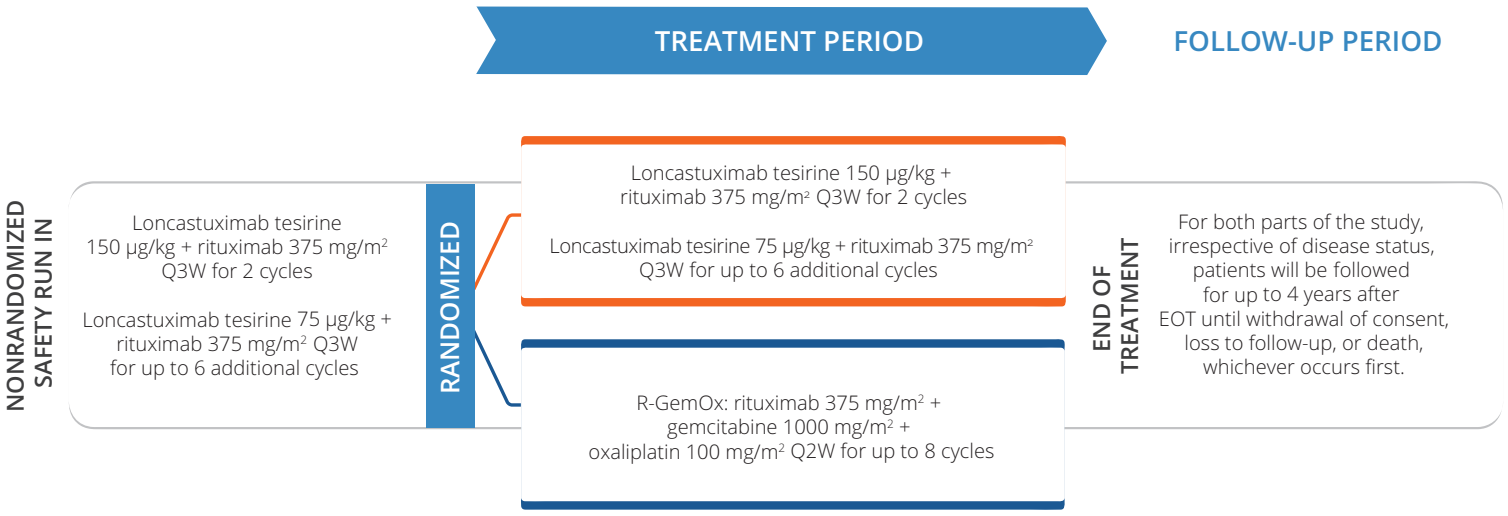
[402-311] - A Phase 3 Randomized Study of Loncastuximab Tesirine Combined With Rituximab Versus Immunochemotherapy in Patients With Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL)

NCT04384484

RECRUITING

LOTIS

A Phase 3 Randomized Study of Loncastuximab Tesirine Combined With Rituximab Versus Immunochemotherapy in Patients With Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL)



PRIMARY ENDPOINT

Progression-free survival (PFS) defined as the time between randomization and the first documentation of recurrence or progression by independent central review, or death

KEY SECONDARY ENDPOINTS

- Overall survival (OS) defined as the time between randomization and death
- Overall response rate (ORR) by independent central review according to the 2014 Lugano classification

