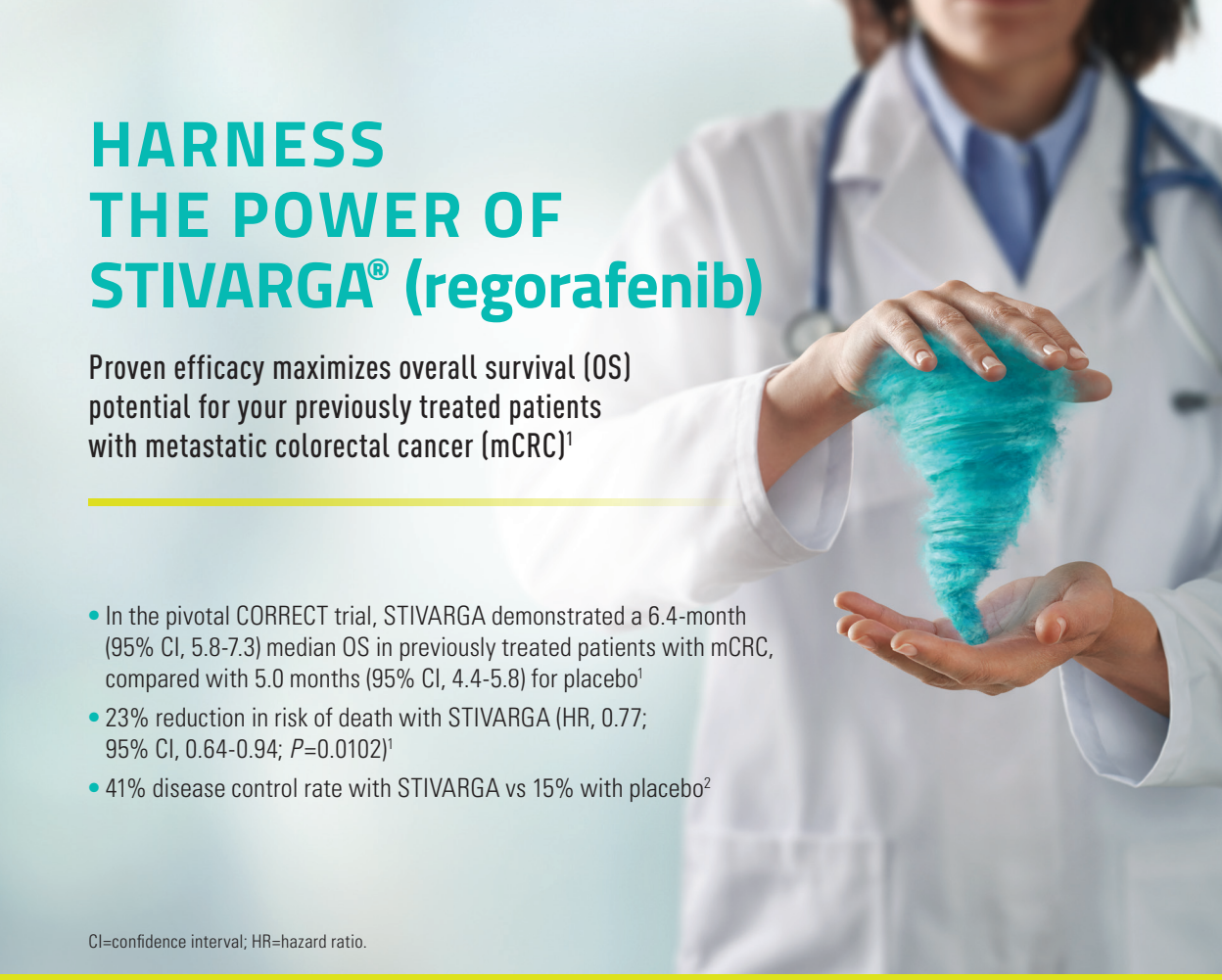

HARNESS THE POWER OF STIVARGA® (regorafenib)

Proven efficacy maximizes overall survival (OS) potential for your previously treated patients with metastatic colorectal cancer (mCRC)[1]

- In the pivotal CORRECT trial, STIVARGA demonstrated a 6.4-month (95% CI, 5.8-7.3) median OS in previously treated patients with mCRC, compared with 5.0 months (95% CI, 4.4-5.8) for placebo[1]
- 23% reduction in risk of death with STIVARGA (HR, 0.77; 95% CI, 0.64-0.94; *P*=0.0102)[1]
- 41% disease control rate with STIVARGA vs 15% with placebo[2]

CI=confidence interval; HR=hazard ratio.

