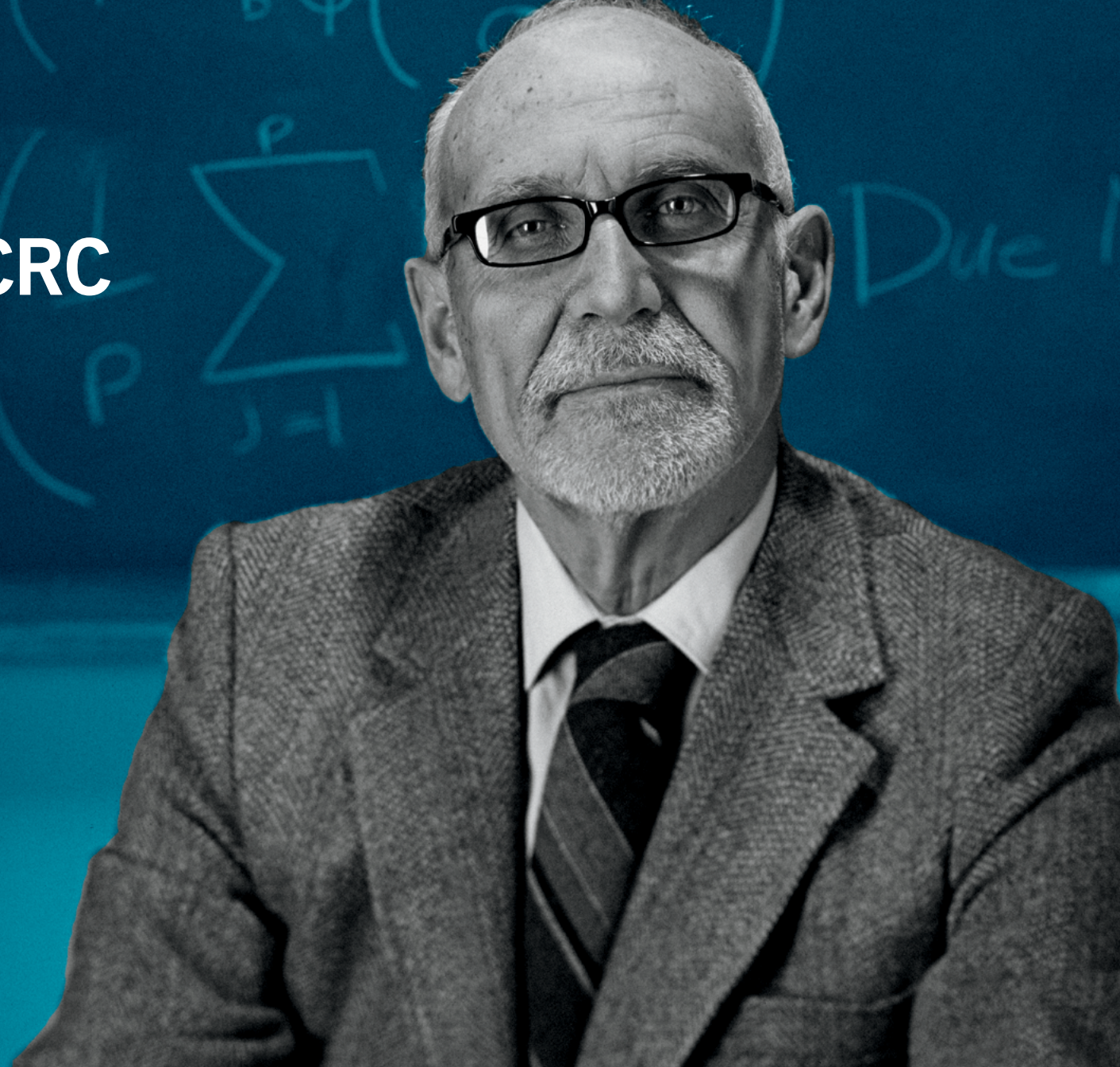
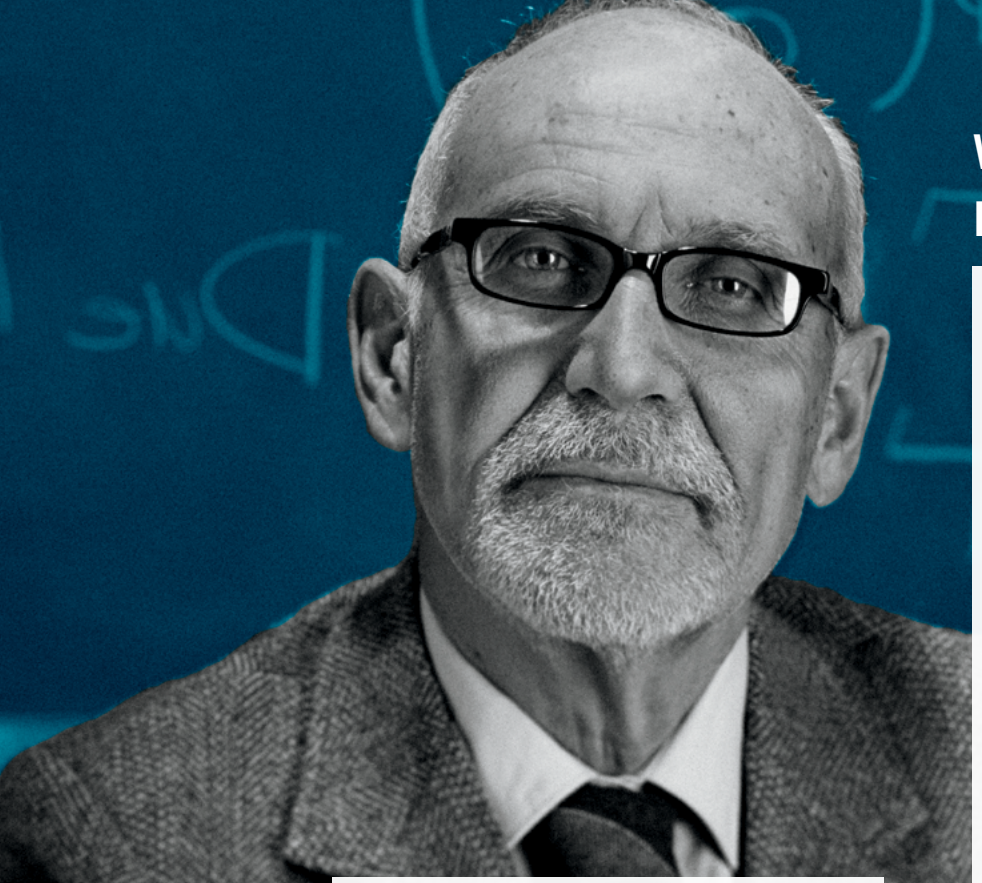
MEET ROY*:
A PATIENT WITH LIVER-LIMITED mCRC

