Physician Fact Sheet

The Physician Fact Sheet is intended for Healthcare Professionals only.

TrilynX™ CLINICAL TRIAL

The TrilynX Clinical Trial is a randomized, double-blind, placebo-controlled, Phase 3 study of xevinapant (also known as Debio 1143) in combination with platinum-based chemotherapy and concomitant standard fractionation intensity-modulated radiotherapy in patients with locally advanced squamous cell carcinoma of the head and neck (LA-SCCHN), suitable for definitive chemoradiotherapy.

The TrilynX Clinical Trial

The TrilynX Clinical Trial is evaluating an investigational drug, xevinapant (also known as Debio 1143), to see if it may optimize the effectiveness of chemoradiotherapy (CRT) when administered together. All patients receive platinum-based CRT; in addition, they will be randomized 1:1 to receive xevinapant or placebo.

This clinical trial is enrolling patients with LA-SCCHN in at least 1 of the following sites:

- Oropharynx (must be HPV negative)
- Hypopharynx
- Larynx

About Xevinapant

Xevinapant is an oral solution that acts as an antagonist of IAPs (inhibitor of apoptosis proteins) that is being evaluated to see if it may sensitize tumor cells to CRT by promoting apoptosis (programmed cell death) and fostering antitumor immunity. Xevinapant was granted breakthrough therapy designation by the FDA in early 2020.

Phase 2 study results revealed that xevinapant resulted in a 21% improvement versus placebo in the locoregional control rate at 18 months after CRT — as well as a marked progression-free survival (PFS) at a 2-year follow-up period.

Key Eligibility Criteria (Extract)

- At least 18 years of age
- Diagnosis of previously untreated LA-SCCHN (stage III, IVA or IVB) suitable for definitive CRT in at least 1 of the following sites: oropharynx, hypopharynx and/or larynx
- ECOG performance status 0 or 1
- In oropharyngeal cancer patients, primary tumors must be HPV negative
- No hearing loss or ≤ grade 2 hearing impairment (according to NCI-CTCAE v.5)
- Peripheral neuropathy < grade 2
- Adequate hematologic, renal and hepatic function

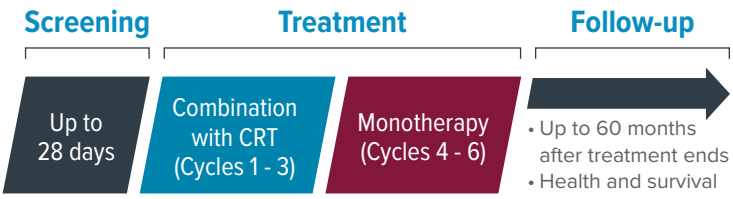
The study team can provide information on additional eligibility criteria.

Study Overview

This study has 3 periods: Screening, Treatment and Follow-up.

The Treatment Period includes 2 parts:

1. Combination therapy (CRT + xevinapant or placebo)
2. Monotherapy (xevinapant or placebo)



Participants who qualify and decide to join will receive:

- Study-related medical care and the liquid investigational drug or placebo
- Chemotherapy and radiation therapy
- Close monitoring by doctors and research teams who specialize in head and neck cancers
- Reimbursement for transportation as needed

To learn more, please visit TrilynXClinicalTrial.com or ClinicalTrials.gov and search NCT04459715.