Indication

STIVARGA is indicated for the treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type, an anti-EGFR therapy.

Important Safety Information

WARNING: HEPATOTOXICITY

- **Severe and sometimes fatal hepatotoxicity has occurred in clinical trials.**
- **Monitor hepatic function prior to and during treatment.**
- **Interrupt and then reduce or discontinue STIVARGA for hepatotoxicity as manifested by elevated liver function tests or hepatocellular necrosis, depending upon severity and persistence.**

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Right patient, right time

Not actual patient cases.

PATIENT 1

Personal characteristics

- 60-year-old female
- Currently working and able to drive herself to work

Initial diagnosis

- Rectal cancer (T2, N0, M0); treated with sigmoid/rectal resection with 0/15 positive nodes
  - ECOG PS=0
  - *RAS* mutant, MSS

15 MONTHS AFTER DIAGNOSIS

- Recurrent disease with liver metastases detected
  - R0 liver resection followed by treatment with FOLFOX + bevacizumab

4 MONTHS AFTER LIVER METASTASIS

- Recurrent disease with hypermetabolic lung nodule observed
  - Treated with FOLFIRI + bevacizumab

TODAY

Clinical characteristics

- CT scan showed tumor no longer responding
- Slight rise in CEA levels (≤5 ng/mL)
- PS score=1

PATIENT 2

Personal characteristics

- 66-year-old male
- Helps care for his grandchildren
- Prioritizes time with his family

Initial diagnosis

- Adenocarcinoma of the sigmoid colon (T2, N0, M0)
  - ECOG PS=0
  - *KRAS* WT, MSS
  - Treated with sigmoid resection with 0/12 positive nodes

19 MONTHS AFTER DIAGNOSIS

- Liver metastases discovered through imaging
  - Treated with FOLFIRI + cetuximab

3 MONTHS AFTER LIVER METASTASIS

- Liver tumor growth >15%, and CT showed diaphragmatic involvement
  - Treated with FOLFOX + bevacizumab

TODAY

Clinical characteristics

- Stable disease
- No longer able to tolerate cytotoxic therapy
- PS score=1

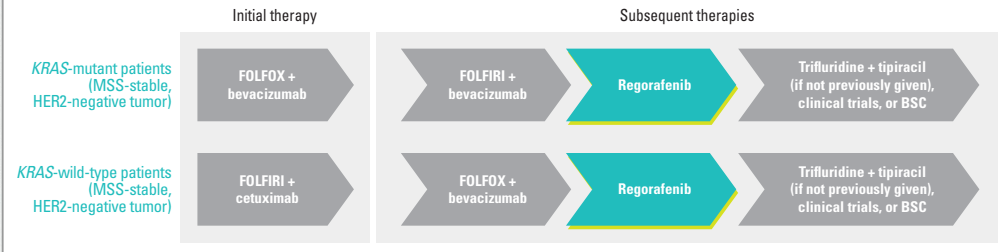
ECOG PS=Eastern Cooperative Oncology Group Performance Status.

Important Safety Information (continued)

Hepatotoxicity: Severe drug-induced liver injury with fatal outcome occurred in STIVARGA® (regorafenib)-treated patients across all clinical trials. In most cases, liver dysfunction occurred within the first 2 months of therapy and was characterized by a hepatocellular pattern of injury. In metastatic colorectal cancer (mCRC), fatal hepatic failure occurred in 1.6% of patients in the STIVARGA arm and in 0.4% of patients in the placebo arm.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) list regorafenib (STIVARGA®) as a potential option for patients who have been previously treated with at least 2 chemo-based therapies (Category 2A)[3,4*†]

Potential treatment algorithms[3,4‡]



Designated Category 2A by the NCCN.[3,4†]

*Regorafenib and trifluridine + tipiracil are treatment options for patients who have progressed through all available regimens.