*A hypothetical case study of a patient eligible for first-line mCRC therapy.



mCRC = metastatic colorectal cancer.



PATIENT Roy*
GENDER Male
AGE 64
OCCUPATION Middle-School Teacher

*This case study is a hypothetical example and does not represent an actual patient.

WHAT CLINICAL CHARACTERISTICS AFFECT YOUR FIRST-LINE TREATMENT DECISION?

Medical history
- Mild hyperlipidemia, controlled on statin therapy

Presentation
- 3-month history of worsening constipation, bloating, and blood in stool
- Colonoscopy confirmed 4-cm, non-obstructing mass in the left colon

Pathology report
- Moderately differentiated adenocarcinoma

Performance status
- ECOG PS = 1

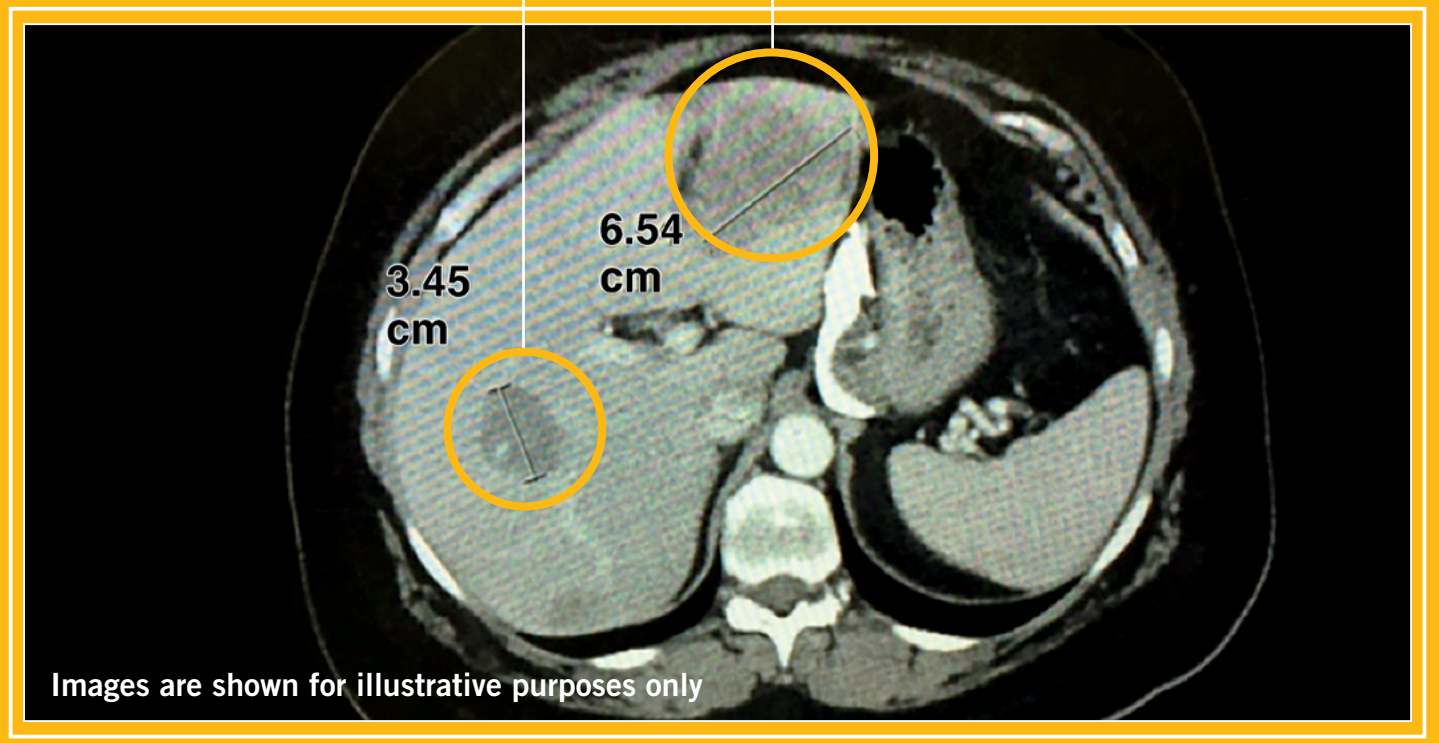
Laboratory results
- ALT: 70 U/L; AST: 180 U/L
- CBC: Moderate anemia (9.2 g/dL)

