Physician Fact Sheet

TrilynX CLINICAL TRIAL

The TrilynX Clinical Trial is a randomised, double-blind, placebo-controlled, Phase 3 study of 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 medication, Debio 1143, to see if it may optimise the effectiveness of chemoradiotherapy (CRT) when administered together. All patients receive platinum-based CRT; in addition, they will be randomised 1:1 to receive Debio 1143 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 Debio 1143

Debio 1143 is an oral solution that acts as an antagonist of IAPs (inhibitor of apoptosis proteins) that is being evaluated to see if it may sensitise tumour cells to CRT by promoting apoptosis (programmed cell death) and fostering anti-tumour immunity. Debio 1143 was granted breakthrough therapy designation by the FDA in early 2020.

Phase 2 study results revealed that Debio 1143 resulted in a 21% improvement in the locoregional control rate at 18 months after CRT — as well as a marked Progression-Free Survival (PFS) benefit at a 2-year follow-up period. To date, safety results on Debio 1143 given in combination with CRT suggest an acceptable and predictable overall safety profile.

Key Eligibility Criteria

- At least 18 years of age (or equivalent majority age in your country)
- Diagnosis in 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 tumours must be HPV negative
- No hearing loss
- Peripheral neuropathy < grade 2
- Adequate haematologic, renal and hepatic function

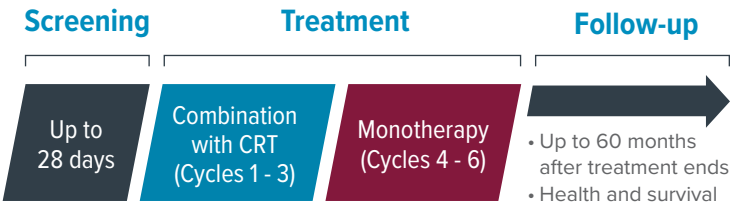
The study team can provide information on additional eligibility criteria.

Study Overview

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

The Treatment Period includes 2 parts:

1. Combination therapy (CRT + Debio 1143 or placebo)
2. Monotherapy (Debio 1143 or placebo)



Participants who qualify and enrol will receive:

- Study-related medical care and the liquid investigational medication
- Chemotherapy and radiation therapy
- Close monitoring by physicians who specialise in head and neck cancers
- Reimbursement for transportation as needed

To learn more, please visit [TrilynXClinicalTrial.com or ClinicalTrials.gov and search Debio 1143-SCCHN-301.]

About Debiopharm

Debiopharm is a global biopharmaceutical company headquartered in Switzerland whose main area of expertise is oncology. Debiopharm is committed to bringing innovative, life-saving treatments to people with cancer.

For more information about Debiopharm, visit debiopharm.com.

Debiopharm
WE DEVELOP FOR PATIENTS