BSC=best supportive care; FOLFIRI=folinic acid, fluorouracil, and irinotecan; FOLFOX=folinic acid, fluorouracil, and oxaliplatin; MSS=microsatellite stable.

†Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.[3,4]

‡For a complete listing of treatment options, see NCCN.org.

Important Safety Information (continued)

Liver Function Monitoring: Obtain liver function tests (ALT, AST, and bilirubin) before initiation of STIVARGA and monitor at least every 2 weeks during the first 2 months of treatment. Thereafter, monitor monthly or more frequently as clinically indicated. Monitor liver function tests weekly in patients experiencing elevated liver function tests until improvement to less than 3 times the upper limit of normal (ULN) or baseline values. Temporarily hold and then reduce or permanently discontinue STIVARGA, depending on the severity and persistence of hepatotoxicity as manifested by elevated liver function tests or hepatocellular necrosis.

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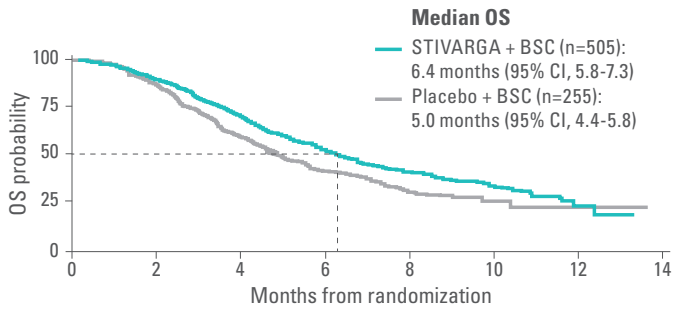
Harness the proven efficacy of STIVARGA® (regorafenib) to maximize OS potential for your previously treated patients with mCRC

Significant improvement in OS in CORRECT[1,2*]



6.4 MONTHS vs 5.0 months
HR: 0.77 (95% CI, 0.64-0.94)
P<0.0102

*OS was the primary endpoint of CORRECT.[1]

CORRECT (COloRectal cancer treated with REgorafenib or plaCebo after failure of standard Therapy) was a large, international, placebo-controlled, double-blind, randomized (2:1), phase 3 trial that evaluated the efficacy and safety of STIVARGA in patients with mCRC who had progressed after all approved standard therapies (N=760).[1,2]

- STIVARGA improved OS in CORRECT, which included patients with historically collected *KRAS* status (N=729)[1]
  – Historical *KRAS* status was assessed (59% mutant, 41% wild-type *KRAS*)
- There were 275 deaths out of 505 patients treated with STIVARGA (55%) vs 157 deaths out of 255 patients treated with placebo (62%)[1]

23% reduction in the risk of death with STIVARGA in CORRECT (HR: 0.77 [95% CI, 0.64-0.94]; *P*=0.0102)[1]

Important Safety Information (continued)

Infections: STIVARGA caused an increased risk of infections. The overall incidence of infection (Grades 1-5) was higher (32% vs 17%) in 1142 STIVARGA-treated patients as compared to the control arm in randomized placebo-controlled trials. The incidence of grade 3 or greater infections in STIVARGA-treated patients was 9%. The most common infections were urinary tract infections (5.7%), nasopharyngitis (4.0%), mucocutaneous and systemic fungal infections (3.3%) and pneumonia (2.6%). Fatal outcomes caused by infection occurred more often in patients treated with STIVARGA (1.0%) as compared to patients receiving placebo (0.3%); the most common fatal infections were respiratory (0.6% vs 0.2%). Withhold STIVARGA for Grade 3 or 4 infections, or worsening infection of any grade. Resume STIVARGA at the same dose following resolution of infection.

