

Incyte Highlights New Data Advancing its Gastrointestinal Cancer Portfolio at ESMO 2026

October 26, 2026

INCB161734 (KRAS G12D inhibitor) and INCA33890¹ (TGFβR2×PD-1 bispecific antibody) data reinforce ongoing and planned registrational trials, including DAWN-303 in pancreatic ductal adenocarcinoma (PDAC) and NEXERA-303 in colorectal cancer (CRC), respectively

New data evaluating INCB161734 in CRC highlight its clinical activity across KRAS G12D-mutated tumor types and support initiation of a Phase 3 study in second-line CRC planned for 2027

INCB161734 and INCA33890 demonstrated manageable safety profiles in combination with standard-of-care (SoC) chemotherapies

New collaborations with Bristol Myers Squibb and Synnovion in PDAC to evaluate INCB161734 in combination with navlimetostat, an MTA-cooperative PRMT5 inhibitor, and SNV1521, a PARP1 inhibitor, respectively

These results and additional updates will be presented at an analyst and investor event on Monday, October 26, 2026, from 7:30 – 9:00 p.m. CET (2:30 – 4:00 p.m. EDT)

WILMINGTON, Del.--(BUSINESS WIRE)--Oct. 26, 2026-- Incyte (Nasdaq:INCY) announced new results from its advancing oncology portfolio, including updated results for its KRAS G12D inhibitor (INCB161734) in pancreatic ductal adenocarcinoma (PDAC) and advanced or metastatic colorectal cancer (CRC), and its TGFβR2×PD-1 bispecific antibody (INCA33890¹) in microsatellite stable CRC (MSS CRC). The data were featured in three rapid oral sessions (Abstract #3137RO, Abstract #1007RO and Abstract #1954RO, respectively) at the European Society of Medical Oncology (ESMO) Congress 2026.

"At Incyte we are focused on improving outcomes for people living with cancer. The data presented for INCB161734 and INCA33890 show the potential of both programs to improve the standard-of-care in hard-to-treat diseases," said Pablo J. Cagnoni, M.D., President, Incyte and Global Head of Research and Development. "Across pancreatic and colorectal cancers, we continue to see encouraging evidence of clinical activity and manageable safety profiles, supporting the promise of these programs across tumor types and lines of therapy. Together, INCB161734 and INCA33890 are emerging as the foundation of our growing solid tumor portfolio, with the potential to address significant patient needs."

INCB161734 (KRAS G12D) in Pancreatic Ductal Adenocarcinoma

ON/OFF KRAS Inhibition Shows Deep and Durable Responses Across Combinations, With Manageable Safety

New Phase 1 data (cut-off July 6, 2026; n=54) showed encouraging clinical efficacy and a favorable safety profile for INCB161734 1,200 mg once daily (QD) in combination with standard-of-care (SoC) chemotherapy (gemcitabine/nab-paclitaxel [GEMNabP] (n=26) or modified FOLFIRINOX [mFOLFIRINOX] (n=27)) in patients with metastatic PDAC harboring a documented KRAS G12D mutation.

Deep and durable treatment responses were observed. Specifically:

- INCB161734 plus mFOLFIRINOX
 - Patients treated with INCB161734 in combination with mFOLFIRINOX achieved objective response rates (ORR) of 89% and 81% (confirmed + pending), and a disease control rate (DCR) of 100%.
 - Six-month landmark progression-free survival (PFS) rate in patients treated with INCB161734 in combination with mFOLFIRINOX was 90%.
 - Median treatment duration for INCB161734 + mFOLFIRINOX was 6 months.
 - No treatment-related adverse events (TRAEs) led to treatment discontinuation of INCB161734.
 - The most common TRAEs included diarrhea (68%), nausea (64%), vomiting (57%) and decreased neutrophil count (57%).
- INCB161734 plus GEMNabP
 - Patients treated with INCB161734 in combination with GEMNabP achieved ORRs of 69% and 58% (confirmed + pending), and a DCR of 96%.
 - Six-month landmark PFS in patients treated with INCB161734 in combination with GEMNabP was 80%.
 - Median treatment duration for INCB161734 + GEMNabP was 7 months.
 - TRAEs leading to treatment discontinuation of INCB161734 was low (n=1).
 - The most common TRAEs included diarrhea (65%), nausea (65%), decreased neutrophil count (65%) and anemia (58%).

Across treatment groups, INCB161734 in combination with GEMNabP or mFOLFIRINOX was tolerable and the safety and tolerability profile was broadly consistent with established profiles of SoC regimens. GI TRAEs were mostly Grade 1/2 and improved during treatment.

