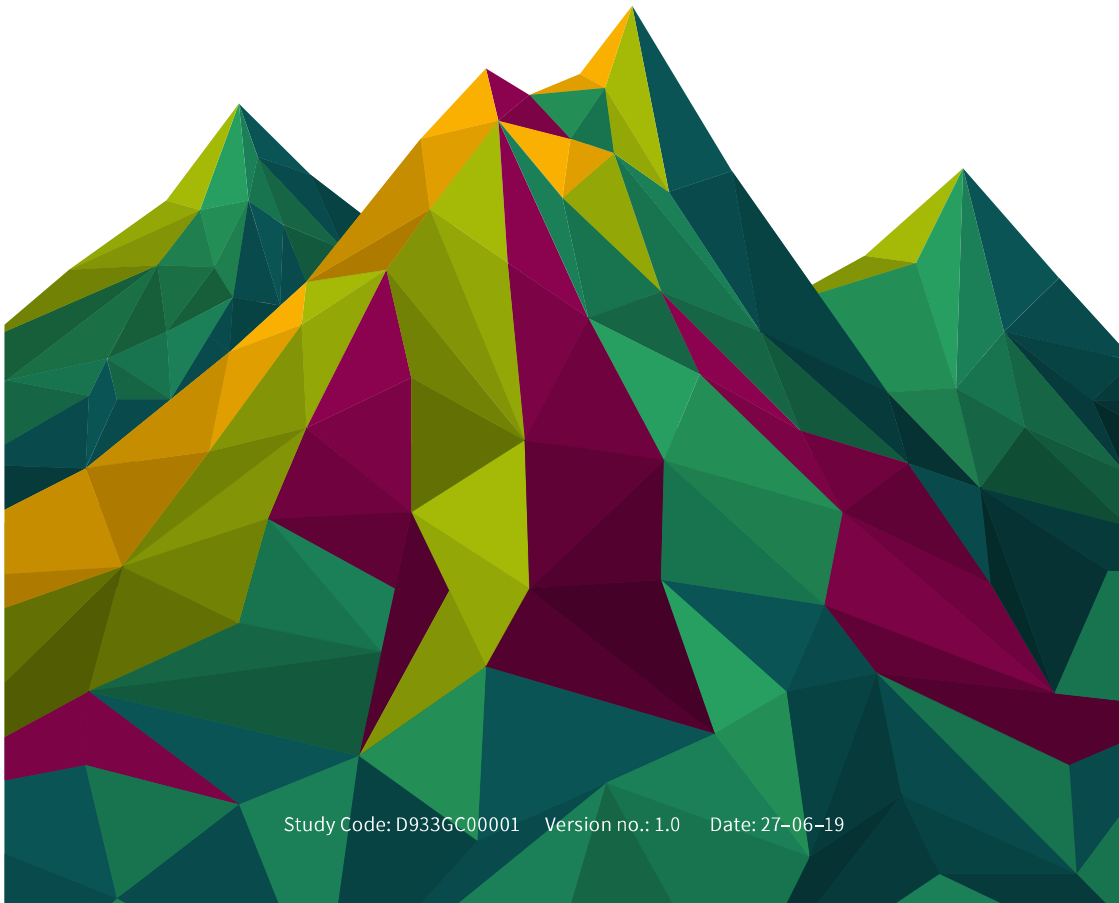


EMERALD-1

Are you interested in taking
part in this clinical trial?

We are currently looking for patients who have
been diagnosed with liver cancer to take part
in a clinical trial called EMERALD-1.



Study Code: D933GC00001 Version no.: 1.0 Date: 27-06-19

What is EMERALD-1?

EMERALD-1 is a study being carried out in patients with liver cancer also called hepatocellular carcinoma (HCC) that has not spread outside the liver. It is looking at whether a drug called durvalumab in combination with transarterial chemoembolization (TACE), either by itself or with another drug called bevacizumab, will work in your type of cancer.

This study is split into 3 groups:



Group A

TACE + durvalumab, followed by durvalumab + bevacizumab placebo*



Group B

TACE + durvalumab, followed by durvalumab + bevacizumab



Group C

TACE + durvalumab placebo, followed by durvalumab placebo* + bevacizumab placebo*

*A placebo is a harmless, dummy treatment which will be given in the same way and look similar to the study drugs being investigated.

