



## **A Study for People with Metastatic Colorectal Cancer (Stage IV)**

*A Randomized, Double-Blind, Phase 3 Study of Standard-of-Care Chemotherapy and Bevacizumab With or Without INCA33890 in the First-Line Treatment of Metastatic Microsatellite Stable Colorectal Cancer*

### **Why is this study being done?**

Most people with advanced colorectal cancer have a type called microsatellite stable (MSS) colorectal cancer.<sup>2</sup> For this type:

- Immunotherapy has not worked well for most patients so far
- Standard chemotherapy can help for a time, but the cancer often grows back
- New treatment options are urgently needed

This study is testing whether adding an investigational immunotherapy to standard treatment can help improve outcomes for people with MSS colorectal cancer.<sup>1</sup>

### **What is the study treatment?**

Everyone in the study receives standard-of-care treatment, which includes:

- Chemotherapy (FOLFOX)
- Bevacizumab (a medicine that blocks blood supply to tumors)

In addition, participants are randomly assigned (randomized) to receive one of the following:

- INCA33890 (the investigational study drug), or
- A placebo (an inactive treatment)

Neither you nor your doctor will know which one you are receiving. This is called a double-blind study.<sup>1</sup>

### **What is INCA33890?**

INCA33890 is an experimental immunotherapy that is still being studied and is not approved for use outside of clinical trials.

- It is designed to help the immune system better recognize and attack cancer
- It works by targeting two immune pathways at the same time (PD-1 and TGF- $\beta$ R2)
- The goal is to help immune cells work more effectively inside the tumor

Researchers are interested in evaluating if this approach is a safe and effective way to treat MSS colorectal cancer.<sup>1</sup>

### **Who can take part?**

You may be able to participate if you:

- Are 18 years or older
- Have stage IV metastatic colorectal cancer
- Have not received prior treatment for metastatic disease (this is first-line treatment)
- Are confirmed to have microsatellite stable (MSS) disease
- Are physically well enough for treatment
- Have cancer that can be measured on imaging scans

Certain conditions may prevent participation, such as:

- A different tumor type (MSI-H or specific gene mutations like BRAF V600E)
- Previous treatment with immunotherapy for earlier stage CRC or a different type of cancer
- Active autoimmune disease or serious infections

The above criteria represent a partial list. The full list may be found at [ClinicalTrials.gov](https://ClinicalTrials.gov). Final eligibility is determined by the study doctors.<sup>1</sup>

### What does participation involve?

- Treatments are given every 2 weeks
- Study drug (INCA33890 or placebo) is given on the same days as chemotherapy
- Minimal clinic visits are expected beyond standard treatment visits
- Standard of care treatment may continue as long as it is helping and side effects are manageable
- The experimental drug can be given for up to 2 years
- Travel and lodging support may be available, depending on location.<sup>1</sup>

### Possible benefits of participation

- You will receive standard colorectal cancer treatment regardless of study group
- You may or may not benefit from the investigational drug
- Information learned from this study may help future patients with colorectal cancer
- You may have additional tests and closer monitoring in the setting of a clinical trial

Because this is a research study, benefit cannot be guaranteed.<sup>3</sup>

### Possible risks and side effects

All treatments can cause side effects. In an earlier study of INCA33890, some participants experienced:

- Immune-related side effects
- Infusion reactions during treatment (may include symptoms such as chills, dizziness, fainting, rash, fever, shortness of breath, flushing, or itching)
- Fatigue, digestive symptoms, or changes in lab tests

Serious side effects were seen in some patients. The above side effects represent a partial list. The full list may be found at [ClinicalTrials.gov](https://ClinicalTrials.gov). Your study team will monitor you closely and explain all known risks before you decide to participate.<sup>3</sup>

## Important things to know

- This is a research study, not standard treatment. In this study you'll receive the investigational treatment or placebo in addition to standard treatment
- The study drug is investigational
- You may leave the study at any time
- Your regular medical care will not be affected if you choose not to participate

## Have questions?

Talk with your doctor or care team to learn whether this study may be an option for you. You can also ask the study team any questions before deciding.

*For more information please visit:*

Clinical Trials.gov and search trial ID# NCT07284849 or put the following address into your browser  
<https://clinicaltrials.gov/study/NCT07284849>

or

<https://incyteclinicaltrials.com/about-clinical-trials>

*This information is provided for educational and patient advocacy purposes only.*

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## References:

<sup>1</sup> ClinicalTrials.gov–NCT07284849

*A Randomized, Double-Blind, Phase 3 Study of Standard-of-Care Chemotherapy and Bevacizumab With or Without INCA33890 in the First-Line Treatment of Metastatic Microsatellite Stable Colorectal Cancer*

<sup>2</sup> Buchler T. *Microsatellite Instability and Metastatic Colorectal Cancer – A Clinical Perspective*. *Frontiers in Oncology*. 2022;12:888181. doi:10.3389/fonc.2022.888181

<sup>3</sup> Garralda 2025 ESMO Presentation, A phase I study of INCA33890, a PD-1/TGFβR2 Bispecific Antibody, for Advanced Solid Tumors