GLOBAL GASTROINTESTINAL TRIAL PROGRAM

Botensilimab + Balstilimab

Active clinical studies in gastrointestinal and other solid tumor cancers — a reference for physicians and researchers.

This sheet summarizes company-sponsored, collaborative, and investigator-sponsored trials (ISTs) studying the immunotherapy combination of botensilimab and balstilimab (BOT+BAL). ISTs are designed and led by independent researchers and academic medical centers, not by Agenus.

This resource is intended to help physicians and researchers understand where studies are open and enrolling, what cancers they involve, and how to find up-to-date trial information. Each study links to its full record on ClinicalTrials.gov.

ABOUT THE THERAPIES

Botensilimab (BOT)
An investigational Fc-enhanced anti–CTLA-4 antibody (also referred to as AGEN1181), designed to boost the immune system's response to tumors.

Balstilimab (BAL)
An investigational anti–PD-1 antibody (also referred to as AGEN2034), studied together with botensilimab as a dual immunotherapy regimen.

Investigator-sponsored
Studies are designed and led by independent researchers and academic institutions, not by Agenus.

AT A GLANCE

17	5	8	14
Studies in this report	Countries	Cancer types studied	Research centers & sponsors

Study directory

17 studies · grouped by setting, then phase

NEOADJUVANT & PERIOPERATIVE STUDIES

Treatment given before surgery · 7 studies

○ Coming Q1 2027
NCT pending
Phase 3

COLON CANCER

A Phase 3 Randomized, Open-Label Study of Botensilimab Plus Balstilimab In the Neoadjuvant Setting followed by Standard of Care Versus Standard of Care Alone in Previously Untreated High-Risk Stage II and Stage III Non–MSI-H/dMMR Colon Cancer (ROBBIN)

Conditions	Previously Untreated High-Risk Stage II and Stage III Non–MSI-H/dMMR Colon Cancer
Regimen	Botensilimab + Balstilimab
Led by	Agenus · Global

● Recruiting
NCT06279130
Phase 2/3

SOLID TUMORS (MULTIPLE)

Pan-tumor Neoadjuvant Basket Study of Immune Check-point Inhibition and Novel Immuno-oncology Combinations (NEOASIS)

Conditions	Resectable dMMR Solid Tumors · Resectable pMMR Solid Tumors
Regimen	Botensilimab + Balstilimab + FLOT chemotherapy (select cohorts)
Led by	The Netherlands Cancer Institute · Netherlands

● Recruiting

NCT05845450

Phase 2

COLORECTAL CANCER

Pre-operative Targeted Treatments in Molecularly Selected Resectable Colorectal Cancer (UNICORN)

Conditions	Resectable Colorectal Cancer · Molecularly selected
Regimen	Botensilimab + Balstilimab
Led by	Gruppo Oncologico del Nord-Ovest · Italy

● Recruiting

NCT06780787

Phase 2

RECTAL CANCER

FOLFOX, Botensilimab, and Balstilimab for the Treatment of Localized Rectal Cancer Before Surgery

Conditions	Rectal Adenocarcinoma · Multiple disease stages
Regimen	Botensilimab + Balstilimab + Capecitabine, Fluorouracil, Leucovorin Calcium, Oxaliplatin, Radiation Therapy
Led by	City of Hope Medical Center · United States

● Recruiting

NCT06843434

Phase 2

RECTAL CANCER

A Study of Botensilimab and Balstilimab for Rectal Adenocarcinoma

Conditions	Microsatellite Stable Rectal Carcinoma · Locally Advanced Rectal Adenocarcinoma
Regimen	Botensilimab + Balstilimab
Led by	Memorial Sloan Kettering Cancer Center · United States

● Recruiting

NCT07595874

Phase 2

COLORECTAL CANCER

Neoadjuvant Botensilimab and Balstilimab for the Treatment of Advanced Resectable Colorectal Cancer (NEST-3)

Conditions	Advanced Colon Adenocarcinoma · Advanced Colorectal Adenocarcinoma · Advanced Rectal Adenocarcinoma · Multiple disease stages
Regimen	Botensilimab + Balstilimab
Led by	City of Hope Medical Center · United States

● Recruiting

NCT07735624

Phase 2

RECTAL CANCER

Neoadjuvant Botensilimab + Balstilimab in MSS/pMMR Early Rectal Cancer (RECTIFY-1)

Conditions	Microsatellite stable (MSS) / mismatch repair proficient (MMRp) early rectal cancer
Regimen	Botensilimab + Balstilimab
Led by	Dana-Farber Cancer Institute · United States

LATER-LINE, METASTATIC & ADVANCED DISEASE STUDIES

10 studies

● Recruiting

NCT06346197

Phase 3

GASTRIC & ESOPHAGEAL

Combination of Immune Checkpoint in Locally Advanced or Metastatic MSI/dMMR Esogastric Adenocarcinomas (CIME)