***RAS* status**
- Wild type (WT) *RAS* (WT in both *KRAS* and *NRAS*)

Imaging results
- CT scan indicated liver-limited metastases: 2 bilobar lesions (right: 3.5 cm; left: 6.5 cm)

Surgery consult on metastatic disease
- Potentially resectable metastases
- Surgeon feels metastatic disease is potentially resectable—treatment goal is to downgrade the tumor

ALT = alanine aminotransferase; AST = aspartate aminotransferase; CBC = complete blood count; CT = computed tomography; ECOG PS = Eastern Cooperative Oncology Group Performance Status; mCRC = metastatic colorectal cancer; R0 resection = complete resection.



WHAT FIRST-LINE TREATMENT IS APPROPRIATE FOR THIS PATIENT?

Vectibix® + FOLFOX: For first-line use in patients with WT *RAS** mCRC[1]

Indication

Vectibix® is indicated for the treatment of patients with wild-type *RAS* (defined as wild-type in both *KRAS* and *NRAS* as determined by an FDA-approved test for this use) metastatic colorectal cancer (mCRC):

- As first-line therapy in combination with FOLFOX.
- As monotherapy following disease progression after prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy.

Limitation of Use

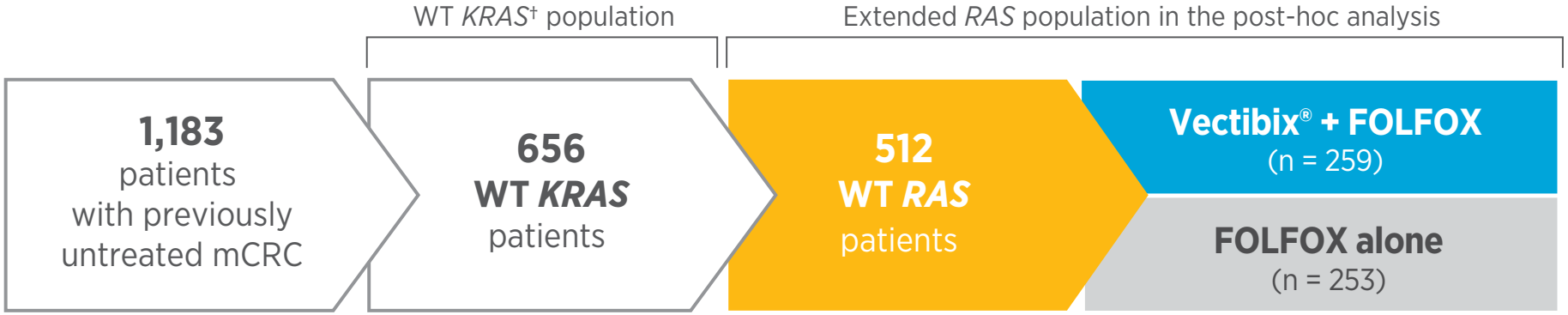
Vectibix® is not indicated for the treatment of patients with *RAS*-mutant mCRC or for whom *RAS* mutation status is unknown.

Boxed WARNING: DERMATOLOGIC TOXICITY

Dermatologic Toxicity: Dermatologic toxicities occurred in 90% of patients and were severe (NCI-CTC grade 3 and higher) in 15% of patients receiving Vectibix monotherapy.

