THE EMERALD-2 STUDY:
DURVALUMAB WITH OR WITHOUT BEVACIZUMAB AS ADJUVANT THERAPY IN PATIENTS WITH HEPATOCELLULAR CARCINOMA AT HIGH RISK OF RECURRENCE FOLLOWING CURATIVE TREATMENT

EMERALD-2
AZ IO TRIALS

Study background

Hepatic resection and ablation are standard treatments for early-stage hepatocellular carcinoma (HCC). They are potentially curative, but the risk of cancer recurrence following treatment is high.[1–3]

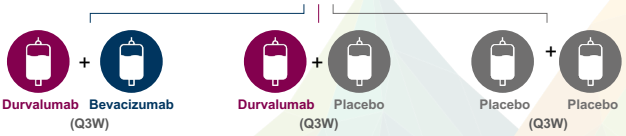
Durvalumab, an anti-programmed cell death ligand-1 (anti-PD-L1) antibody, is under investigation in HCC.[4]

EMERALD-2 is a randomized, placebo-controlled Phase 3 study evaluating the efficacy and safety of durvalumab with or without bevacizumab as adjuvant therapy in patients with HCC at high risk of recurrence following curative resection or ablation.

Study design

Patients with HCC at high risk of recurrence following curative therapy (surgery or ablation ± embolization)

1:1:1 randomization (N=888)



Stratification
Evidence of microvascular invasion.
Geographic region.

Study period
Treatment will continue for up to 12 months (18 cycles) or until clinical progression, unacceptable toxicity, withdrawal of consent or other discontinuation criteria are met.

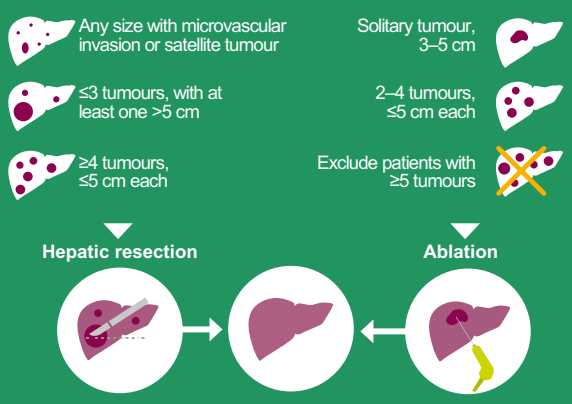
Key endpoints

1 Primary
- RFS of durvalumab monotherapy versus placebo

2 Secondary
- RFS of durvalumab + bevacizumab versus placebo
- 24-month RFS
- Time to relapse
- Overall survival
- Safety and tolerability

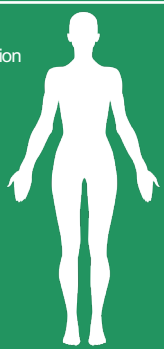
Is your patient eligible to participate in EMERALD-2?

Newly diagnosed confirmed HCC and successful completion of one of the following curative therapies:



Imaging to confirm disease-free status within 28 days prior to randomization

Important Inclusion and Exclusion Criteria



- ✓ Randomized within 12 weeks of completion of curative therapy
- ✓ ≥18 years of age
- ✓ ECOG PS 0–1
- ✓ Child-Pugh score A: 5 or 6
- ✓ Adequate organ and marrow function
- ✗ No known fibrolamellar HCC, sarcomatoid HCC or mixed cholangiocarcinoma and HCC
- ✗ No prior systemic therapy for HCC
- ✗ No evidence of distant metastasis or main portal vein thrombosis
- ✗ No active hepatitis co-infection (HBV and HDV, or HBV and HCV)

Radiation therapy or transarterial radioembolization excluded.

Current status

Enrollment	Estimated last subject in	Estimated primary completion	Estimated final completion
ONGOING	July 2021	September 2022	September 2023

Want to know more?

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

EMERALD-2 study:
https://clinicaltrials.gov/ct2/show/NCT03847428

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. Bruix J, Sherman M. *Hepatology.* 2005;42:1208–1236.
2. Imamura H, et al. *J Hepatol.* 2003;38:200–207.
3. Kianmanesh R, et al. *Surg Oncol Clin N Am.* 2003;12:51–63.
4. Wainberg ZA, et al. Poster presented at: ASCO 2017 Annual Meeting; 2–6 June 2017; Chicago, IL. Poster 4071.

Abbreviations:
ECOG PS – Eastern Cooperative Oncology Group Performance Status
HBV – Hepatitis B Virus
HDV – Hepatitis D Virus
HCV – Hepatitis C Virus
RFS – Recurrence-free Survival

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