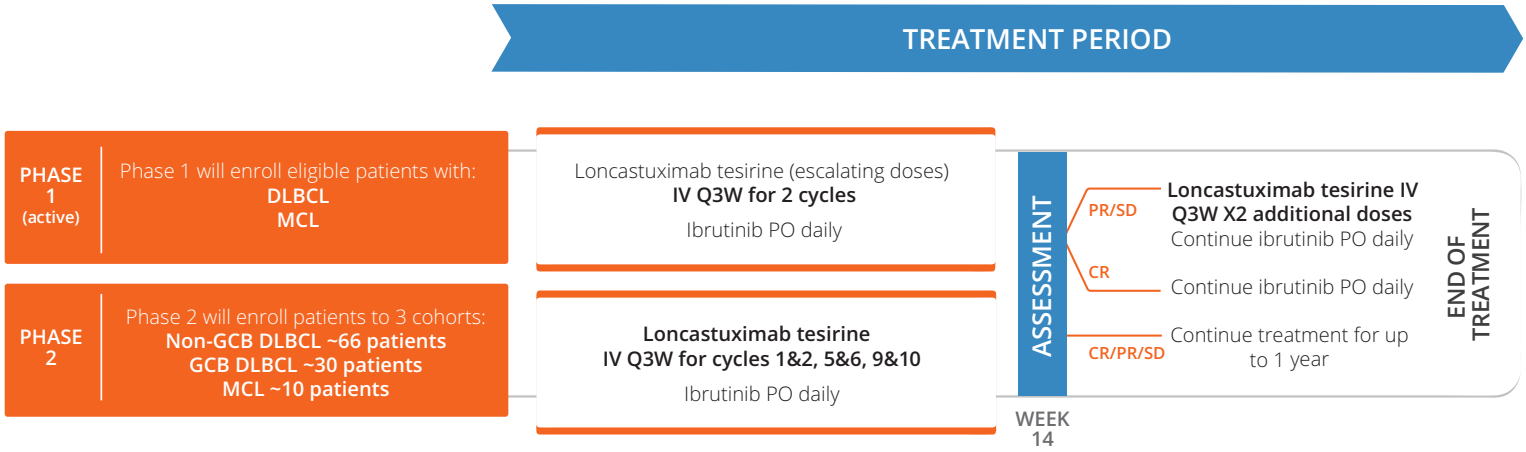
KEY INCLUSION CRITERIA

1. Pathologic diagnosis of DLBCL, as defined by the 2016 WHO classification (including patients with DLBCL transformed from indolent lymphoma), or high-grade B-cell lymphoma, with MYC and BCL2 and/or BCL6 rearrangements
2. Relapsed or refractory disease following at least one multi-agent systemic treatment regimen
3. Not considered by the investigator a candidate for stem cell transplantation based on performance status, advanced age and/or significant medical comorbidities
4. ECOG performance status 0-2

LOTIS·5

LOncastuximab Tesirine ClinIcal AsSessment

A Phase 1/2 Open-Label Study to Evaluate the Safety and Efficacy of Loncastuximab Tesirine and Ibrutinib in Patients with Advanced Diffuse Large B-Cell Lymphoma or Mantle Cell Lymphoma



PRIMARY ENDPOINT

- Phase 2: Complete Response Rate (CRR) [Time Frame: Up to 2 years] according to the 2014 Lugano classifications determined by the investigator and/or independent review committee (IRC). CRR defined as the number of participants with a best overall response (BOR) of complete response (CR) in non-germinal center B-cell diffuse large B-cell lymphoma (non-GCB DLBCL) participant cohort only (Phase 2).

KEY SECONDARY ENDPOINTS

- Phase 2: Overall Response Rate (ORR) [Time Frame: Up to 2 years] according to the 2014 Lugano classification, defined as the number of participants with a best overall response (BOR) of complete response (CR) or partial response (PR).
- Phase 2: Complete Response Rate (CRR) in GCB DLBCL, all DLBCL and MCL Participants [Time Frame: Up to 2 years] CRR according to the 2014 Lugano classifications determined by the investigator and/or independent review committee (IRC). CRR defined as the number of participants with a best overall response (BOR) of complete response (CR) in non-GCB DLBCL, GCB DLBCL, all DLBCL, and MCL participants.