Conditions	Locally Advanced or Metastatic Esogastric Adenocarcinoma · MSI-H / dMMR
Regimen	Botensilimab + Balstilimab
Led by	Centre Léon Bérard · France

Recruiting
NCT06589440
Phase 2

COLORECTAL CANCER

Phase 2 Study of SR-8541A in Combination With Botensilimab and Balstilimab in Subjects With Refractory Metastatic Microsatellite Stable Colorectal Cancer (MSS-CRC)

Conditions Refractory Metastatic Microsatellite Stable Colorectal Cancer (MSS-CRC)
Regimen Botensilimab + Balstilimab + SR-8541A
Led by Stingray Therapeutics · United States

Recruiting
NCT06843551
Phase 2

PANCREATIC CANCER

The Miami "EMPIRE" Trial - Eradication of Metastatic Pancreatic Cancer With Immuno-Radiation

Conditions Metastatic Pancreatic Ductal Adenocarcinoma · Metastatic Pancreatic Cancer
Regimen Botensilimab + Balstilimab + Stereotactic Body Radiation Therapy
Led by University of Miami · United States

Recruiting
NCT07227636
Phase 2

COLORECTAL CANCER

A Study of Botensilimab and Balstilimab for Colorectal Cancer With ctDNA+ After Surgery and Chemotherapy

Conditions Colorectal Cancer · Rectal Cancer
Regimen Botensilimab + Balstilimab
Led by Memorial Sloan Kettering Cancer Center · United States

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Recruiting
NCT07550088
Phase 2

COLORECTAL CANCER

BAL/BOT/agenT-797 in pMMR CRC With Liver Metastases

Conditions Colorectal Cancer Metastatic
Regimen Botensilimab + Balstilimab + agenT-797
Led by Scripps Health · United States

Recruiting
NCT06782932
Phase 1/2

PANCREATIC CANCER

Comparing Neoadjuvant/Adjuvant GVAX vs a mKRASvax Given With Anti-PD-1 and Anti-CD137 for Surgically Resectable Pancreatic Cancer

Conditions Surgically Resectable Pancreatic Adenocarcinoma
Regimen Balstilimab (anti–PD-1) + AGEN2373 (anti–CD137) + GVAX or mKRASvax vaccine
Led by Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins · United States

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Recruiting
NCT06336902
Phase 1

COLORECTAL CANCER

Botensilimab Plus Balstilimab and Fasting Mimicking Diet Plus Vitamin C for Patients With KRAS-Mutant Metastatic Colorectal Cancer

Conditions Metastatic Colorectal Adenocarcinoma · Multiple disease stages
Regimen Botensilimab + Balstilimab + Dietary Intervention, Vitamin C
Led by University of Southern California · United States

Recruiting
NCT06411691
Phase 1

COLORECTAL & PANCREATIC

KRAS-Targeted Vaccine Combined With Balstilimab and Botensilimab for Patients With Stage IV MMR-p Colorectal Cancer and Pancreatic Ductal Cancer

Conditions Colorectal Cancer · Pancreatic Cancer
Regimen Botensilimab + Balstilimab + KRAS Vaccine with Poly-ICLC adjuvant
Led by Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins · United States

● Recruiting

NCT07128355

Phase 1

COLORECTAL CANCER

Botensilimab, Balstilimab, and SBRT in Colorectal Cancer

Conditions	Non-MSI-H or pMMR Colorectal Cancer With Liver Metastasis
Regimen	Botensilimab + Balstilimab + Stereotactic Body Radiation Therapy (SBRT)
Led by	Massachusetts General Hospital · United States

● Recruiting

NCT07193862

Phase 1

COLORECTAL CANCER

Pilot Study of an Implantable Microdevice for In Situ Evaluation of Drug Response in Patients With Colorectal Liver Metastasis

Conditions	Colorectal Cancer Metastatic
Regimen	Botensilimab + Balstilimab
Led by	Northwell Health · United States

TERMS YOU MAY ENCOUNTER

NCT number
The unique ID for a study on ClinicalTrials.gov. Search it there for current details and contacts.

Neoadjuvant
Treatment given before surgery, often to shrink a tumor or test response.

MSS / pMMR
Microsatellite stable / mismatch-repair proficient tumors — types that have historically responded less to immunotherapy.

Refractory
Cancer that no longer responds to a treatment it was given.

Study phase
Stage of testing. Phase 1 focuses on safety, Phase 2 on how well a treatment works, and Phase 3 compares it against standard care in larger groups.

Metastatic
Cancer that has spread from where it started to other parts of the body.

MSI-H / dMMR
Microsatellite instability-high / mismatch-repair deficient tumors.

Regimen partners
Additional drugs, radiation, or other therapies studied alongside the immunotherapy backbone.

For informational purposes only. This fact sheet is compiled from publicly available listings on ClinicalTrials.gov and is not medical advice, an endorsement, or an offer of treatment. The investigational therapies listed are not approved by the FDA or other regulators. Study status changes frequently — always confirm current details, eligibility, and locations on the official record and encourage patients to discuss options with their care team.