STIVARGA® (regorafenib) significantly improved progression-free survival (PFS)[1,2]

- Median PFS of 2.0 months (95% CI, 1.9-2.3) with STIVARGA + BSC (n=505) vs 1.7 months (95% CI, 1.7-1.8) with placebo + BSC (n=255)
- STIVARGA reduced the risk of death or disease progression by 51% in CORRECT (HR: 0.49 [95% CI, 0.42-0.58]; *P*<0.0001)

Disease control rates (DCR) in CORRECT[2]

- 41% DCR with STIVARGA included 41% stable disease rate and 1% partial response rate (n=207/505)
- 15% DCR with placebo included 15% stable disease rate and 0.4% partial response rate (n=38/255)
  - Disease control is defined as a proportion of patients with a best response of complete or partial response or stable disease; assessment of stable disease had to be made at least 6 weeks after randomization

In CORRECT, patients were able to receive cytotoxic therapy following treatment with STIVARGA[2,5]

26% of patients in the CORRECT trial received cytotoxic therapy after STIVARGA

Systemic anticancer treatment during CORRECT trial follow-up	STIVARGA, n (%) (n=505)	Placebo, n (%) (n=255)
Patients with ≥1 medication	131 (26)	76 (30)
Any antineoplastic or immunomodulation agent	130 (26)	74 (29)

STIVARGA offers a break from chemotherapy-based agents and allows the use of chemotherapy after STIVARGA[2,5-8]

Important Safety Information (continued)

Hemorrhage: STIVARGA caused an increased incidence of hemorrhage. The overall incidence (Grades 1-5) was 18.2% in 1142 patients treated with STIVARGA vs 9.5% with placebo in randomized, placebo-controlled trials. The incidence of grade 3 or greater hemorrhage in patients treated with STIVARGA was 3.0%. The incidence of fatal hemorrhagic events was 0.7%, involving the central nervous system or the respiratory, gastrointestinal, or genitourinary tracts. Permanently discontinue STIVARGA in patients with severe or life-threatening hemorrhage and monitor INR levels more frequently in patients receiving warfarin.

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STIVARGA® (regorafenib) safety profile

AEs reported in ≥10% of mCRC patients treated with STIVARGA and reported more commonly than in patients receiving placebo[1]*

	STIVARGA (n=500)		Placebo (n=253)	
AEs	**All grades**	**Grade ≥3**	**All grades**	**Grade ≥3**
General disorders and administration site conditions				
Asthenia/fatigue	64%	15%	46%	9%
Pain	59%	9%	48%	7%
Fever	28%	2%	15%	0%
Metabolism and nutrition disorders				
Decreased appetite and food intake	47%	5%	28%	4%
Skin and subcutaneous tissue disorders				
HFSR/PPES	45%	17%	7%	0%
Rash†	26%	6%	4%	<1%
Gastrointestinal disorders				
Diarrhea	43%	8%	17%	2%
Mucositis	33%	4%	5%	0%
Investigations				
Weight loss	32%	<1%	10%	0%
Infections and infestations				
Infection‡	31%	9%	17%	6%
Vascular disorders				
Hypertension	30%	8%	8%	<1%
Hemorrhage‡	21%	2%	8%	<1%
Respiratory, thoracic, and mediastinal disorders				
Dysphonia	30%	0%	6%	0%
Nervous system disorders				
Headache	10%	<1%	7%	0%

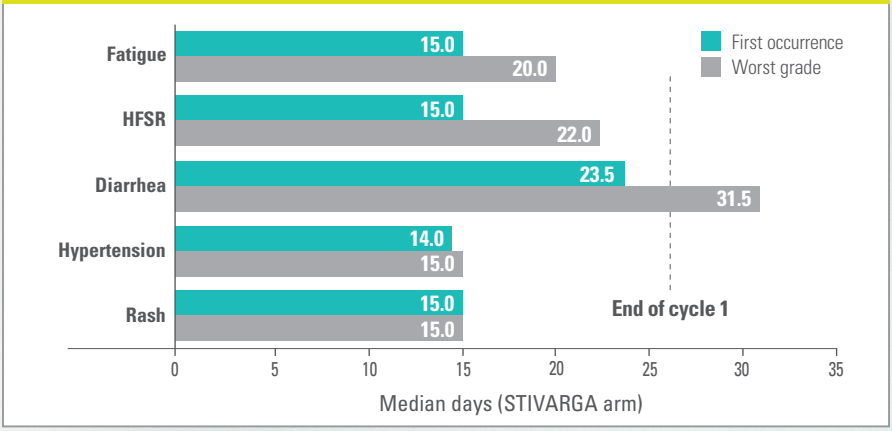
AEs=adverse events; HFSR/PPES=hand-foot skin reaction/palmar-plantar erythrodysesthesia syndrome.
*Adverse reactions graded according to National Cancer Institute Common Toxicity for Adverse Events version 3.0 (NCI CTCAE v3.0).
†The term "rash" represents reports of events of drug eruption, rash, erythematous rash, generalized rash, macular rash, maculopapular rash, papular rash, and pruritic rash.
‡Fatal outcomes observed.