The global Phase 3 study (DAWN-303) evaluating INCB161734 in combination with investigator's choice of both SoC chemotherapies in first-line metastatic PDAC is ongoing with topline data anticipated in 2028. A Phase 3 study in the adjuvant PDAC setting is planned for 2027.

Additionally, two new clinical trial collaborations to evaluate novel combinations with INCB161734 in PDAC are planned:

- A Phase 1b trial will evaluate INCB161734 in combination with navlimetostat, Bristol Myers Squibb's MTA-cooperative

PRMT5 inhibitor, in patients with advanced or metastatic PDAC.

- A planned Phase 1b trial will evaluate INCB161734 in combination with SNV1521, Synnovator's PARP1 inhibitor, in patients with advanced or metastatic PDAC.

INCB161734 (KRAS G12D) in Colorectal Cancer

Clinical Activity and Manageable Safety as Monotherapy and in Combination in Patients with Advanced/Metastatic CRC

New Phase 1 data (cut-off July 6, 2026; n=49) demonstrated antitumor activity and a manageable safety profile for INCB161734 1,200 mg QD as monotherapy and in combination with cetuximab in patients with advanced/metastatic KRAS G12D-mutated CRC.

Specifically:

- Heavily pretreated patients who received INCB161734 in combination with cetuximab (n=22) achieved an ORR of 36% and a DCR of 100%. Median PFS (95% CI) was 7.2 (5.4, NE) months.
- As a monotherapy (n=24) and in combination (n=25, INCB161734 had a manageable safety profile.
 - No dose-limiting toxicities (DLTs) were observed in the combination dose escalation, and a maximum tolerated dose (MTD) was not reached.
 - TRAEs leading to discontinuation or dose modification for INCB161734 were low across monotherapy and combination treatment groups.

The Phase 3 study (DAWN-302) evaluating INCB161734 plus cetuximab for previously treated metastatic CRC is expected to initiate in the first half of 2027.

In addition to the previously announced [collaboration with Genmab](#) in CRC, Phase 1 studies and cohorts are ongoing or planned to explore INCB161734's potential to address resistance mechanisms, including an ongoing study of INCB161734 plus cetuximab and SoC chemotherapy in front-line metastatic CRC and a tumor-agnostic cohort.

INCA33890 (TGFβR2×PD-1) in MSS CRC

Notable Clinical Activity Across Treatment Combinations and Key Patient Subgroups, With Manageable Safety

In patients with advanced or MSS CRC, new Phase 1 data (cut-off August 26, 2026; n=94) demonstrated encouraging preliminary efficacy across cohorts and within subgroups and a manageable safety profile with INCA33890 900 mg intravenously (IV) every two weeks (Q2W) in combination with SoC therapies (bevacizumab [n=39], FOLFOX plus bevacizumab [n=43], FOLFIRI plus bevacizumab [n=6] or cetuximab [n=6]).

Of note:

- In the first-line setting, patients treated with INCA33890 in combination with FOLFOX and bevacizumab (n=42) achieved a 71% ORR and 100% DCR. The six-month PFS was 81%.
 - Responses were observed across subgroups, with an ORR of 83% (24/29) in patients with liver metastases and 62% (8/13) in patients with peritoneal metastases.
 - ORR was 81% (21/26) in patients with tumors with PD-L1 TAP ≥1%.
 - The most common treatment-emergent adverse events (TEAEs) in the first-line setting were neuropathy (77%), neutropenia (58%) and stomatitis (47%).
 - Treatment discontinuation was observed in four patients (9%).
- INCA33890 in combination with SoC therapies were tolerable with no DLTs observed.

The Phase 3 NEXERA-303 study evaluating INCA33890 plus FOLFOX and bevacizumab as a first-line treatment for patients with MSS CRC is ongoing with topline data expected in 2029. A Phase 2 study in MSS CRC in the adjuvant setting post-chemotherapy is also ongoing.

More information regarding the 2026 ESMO Congress and the data from Incyte's portfolio being featured at the meeting can be found on the ESMO website: <https://www.esmo.org/meeting-calendar/esmo-congress-2026>.

Analyst Event and Webcast

The data from the ESMO oral presentations will be discussed at an in-person analyst and investor event at ESMO on Monday, October 26, 2026, from 7:30 – 9:00 p.m. CET (2:30 – 4:00 p.m. EDT).

The event will be webcast and can be accessed via the [Events and Presentations](#) tab of the [Investor section of Incyte.com](#); the replay will be available for 30 days.