THE PRIME STUDY

A PHASE 3, OPEN-LABEL, RANDOMIZED (1:1), MULTICENTER STUDY OF VECTIBIX® Q2W + FOLFOX VS FOLFOX Q2W ALONE[1,2]



- **Patients with mutant type (MT) *RAS* tumors should not be treated with Vectibix®[1]**
- Of the 656 patients with WT *KRAS*, 620 patients were assessed for *RAS* mutation status, of which 17% harbored mutations in *KRAS* exons 3 and 4 or in *NRAS* exons 2, 3, and 4. Post-hoc analyses of PFS, OS, and ORR were conducted in 512 patients with WT *RAS*[1,2]

*Defined as wild type in both *KRAS* and *NRAS*.[1]
†Exon 2 in codons 12 and 13.[1,3]

mCRC = metastatic colorectal cancer; ORR = objective response rate; OS = overall survival; PFS = progression-free survival; PRIME = Panitumumab Randomized Trial In Combination with Chemotherapy for Metastatic Colorectal Cancer to Determine Efficacy; Q2W = every 2 weeks; WT = wild type.

27.8% IMPROVEMENT IN MEDIAN PFS WITH VECTIBIX® + FOLFOX VS FOLFOX ALONE[1]

PFS in the WT *RAS* mCRC population	**Vectibix® + FOLFOX** (n = 259)	**FOLFOX alone** (n = 253)
Median months (95% CI)	**10.1** (9.3–12.0)	**7.9** (7.2–9.3)
Difference in median (months)	**2.2**	
Hazard ratio (95% CI)	**0.72** (0.58–0.90)	

28%

reduction in the risk of disease progression or death[1]

- There are no OS or PFS benefits in patients treated with Vectibix® with *RAS*-mutant mCRC[1]

*Defined as wild type in both *KRAS* and *NRAS*.[1]

CI = confidence interval; mCRC = metastatic colorectal cancer; PFS = progression-free survival; WT = wild type.

Important Safety Information

- In study 20020408, dermatologic toxicities occurred in 90% of patients and were severe (NCI-CTC grade 3 and higher) in 15% of patients with mCRC receiving Vectibix®. The clinical manifestations included, but were not limited to, acneiform dermatitis, pruritus, erythema, rash, skin exfoliation, paronychia, dry skin, and skin fissures.
- Monitor patients who develop dermatologic or soft tissue toxicities while receiving Vectibix® for the development of inflammatory or infectious sequelae. Life-threatening and fatal infectious complications including necrotizing fasciitis, abscesses, and sepsis have been observed in patients treated with Vectibix®. Life-threatening and fatal bullous mucocutaneous disease with blisters, erosions, and skin sloughing has also been observed in patients treated with Vectibix®. It could not be determined whether these mucocutaneous adverse reactions were directly related to EGFR inhibition or to idiosyncratic immune-related effects (eg, Stevens Johnson syndrome or toxic epidermal necrolysis). Withhold or discontinue Vectibix® for dermatologic or soft tissue toxicity associated with severe or life-threatening inflammatory or infectious complications. Dose modifications for Vectibix® concerning dermatologic toxicity are provided in the product labeling.

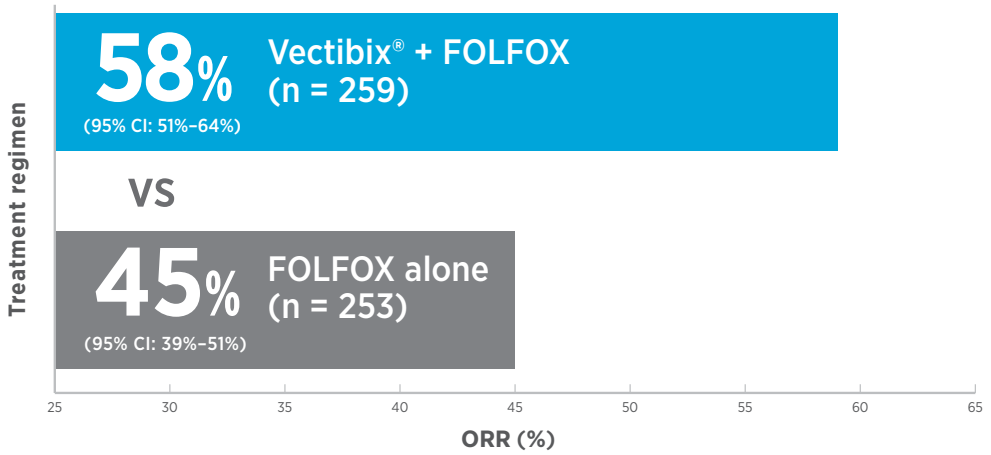
Please see full Important Safety Information, including **Boxed WARNING**, on the inside back cover.

Vectibix®
(panitumumab)
100mg/5ml | 20mg/ml for injection

First and only FDA-approved option for WT *RAS* in mCRC

VECTIBIX® + FOLFOX IMPROVED ORR* VS FOLFOX ALONE[1]

ORR IN PATIENTS WITH WT *RAS*† mCRC[1]