This study is “double-blinded”. This means that you and the study doctor will not know which study drugs you are being given.

Who can join?

EMERALD-1 is suitable for patients who:



Have been diagnosed with HCC



Are 18 years or older



Can receive TACE



Have never been treated with chemotherapy, similar medications or TACE therapy for their HCC in the past



Have not had previous treatment with durvalumab

What is involved?

Screening

(to confirm whether you can take part)



A physical examination



Electrocardiogram



Blood tests



Urine tests



Pregnancy test (if required)



CT or MRI and possibly other imaging

Treatment

During this period, you will be asked to:



Attend the study clinic to receive your study treatment and periodic imaging



Record/monitor your own health using an electronic hand-held device (ePRO)



Report new or worsening side effects

Follow-up



Attend a few follow-up appointments



Continue to complete your ePRO questionnaires

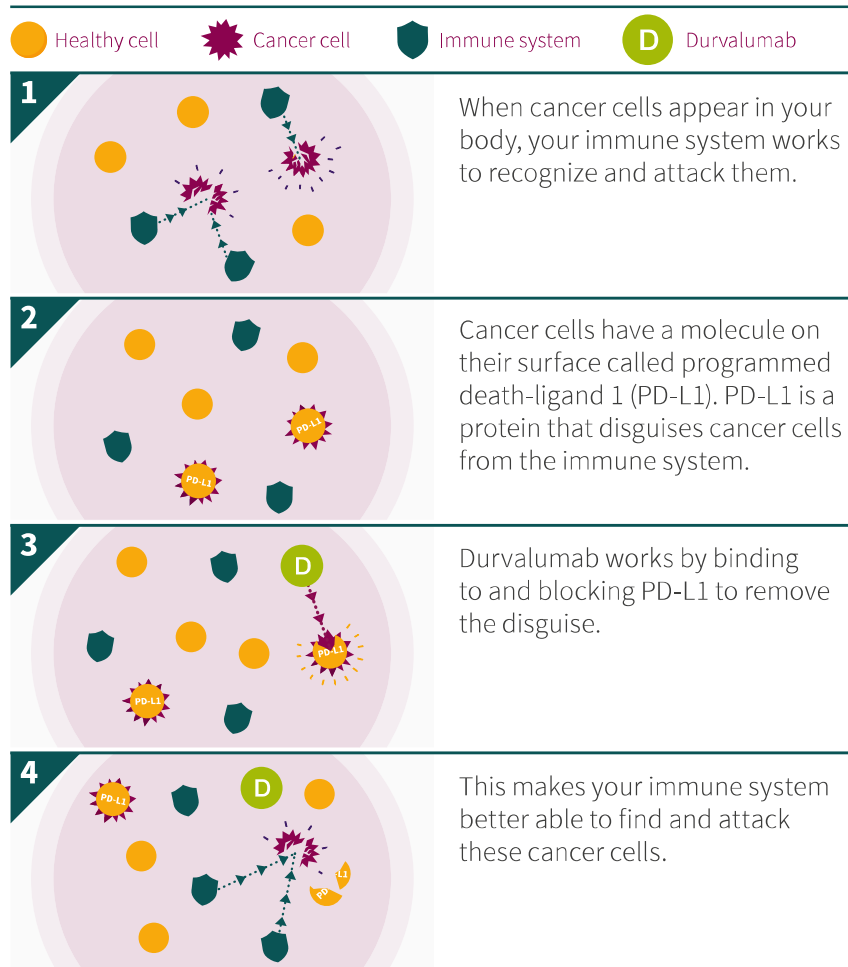


Follow-up is very important because it allows the safety of the medicines to be monitored

How do the study treatments work?

Durvalumab

Durvalumab is an immunotherapy—a type of cancer treatment that works to help your immune system find and attack cancer.



Bevacizumab

Depending on the study group that you are allocated, you may also receive another drug called bevacizumab. Bevacizumab works by disrupting the blood supply that feeds the tumor and potentially also helps your immune system fight the tumor.

