

# BOTENSILIMAB (BOT) + BALSTILIMAB (BAL) IMMUNOTHERAPY COMBINATION IN PEOPLE WITH DIFFICULT-TO-TREAT METASTATIC COLORECTAL CANCER

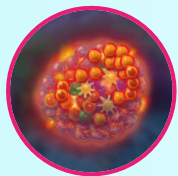
Full presentation title: Results from an expanded phase 1 trial of botensilimab, a multifunctional anti-CTLA-4, plus balstilimab (anti-PD-1) for metastatic heavily pretreated microsatellite stable colorectal cancer

## Key Takeaways:

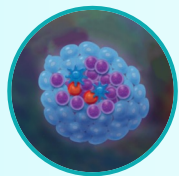
- A novel immunotherapy combination, **botensilimab and balstilimab (BOT + BAL)**, was tested as a treatment for people with metastatic colorectal cancer that failed previous therapies
- This combination has shown clinical activity and notable overall survival in people without active liver metastases: **23%** had deep, durable responses and **74%** were alive at 1 year\*
- Side effects were manageable and reversible\*
- People with “cold” tumors who normally would not respond to any immunotherapy benefited from BOT + BAL treatment
- The BOT + BAL combination is currently being tested worldwide in more people with difficult-to-treat metastatic colorectal cancer

## Why is this important?

- “Hot” tumors are easier for the immune system to find and destroy. “Cold” tumors are not seen well by the immune system, so are harder to treat.
- Most (95%) people with metastatic colorectal cancer have “cold” tumors
- Current standard treatments are not very effective and have poor outcomes in people with “cold” metastatic colorectal cancer after failing first-line standard therapies
- Median overall survival time: **~6-9 months**



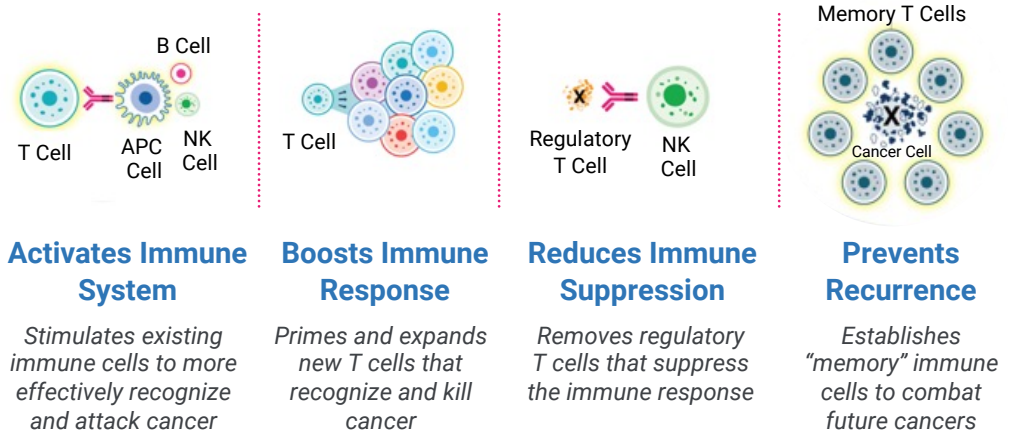
**Hot Tumor**  
(easy for immune system to see)



**Cold Tumor**  
(hard for immune system to see)

## Novel immunotherapy combination: BOT + BAL

**BOT + BAL** is a novel **immunotherapy combination** is being evaluated and has shown clinical activity in “cold” metastatic colorectal cancer. These medicines were specifically designed to harness the power of the person’s own immune system to recognize and destroy cancer cells through multiple mechanisms of action:



\*Botensilimab and balstilimab are investigational immunotherapies used alone or in combination. These products have not been reviewed and approved by any regulatory agency.

Based on data as of May 26, 2023.

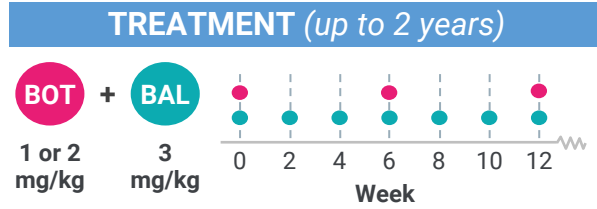
Presented at the European Society for Medical Oncology World Congress on Gastrointestinal Cancer, 28 June–1 July 2023; presentation number LBA-4.

# RESULTS:

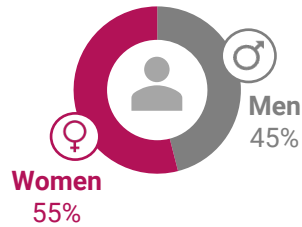
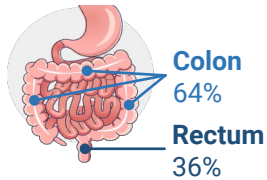
**Aim:** This was an early (Phase 1) clinical study to evaluate if the BOT + BAL combination is a safe and effective treatment for people with “cold” metastatic colorectal cancer

## Who took part in the study?

As of May 26, 2023, **101** people with “cold” metastatic colorectal cancer received BOT (once every 6 wks) + BAL (once every 2 wks)



### Primary cancer site



### Received ~4 previous cancer treatments

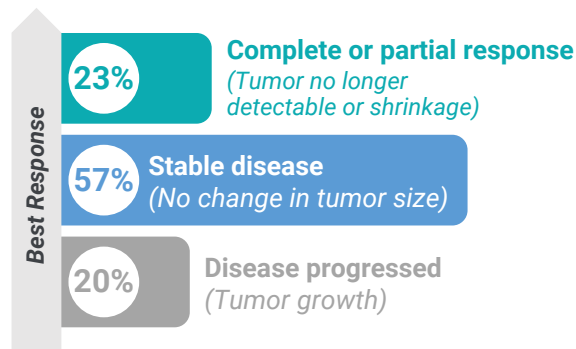


## Deep and durable responses seen\*

In those without active liver metastases:

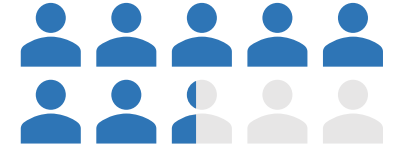
**69%** had ongoing responses, including many lasting more than 1 year

**80%** had controlled disease – tumor was no longer detectable, shrunk in size, or was stable



## People lived longer than reported for standard-of-care\*

- Notably, **74%** of patients without active liver metastases were alive at 1 year
- Median overall survival time: **~1.7 years**



## Manageable side effects\*

- Main drug-related side effects included:



**40%**  
Diarrhea / Colitis



**32%**  
Fatigue



**27%**  
Decreased appetite

- Side effects were manageable and reversible
- No drug-related deaths and no unexpected side effects

## What do these results mean?

- In this study, the BOT + BAL immunotherapy combination treatment has shown clinical activity and notable overall survival, with manageable side effects in people with heavily pretreated, metastatic “cold” colorectal tumors
- People with “cold” tumors who normally would not respond to any immunotherapy benefited from BOT + BAL treatment

## What happens next?

- A large, worldwide phase 2 trial called **Activate Against Colorectal Cancer** ([NCT05608044](https://clinicaltrials.gov/ct2/show/study/NCT05608044)) is currently enrolling to test the BOT + BAL combination in more people with “cold” metastatic colorectal cancer

**activate**   
AGAINST COLORECTAL CANCER