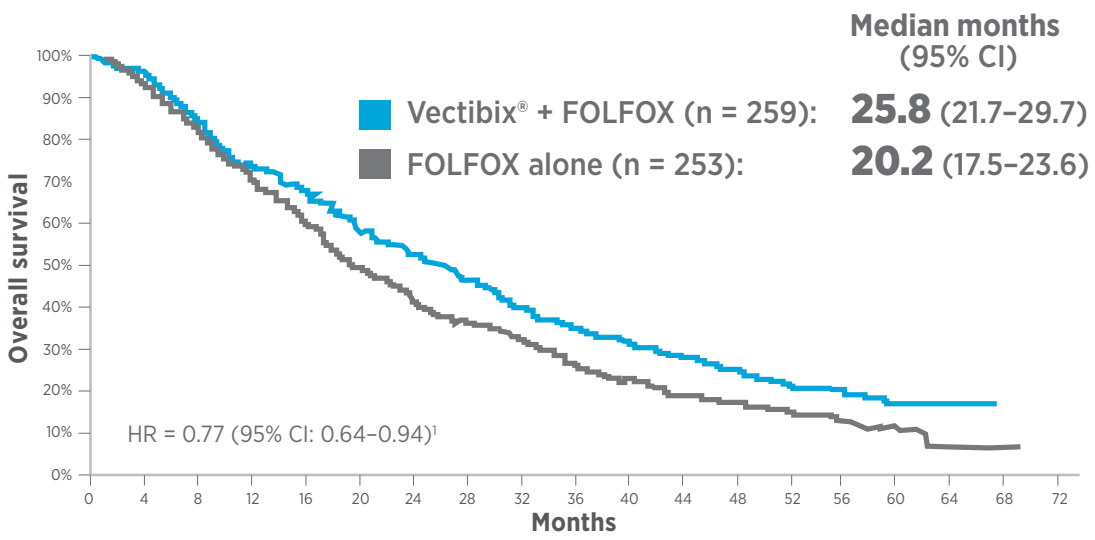
*Objective tumor response was evaluated by blinded central radiology review using modified RECIST criteria.[2]
†Defined as wild type in both *KRAS* and *NRAS*.[1]

CI = confidence interval; mCRC = metastatic colorectal cancer; ORR = objective response rate; PRIME = Panitumumab Randomized Trial In Combination with Chemotherapy for Metastatic Colorectal Cancer to Determine Efficacy; RECIST = Response Evaluation Criteria In Solid Tumors; WT = wild type.

Important Safety Information

- Vectibix® is not indicated for the treatment of patients with colorectal cancer that harbor somatic *RAS* mutations in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), and exon 4 (codons 117 and 146) of either *KRAS* or *NRAS* and hereafter is referred to as "*RAS*."
- Retrospective subset analyses across several randomized clinical trials were conducted to investigate the role of *RAS* mutations on the clinical effects of anti-EGFR-directed monoclonal antibodies (panitumumab or cetuximab). Anti-EGFR antibodies in patients with tumors containing *RAS* mutations resulted in exposing those patients to anti-EGFR related adverse reactions without clinical benefit from these agents. Additionally, in Study 20050203, 272 patients with *RAS*-mutant mCRC tumors received Vectibix® in combination with FOLFOX and 276 patients received FOLFOX alone. In an exploratory subgroup analysis, OS was shorter (HR = 1.21, 95% CI: 1.01-1.45) in patients with *RAS*-mutant mCRC who received Vectibix® and FOLFOX versus FOLFOX alone.

5.6-MONTH INCREASE IN MEDIAN OS[1†]



23% reduction in the risk of death[1]

- There are no OS or PFS benefits in patients treated with Vectibix® with *RAS*-mutant mCRC[1]

*Defined as wild type in both *KRAS* and *NRAS*.[1]
†OS with updated information based on events in 82% of patients.[1]
‡Response was evaluated by investigators per RECIST version 1.1.[4]

BSC = best supportive care; CI = confidence interval; HR = hazard ratio; mCRC = metastatic colorectal cancer; ORR = objective response rate; OS = overall survival; PFS = progression-free survival; RECIST = Response Evaluation Criteria in Solid Tumors.

- In patients with WT *RAS*, Vectibix® was also shown to be efficacious in prespecified analyses. Study 20100007 was a phase 3 trial evaluating Vectibix® + BSC vs BSC alone in chemorefractory patients with WT *KRAS* mCRC (N = 377). Prespecified analyses were conducted in 270 WT *RAS* patients.[1,2] These analyses showed the following:
  - Median OS was 10 months (95% CI: 8.7–11.6) in Vectibix® + BSC arm vs 6.9 months in the BSC arm alone (95% CI: 5.2–7.9); HR = 0.70 (95% CI: 0.53–0.93; *P* = 00135)[1]
  - Median PFS was 5.2 months (95% CI: 3.5–5.3) in Vectibix® + BSC arm vs 1.7 months in the BSC arm alone (95% CI: 1.6–2.2); HR = 0.46 (95% CI: 0.35–0.59; *P* < 0.0001)[1]
  - ORR‡ was 31% (95% CI: 23.5%–39.3%) in Vectibix® + BSC arm vs 2.3% in the BSC arm alone (95% CI: 0.5%–6.7%)[1]

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100mg/5ml | 20mg/ml for injection
First and only FDA-approved option for WT *RAS* in mCRC

Safety profile in patients with WT *KRAS** mCRC[1]

- The safety profile in patients with WT *RAS*† was similar to that of patients with WT *KRAS*[1]