Important Safety Information (continued)

Gastrointestinal Perforation or Fistula: Gastrointestinal perforation occurred in 0.6% of 4518 patients treated with STIVARGA across all clinical trials of STIVARGA administered as a single agent; this included eight fatal events. Gastrointestinal fistula occurred in 0.8% of patients treated with STIVARGA and in 0.2% of patients in the placebo arm across randomized, placebo-controlled trials. Permanently discontinue STIVARGA in patients who develop gastrointestinal perforation or fistula.

Median time to select treatment-related AEs ≥Grade 3 occurring in ≥5% of patients in either arm of the CORRECT trial

Median time to first occurrence and worst grade of select common AEs in STIVARGA® (regorafenib)-treated patients[2,9]



- AEs can occur at any time during the course of treatment, and monitoring is critical during the first cycle and throughout therapy[2,10]
- Skin toxicity (HFSR/PPE or rash) was the most common cause of permanent drug discontinuation[1]

8.2% of STIVARGA patients discontinued treatment because of drug-related AEs vs 1.2% of placebo patients[1]

Important Safety Information (continued)

Dermatological Toxicity: In randomized, placebo-controlled trials, adverse skin reactions occurred in 71.9% of patients with STIVARGA arm and 25.5% of patients in the placebo arm including hand-foot skin reaction (HFSR) also known as palmar-plantar erythrodysesthesia syndrome (PPES) and severe rash, requiring dose modification. In the randomized, placebo-controlled trials, the overall incidence of HFSR was higher in 1142 STIVARGA-treated patients (53% vs 8%) than in the placebo-treated patients. Most cases of HFSR in STIVARGA-treated patients appeared during the first cycle of treatment. The incidences of Grade 3 HFSR (16% vs <1%), Grade 3 rash (3% vs <1%), serious adverse reactions of erythema multiforme (<0.1% vs 0%), and Stevens-Johnson syndrome (<0.1% vs 0%) were higher in STIVARGA-treated patients. Across all trials, a higher incidence of HFSR was observed in Asian patients treated with STIVARGA (all grades: 72%; Grade 3: 18%). Toxic epidermal necrolysis occurred in 0.02% of 4518 STIVARGA-treated patients across all clinical trials of STIVARGA administered as a single agent. Withhold STIVARGA, reduce the dose, or permanently discontinue depending on the severity and persistence of dermatologic toxicity.

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CONCUR study design

CONCUR: a randomized, double-blind, placebo-controlled, phase 3 trial[11]

- CONCUR was an independent study of STIVARGA® (regorafenib) vs placebo in Asian patients with mCRC who had received ≥2 prior lines of treatment. Study design, patient population, sample size, results, and conclusions may vary from the CORRECT study. In CONCUR, the primary endpoint was OS and secondary endpoints were PFS, ORR, and DCR
- 204 total patients were evaluated in the study; 136 were enrolled in the STIVARGA arm and 68 were in the placebo arm. Patients received STIVARGA 160 mg or matching placebo orally once a day for the first 21 days of each 28-day treatment cycle until disease progression, death, unacceptable toxicity, or patient withdrawal or discontinuation

CONCUR study: baseline characteristics[11]