KEY INCLUSION CRITERIA

1. Pathologic diagnosis of DLBCL or MCL
2. Participants with DLBCL must have relapsed or refractory disease and have failed or been intolerant to available standard therapy
3. Participants with MCL must have relapsed or refractory disease and have received at least one prior line of therapy
4. ECOG performance status 0 to 2

LOTIS·3

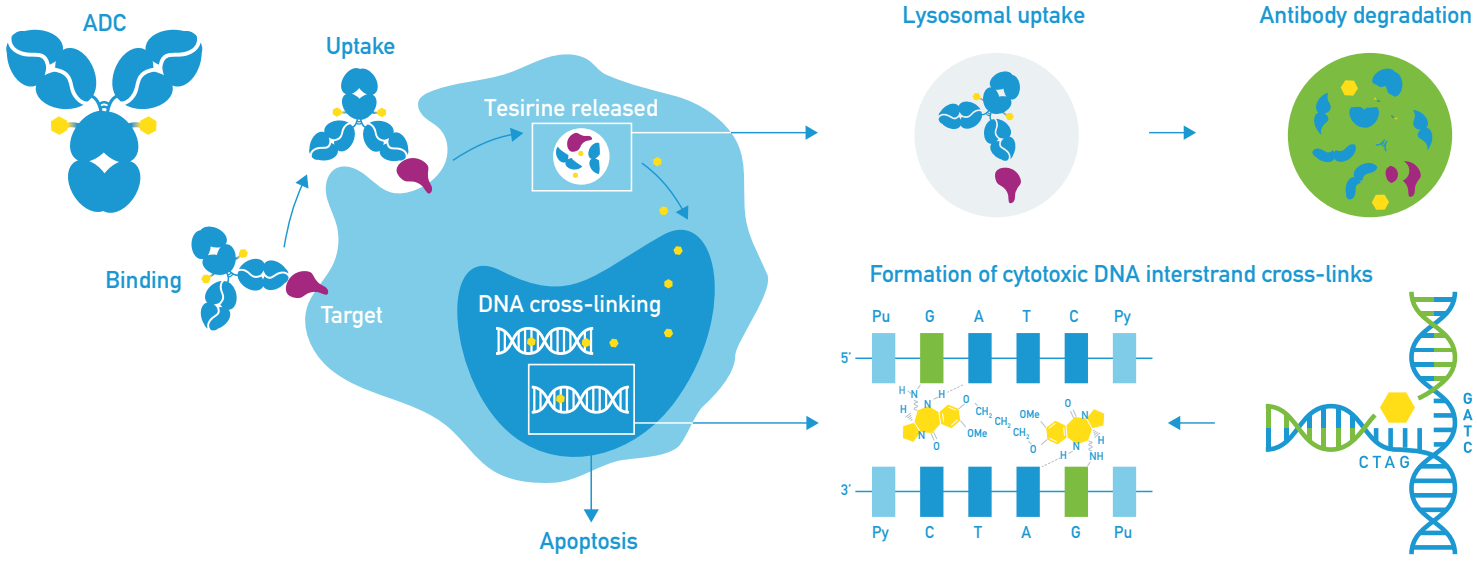
LOncastuximab Tesirine ClinIcal AsSessment

ADC Therapeutics is advancing next-generation PBD-based ADCs

ADC Therapeutics is leading the development and commercialization of next-generation ADCs with highly potent and targeted PBD dimer technology. These PBD-based ADCs are expected to provide a novel way to treat hematological cancers and solid tumors, address significant unmet medical needs, and improve the lives of people with cancer.

An MOA that features the "stealth-like" properties of PBD dimer toxins

- The antigen-targeted antibody binds to a specific tumor cell surface antigen and internalizes the drug conjugate
- The potent PBD dimer is released inside the cell, where it then creates a covalent cross-link between the strands of the DNA double helix
- Because these cross links do not trigger DNA repair, they are invisible to repair mechanisms and can covertly persist to interrupt cell division



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Learn more about the LOTIS Clinical Development Program

For additional outcome measures and inclusion/exclusion criteria, and a list of active study sites, visit www.ClinicalTrials.gov.

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ADCTherapeutics.com

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