THE EMERALD-1 STUDY: TACE IN COMBINATION WITH EITHER DURVALUMAB MONOTHERAPY OR DURVALUMAB PLUS BEVACIZUMAB IN PATIENTS WITH LOCOREGIONAL HCC

EMERALD-1
AZ IO TRIALS

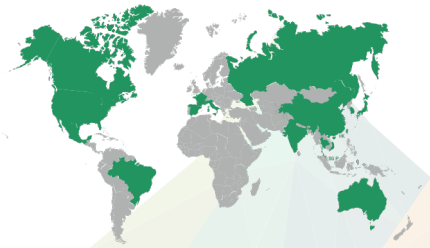
Study background

Transarterial chemoembolization (TACE), a standard treatment for locoregional hepatocellular carcinoma (HCC), achieves tumor responses, but progression often occurs within 1 year.[1]

Durvalumab, an anti-programmed cell death ligand-1 (PD-L1) antibody, is under investigation in advanced HCC.[2]

EMERALD-1 is a randomized, double-blind, Phase 3 study of TACE plus durvalumab monotherapy or durvalumab with bevacizumab in patients with locoregional HCC.

Participating countries and regions



Endpoints

1 Primary

- Progression-free survival

2 Secondary

- Overall survival
- Time to progression
- Objective response rate
- Duration of response
- Disease control rate
- Efficacy by PD-L1
- Safety
- Pharmacokinetics
- Disease-related symptoms
- Health-related quality of life

Exploratory

- Association between candidate biomarkers and efficacy

Current status

Enrollment	Estimated primary completion	Estimated final completion
ONGOING	2021	2024

Study design

Patients with HCC who are unsuitable for curative therapy with no prior systemic therapy

1:1:1 randomization (N=600)

Arm A	Arm B	Arm C
TACE + Durvalumab (Q4W)	TACE + Durvalumab (Q4W)	TACE + Placebo (Q4W)
Durvalumab + Placebo (Q3W)	Durvalumab + Bevacizumab (Q3W)	Placebo + Placebo (Q3W)

Stratification

TACE modality (DEB-TACE vs cTACE)

Geographic region (Japan vs Asia [non-Japan] vs Other)

Portal vein invasion (Vp1 or Vp2+/-Vp1 vs none)

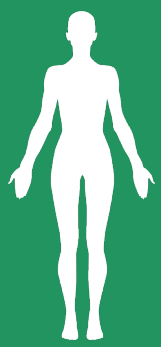
Study period

Treatment should continue until clinical progression, mRECIST-defined radiological progression, unacceptable toxicity, withdrawal of consent or other discontinuation criteria are met.

Is your patient eligible to participate in EMERALD-1?

They may be eligible if they are ≥18 years of age and have:

- ✓ Confirmed HCC not amenable to curative therapy or transplantation
- ✓ Child-Pugh score A–B7
- ✓ ECOG PS 0–1
- ✓ Adequate organ and marrow function



- ✗ No history of nephrotic or nephritic syndrome
- ✗ No prior systemic therapy for HCC
- ✗ No extrahepatic disease
- ✗ No clinically significant cardiovascular disease or GI perforation or bleeding within last 6 months
- ✗ No evidence of main portal vein thrombosis (Vp3/Vp4)

Want to know more?

AstraZeneca Clinical Study Information Center
information.center@astrazeneca.com

https://clinicaltrials.gov/ct2/show/NCT03778957

The information provided is intended for potential clinical investigators and other interested HCPs who may wish to enroll or refer patients to clinical trials.

FOR HEALTHCARE PROFESSIONALS USE ONLY: NOT FOR USE WITH PATIENTS

References

1. Lencioni R, et al. *Hepatology.* 2016;64:106–116.
2. Kelley RK, et al. *J Clin Oncol.* 2017;35(15_suppl). Abs 4073.

Abbreviations:

Q4W – Every 4 weeks; Q3W – Every 3 weeks
DEB-TACE – Drug-eluting bead transarterial chemoembolization
cTACE – Conventional transarterial chemoembolization
ECOG PS – Eastern Cooperative Oncology Group Performance Status
GI - Gastrointestinal
HCP – Healthcare Provider

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