What is TACE?

During the study you will have up to 4 TACE procedures.

TACE is a common treatment for HCC that has not spread outside the liver. It is a procedure that blocks or slows down the blood supply to the cancer and delivers chemotherapy directly to the tumor.

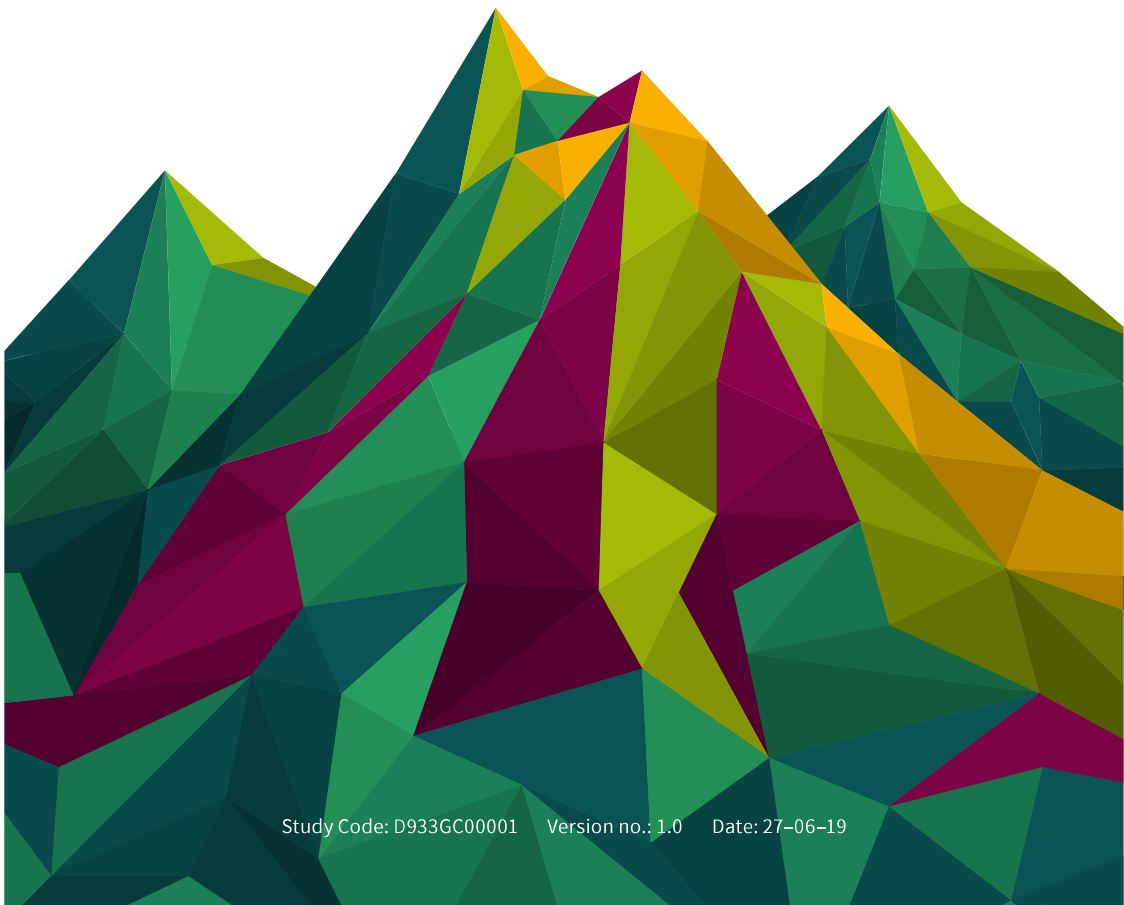
Chemotherapy stops the cancer cells from dividing and causes the cancer cells to die.

Why are they being used together?

Clinical studies have suggested that receiving targeted drugs such as durvalumab and bevacizumab together may work in treating HCC patients.

If you are interested in taking part in this study, please speak with your doctor for more information.

**The findings of this trial will be
used to help develop treatments
for future HCC patients.**



Study Code: D933GC00001 Version no.: 1.0 Date: 27-06-19