Adverse reactions (≥ 5% difference) observed in patients with WT *KRAS* tumors treated with Vectibix® + FOLFOX compared to FOLFOX alone[1‡]	Vectibix® + FOLFOX (n = 322)		FOLFOX alone (n = 327)	
SYSTEM ORGAN CLASS Preferred term	Any grade n (%)	Grade 3–4 n (%)	Any grade n (%)	Grade 3–4 n (%)
EYE DISORDERS				
Conjunctivitis	58 (18%)	5 (2%)	10 (3%)	—
GASTROINTESTINAL DISORDERS				
Diarrhea	201 (62%)	59 (18%)	169 (52%)	29 (9%)
Stomatitis	87 (27%)	15 (5%)	42 (13%)	1 (< 1%)
GENERAL DISORDERS AND ADMINISTRATION-SITE CONDITIONS				
Mucosal inflammation	82 (25%)	14 (4%)	53 (16%)	1 (< 1%)
Asthenia	79 (25%)	16 (5%)	62 (19%)	11 (3%)
INFECTIONS AND INFESTATIONS				
Paronychia	68 (21%)	11 (3%)	—	—
INVESTIGATIONS				
Weight decreased	58 (18%)	3 (< 1%)	22 (7%)	—
METABOLISM AND NUTRITION DISORDERS				
Anorexia	116 (36%)	14 (4%)	85 (26%)	6 (2%)
Hypomagnesemia	96 (30%)	21 (7%)	26 (8%)	1 (< 1%)
Hypokalemia	68 (21%)	32 (10%)	42 (13%)	15 (5%)
Dehydration	26 (8%)	8 (2%)	10 (3%)	5 (2%)
RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS				
Epistaxis	46 (14%)	—	30 (9%)	—
SKIN AND SUBCUTANEOUS TISSUE DISORDERS				
Rash	179 (56%)	55 (17%)	24 (7%)	1 (< 1%)
Acneiform dermatitis	104 (32%)	33 (10%)	—	—
Pruritus	75 (23%)	3 (< 1%)	14 (4%)	—
Dry skin	68 (21%)	5 (2%)	13 (4%)	—
Erythema	50 (16%)	7 (2%)	14 (4%)	—
Skin fissures	50 (16%)	1 (< 1%)	1 (< 1%)	—
Alopecia	47 (15%)	—	30 (9%)	—
Acne	44 (14%)	10 (3%)	1 (< 1%)	—
Nail disorder	32 (10%)	4 (1%)	4 (1%)	—
Palmar-plantar erythrodysesthesia syndrome	30 (9%)	4 (1%)	9 (3%)	2 (< 1%)

- Adverse reactions that did not meet the threshold criteria for inclusion in this table were flushing (3% vs < 1%), abdominal pain (28% vs 23%), localized infection (3.7% vs < 1%), cellulitis (2.5% vs 0%), hypocalcemia (5.6% vs 2.1%), and deep vein thrombosis (5.3% vs 3.1%)[1]

*Exon 2 in codons 12 and 13.[1,3]
†Defined as wild type in both *KRAS* and *NRAS*.[1]
‡Of the 656 patients in the PRIME study with WT *KRAS* mCRC, 649 were evaluated for safety.[1]
mCRC = metastatic colorectal cancer; PRIME = Panitumumab Randomized Trial in Combination With Chemotherapy for Metastatic Colorectal Cancer to Determine Efficacy; WT = wild type.

Safety profile in patients with WT *KRAS** mCRC[1,5]

- The safety profile in patients with WT *RAS*† was similar to that of patients with WT *KRAS*[1]

Selected chemotherapy-associated adverse reactions[5‡]	Vectibix® + FOLFOX (n = 322)		FOLFOX alone (n = 327)	
SYSTEM ORGAN CLASS Preferred term	Any grade n (%)	Grade 3–4 n (%)	Any grade n (%)	Grade 3–4 n (%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS				
Neutropenia	194 (60%)	133 (41%)	202 (62%)	132 (40%)
Thrombocytopenia	62 (19%)	12 (4%)	88 (27%)	15 (5%)
Anemia	50 (16%)	14 (4%)	43 (13%)	9 (3%)
GASTROINTESTINAL DISORDERS				
Nausea	145 (45%)	16 (5%)	165 (50%)	3 (1%)
Vomiting	98 (30%)	11 (3%)	105 (32%)	9 (3%)
Constipation	94 (29%)	5 (2%)	91 (28%)	2 (1%)
GENERAL DISORDERS AND ADMINISTRATION-SITE CONDITIONS				
Pyrexia (fever)	100 (31%)	2 (1%)	93 (28%)	7 (2%)
Fatigue	119 (37%)	32 (10%)	112 (34%)	10 (3%)
NERVOUS SYSTEM DISORDERS				
Peripheral neuropathy	61 (19%)	18 (6%)	80 (24%)	18 (5%)
Peripheral sensory neuropathy	47 (15%)	5 (2%)	53 (16%)	6 (2%)
Paresthesia	107 (33%)	28 (9%)	110 (34%)	21 (6%)
PSYCHIATRIC DISORDERS				
Insomnia	43 (13%)	1 (< 1%)	51 (16%)	1 (< 1%)

*Exon 2 in codons 12 and 13.[1,3]
†Defined as wild type in both *KRAS* and *NRAS*.[1]
‡Of the 656 patients in the PRIME study with WT *KRAS* mCRC, 649 were evaluated for safety.[1]
mCRC = metastatic colorectal cancer; PRIME = Panitumumab Randomized Trial in Combination With Chemotherapy for Metastatic Colorectal Cancer to Determine Efficacy; WT = wild type.