About INCB161734

INCB161734 is an investigational, novel, selective and orally bioavailable small molecule ON/OFF KRAS G12D inhibitor. KRAS is one of the most frequently altered oncogenic drivers across solid tumors, and the KRAS G12D mutation is among the most common KRAS alterations, occurring in approximately 40% of pancreatic ductal adenocarcinoma (PDAC) cases and approximately 15% of colorectal cancer (CRC) cases.

INCB161734 is being evaluated in the global Phase 3 DAWN-303 ([NCT07522073](#)) study which is currently enrolling patients with previously untreated KRAS G12D-mutated PDAC to further evaluate the efficacy and safety of INCB161734 in combination with standard-of-care (SoC) chemotherapy. Incyte will also be initiating the Phase 3 DAWN-302 study evaluating INCB161734 in combination with cetuximab in patients with previously treated metastatic colorectal cancer.

INCB161734 is also being evaluated as a monotherapy and in combination SoC chemotherapy (gemcitabine/nab-paclitaxel [GEMNabP] or modified FOLFIRINOX [mFOLFIRINOX]), in an ongoing open-label Phase 1 study across KRAS G12D-mutated solid tumors ([NCT06179160](#)).

About INCA33890

INCA33890 is an investigational, TGFβR2×PD-1 bispecific antibody, developed in collaboration with Merus (now part of Genmab) using their Bionics® antibody platform, engineered to block TGF-β-mediated signaling in immune cells co-expressing TGF-βR2 and PD-1. TGFβ is known to promote cancer immune evasion and predicts poor response to PD-(L)1 targeted therapies. INCA33890 aims to spare tissues where TGF-β signaling is important for normal function, avoiding the known toxicity of a broad blocking of the TGF-β pathway. INCA33890 offers a novel, promising, potentially first-in-class targeted treatment strategy for patients with advanced or metastatic solid tumors, including microsatellite stable colorectal cancer (MSS CRC).^{2,3,4,5}

INCA33890 is being evaluated in a Phase 1 study ([NCT05836324](#)) in patients with advanced or metastatic solid tumors. It is also being evaluated in Phase 2 and Phase 3 studies, including the Phase 2 NEXERA-204 study ([NCT07823322](#)) assessing INCA33890 monotherapy for the treatment of circulating tumor DNA-positive stage 2/3 MSS CRC after curative resection and chemotherapy. Additionally, the Phase 3 NEXERA-303 study ([NCT07284849](#)) evaluating the efficacy and safety of INCA33890 in combination with FOLFOX and bevacizumab for patients with previously untreated metastatic MSS CRC is currently enrolling.

About Incyte

Incyte is redefining what's possible in biopharmaceutical innovation. Through deep scientific expertise and a relentless focus on patients, we have built an established portfolio of first-in-class medicines and an extensive portfolio of next-generation medicines across our key franchises: Hematology, Oncology, and Inflammation and Autoimmunity.

To learn more, visit [incyte.com](#) or [investor.incyte.com](#). Follow us on social media: [LinkedIn](#), [X](#) and [Instagram](#).

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding the presentation of data from Incyte's clinical development pipeline, the potential offered by INCB161734 and INCA33890, expectations regarding planned or ongoing clinical trials for each, including the timing for enrollment, initiation and data read outs, whether or when any development compounds or combinations will be approved or commercially available for use in humans anywhere in the world, and Incyte's aspirations and goals as set forth under the heading "About Incyte."

Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including the sufficiency of clinical trial data to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials and the ability to enroll subjects in accordance with planned schedules; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; the efficacy or safety of Incyte's and its partners' products; the ability of Incyte and its partners' to achieve commercial success for their marketed products and product candidates, if approved; Incyte's and its partners' ability to obtain and maintain protection of intellectual property for their products and technology; Incyte's reliance on third parties and partners; the acceptance of Incyte's and its partners' products in the marketplace; market competition, sales, marketing, manufacturing and distribution requirements; greater than expected expenses, including expenses relating to litigation or strategic activities; and those risks and uncertainties discussed in greater detail in Incyte's reports filed with the U.S. Securities and Exchange Commission, including its annual report on Form 10-K for the year ended December 31, 2025, and its quarterly report on Form 10-Q for the quarter ended June 30, 2026. Incyte disclaims any intent or obligation to update these forward-looking statements.

¹ INCA33890, a TGFβR2×PD-1 bispecific Bionics antibody, is developed in collaboration with Merus (legacy partnership); Merus is now part of Genmab A/S.

² Deng Z, et al. *Signal Transduct Target Ther*. 2024;9:61.

³ Mariathasan S, et al. *Nature*. 2018;554:544-548.

⁴ Donkor MK, et al. *Immunity*. 2011;35:123-34.

⁵ Gulley JL, et al. *Mol Oncol*. 2022;16:2117-2134.

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