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First and only FDA-approved option for WT *RAS* in mCRC

IMPORTANT SAFETY INFORMATION

BOXED WARNING: DERMATOLOGIC TOXICITY

Dermatologic Toxicity: Dermatologic toxicities occurred in 90% of patients and were severe (NCI-CTC grade 3 and higher) in 15% of patients receiving Vectibix monotherapy *[see Dosage and Administration (2.3), Warnings and Precautions (5.1), and Adverse Reactions (6.1)]*.

- In Study 20020408, dermatologic toxicities occurred in 90% of patients and were severe (NCI-CTC grade 3 and higher) in 15% of patients with mCRC receiving Vectibix®. The clinical manifestations included, but were not limited to, acneiform dermatitis, pruritus, erythema, rash, skin exfoliation, paronychia, dry skin, and skin fissures.
- Monitor patients who develop dermatologic or soft tissue toxicities while receiving Vectibix® for the development of inflammatory or infectious sequelae. Life-threatening and fatal infectious complications including necrotizing fasciitis, abscesses, and sepsis have been observed in patients treated with Vectibix®. Life-threatening and fatal bullous mucocutaneous disease with blisters, erosions, and skin sloughing has also been observed in patients treated with Vectibix®. It could not be determined whether these mucocutaneous adverse reactions were directly related to EGFR inhibition or to idiosyncratic immune-related effects (eg, Stevens Johnson syndrome or toxic epidermal necrolysis). Withhold or discontinue Vectibix® for dermatologic or soft tissue toxicity associated with severe or life-threatening inflammatory or infectious complications. Dose modifications for Vectibix® concerning dermatologic toxicity are provided in the product labeling.
- Vectibix® is not indicated for the treatment of patients with colorectal cancer that harbor somatic *RAS* mutations in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), and exon 4 (codons 117 and 146) of either *KRAS* or *NRAS* and hereafter is referred to as "*RAS*."
- Retrospective subset analyses across several randomized clinical trials were conducted to investigate the role of *RAS* mutations on the clinical effects of anti-EGFR-directed monoclonal antibodies (panitumumab or cetuximab). Anti-EGFR antibodies in patients with tumors containing *RAS* mutations resulted in exposing those patients to anti-EGFR related adverse reactions without clinical benefit from these agents. Additionally, in Study 20050203, 272 patients with *RAS*-mutant mCRC tumors received Vectibix® in combination with FOLFOX and 276 patients received FOLFOX alone. In an exploratory subgroup analysis, OS was shorter (HR = 1.21, 95% CI: 1.01-1.45) in patients with *RAS*-mutant mCRC who received Vectibix® and FOLFOX versus FOLFOX alone.
- Progressively decreasing serum magnesium levels leading to severe (grade 3-4) hypomagnesemia occurred in up to 7% (in Study 20080763) of patients across clinical trials. Monitor patients for hypomagnesemia and hypocalcemia prior to initiating Vectibix® treatment, periodically during Vectibix® treatment, and for up to 8 weeks after the completion of treatment. Other electrolyte disturbances, including hypokalemia, have also been observed. Replete magnesium and other electrolytes as appropriate.
- In Study 20020408, 4% of patients experienced infusion reactions and 1% of patients experienced severe infusion reactions (NCI-CTC grade 3-4). Infusion reactions, manifesting as fever, chills, dyspnea, bronchospasm, and hypotension, can occur following Vectibix® administration. Fatal infusion reactions occurred in postmarketing experience. Terminate the infusion for severe infusion reactions.
- Severe diarrhea and dehydration, leading to acute renal failure and other complications, have been observed in patients treated with Vectibix® in combination with chemotherapy.
- Fatal and nonfatal cases of interstitial lung disease (ILD) (1%) and pulmonary fibrosis have been observed in patients treated with Vectibix®. Pulmonary fibrosis occurred in less than 1% (2/1467) of patients enrolled in clinical studies of Vectibix®. In the event of acute onset or worsening of pulmonary symptoms interrupt Vectibix® therapy. Discontinue Vectibix® therapy if ILD is confirmed.

IMPORTANT SAFETY INFORMATION *(continued)*

- In patients with a history of interstitial pneumonitis or pulmonary fibrosis, or evidence of interstitial pneumonitis or pulmonary fibrosis, the benefits of therapy with Vectibix® versus the risk of pulmonary complications must be carefully considered.
- Exposure to sunlight can exacerbate dermatologic toxicity. Advise patients to wear sunscreen and hats and limit sun exposure while receiving Vectibix®.
- Keratitis and ulcerative keratitis, known risk factors for corneal perforation, have been reported with Vectibix® use. Monitor for evidence of keratitis or ulcerative keratitis. Interrupt or discontinue Vectibix® for acute or worsening keratitis.
- In an interim analysis of an open-label, multicenter, randomized clinical trial in the first-line setting in patients with mCRC, the addition of Vectibix® to the combination of bevacizumab and chemotherapy resulted in decreased OS and increased incidence of NCI-CTC grade 3-5 (87% vs 72%) adverse reactions. NCI-CTC grade 3-4 adverse reactions occurring at a higher rate in Vectibix®-treated patients included rash/acneiform dermatitis (26% vs 1%), diarrhea (23% vs 12%), dehydration (16% vs 5%), primarily occurring in patients with diarrhea, hypokalemia (10% vs 4%), stomatitis/mucositis (4% vs < 1%), and hypomagnesemia (4% vs 0).
- NCI-CTC grade 3-5 pulmonary embolism occurred at a higher rate in Vectibix®-treated patients (7% vs 3%) and included fatal events in three (< 1%) Vectibix®-treated patients. As a result of the toxicities experienced, patients randomized to Vectibix®, bevacizumab, and chemotherapy received a lower mean relative dose intensity of each chemotherapeutic agent (oxaliplatin, irinotecan, bolus 5-FU, and/or infusional 5-FU) over the first 24 weeks on study compared with those randomized to bevacizumab and chemotherapy.
- Vectibix® can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment, and for at least 2 months after the last dose of Vectibix®.
- In monotherapy, the most commonly reported adverse reactions (≥ 20%) in patients with Vectibix® were skin rash with variable presentations, paronychia, fatigue, nausea, and diarrhea.
- The most commonly reported adverse reactions (≥ 20%) with Vectibix® + FOLFOX were diarrhea, stomatitis, mucosal inflammation, asthenia, paronychia, anorexia, hypomagnesemia, hypokalemia, rash, acneiform dermatitis, pruritus, and dry skin. The most common serious adverse reactions (≥ 2% difference between treatment arms) were diarrhea and dehydration.

Please see Vectibix® full Prescribing Information, including **Boxed WARNING**.

Vectibix® (panitumumab)
100mg/5ml | 20mg/ml for injection

First and only FDA-approved option for WT *RAS* in mCRC

In a post-hoc analysis of first-line patients with WT *RAS** mCRC[1]

CHOOSE VECTIBIX®: PROVEN EFFICACY IN COMBINATION WITH FOLFOX[1]

IMPROVED PFS

- 10.1 months median PFS with Vectibix® + FOLFOX vs 7.9 months with FOLFOX alone (HR = 0.72, 95% CI: 0.58–0.90)[1]

IMPROVED ORR†

- 58% (95% CI: 51%–64%) of patients with WT *RAS* mCRC experienced a response with Vectibix® + FOLFOX vs 45% (95% CI: 39%–51%) with FOLFOX alone[1]

INCREASED OS

- 25.8 months median OS‡ with Vectibix® + FOLFOX vs 20.2 months with FOLFOX alone (HR = 0.77, 95% CI: 0.64–0.94)[1]

PRIME (Vectibix® + FOLFOX vs FOLFOX alone): N = 1,183 (WT *RAS* n = 512), randomized (1:1), phase 3, open-label, multicenter study of mCRC.[1,2]

- **There are no OS or PFS benefits in patients treated with Vectibix® with *RAS*-mutant mCRC[1]**

Indication

Vectibix® is indicated for the treatment of patients with wild-type *RAS* (defined as wild-type in both *KRAS* and *NRAS* as determined by an FDA-approved test for this use) metastatic colorectal cancer (mCRC):

- As first-line therapy in combination with FOLFOX.
- As monotherapy following disease progression after prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy.

Limitation of Use

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References: 1. Vectibix® (panitumumab) prescribing information, Amgen; 6/2017. **2.** Douillard J-Y, Siena S, Cassidy J, et al. Randomized, phase III trial of panitumumab with infusional fluorouracil, leucovorin, and oxaliplatin (FOLFOX4) versus FOLFOX4 alone as first-line treatment in patients with previously untreated metastatic colorectal cancer: the PRIME study. *J Clin Oncol*. 2010;28(31):4697-4705. **3.** Douillard J-Y, Oliner KS, Siena S, et al. Panitumumab-FOLFOX4 treatment and *RAS* mutations in colorectal cancer. *N Engl J Med*. 2013;369(11):1023-1034. **4.** Kim TW, Elme A, Kusic Z, et al. A phase 3 trial evaluating panitumumab plus best supportive care vs best supportive care in chemorefractory wild-type *KRAS* or *RAS* metastatic colorectal cancer. *Br J Cancer*. 2016;115(10):1206-1214. **5.** Data on file, Amgen.

AMGEN®

Please visit Vectibix.com/hcp for more information.

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