		STIVARGA (n=136)	Placebo (n=68)
Age, years (range)	Median	57.5 (50.0-66.0)	55.5 (48.5-62.0)
Sex (male)		85 (63%)	33 (49%)
Region	China (mainland China; Taiwan; Hong Kong)	112 (82%)	60 (88%)
	Asia (other than China)	24 (18%)	8 (12%)
ECOG PS	0	35 (26%)	15 (22%)
	1	101 (74%)	53 (78%)
***KRAS* mutation**	Yes	46 (34%)	18 (26%)
	No	50 (37%)	29 (43%)
	Unknown	40 (29%)	21 (31%)
Previous systemic anticancer treatment lines (On or after diagnosis of metastatic disease*)	1-2	48 (35%)	24 (35%)
	3	32 (24%)	17 (25%)
	≥4	52 (38%)	27 (40%)
Primary tumor site	Colon	79 (58%)	48 (71%)
	Rectum	53 (39%)	19 (28%)
	Colon and rectum	4 (3%)	1 (1%)

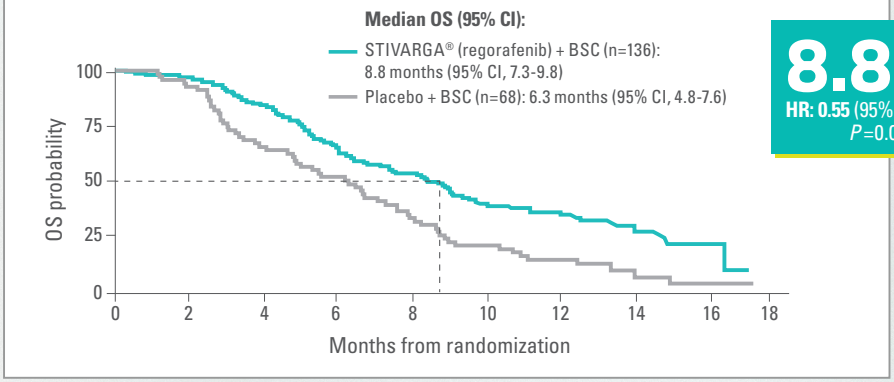
ORR=overall response rate.
*4 patients (3%) in the STIVARGA arm received no prior treatment for metastatic disease.

Important Safety Information (continued)

Hypertension: Hypertensive crisis occurred in 0.2% in STIVARGA-treated patients and in none of the patients in placebo arm across all randomized, placebo-controlled trials. STIVARGA caused an increased incidence of hypertension (30% vs 8% in mCRC). The onset of hypertension occurred during the first cycle of treatment in most patients who developed hypertension (67% in randomized, placebo controlled trials). Do not initiate STIVARGA until blood pressure is adequately controlled. Monitor blood pressure weekly for the first 6 weeks of treatment and then every cycle, or more frequently, as clinically indicated. Temporarily or permanently withhold STIVARGA for severe or uncontrolled hypertension.

OS results from CONCUR

Median OS (primary endpoint) in CONCUR[11]



8.8 MONTHS vs 6.3 months
HR: 0.55 (95% CI, 0.40-0.77)
P=0.00016

- CONCUR was a multicenter, double-blind, placebo-controlled, randomized, phase 3 trial that evaluated the efficacy and safety of STIVARGA in Asian patients with mCRC progressing after standard therapies (N=204). Prior anti-VEGF or anti-EGFR targeted therapy was allowed, but not mandatory[11]
- 45% reduction in the risk of death with STIVARGA in CONCUR (HR: 0.55 [95% CI, 0.40-0.77]; *P*=0.00016)[11]
- AEs leading to death occurred in 12 (9%) patients receiving STIVARGA and 7 (10%) patients receiving placebo[11]

Important Safety Information (continued)

Cardiac Ischemia and Infarction: STIVARGA increased the incidence of myocardial ischemia and infarction (0.9% with STIVARGA vs 0.2% with placebo) in randomized placebo-controlled trials. Withhold STIVARGA in patients who develop new or acute cardiac ischemia or infarction, and resume only after resolution of acute cardiac ischemic events if the potential benefits outweigh the risks of further cardiac ischemia.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS): Reversible posterior leukoencephalopathy syndrome (RPLS), a syndrome of subcortical vasogenic edema diagnosed by characteristics finding on MRI, occurred in one of 4800 STIVARGA-treated patients across all clinical trials. Perform an evaluation for RPLS in any patient presenting with seizures, severe headache, visual disturbances, confusion, or altered mental function. Discontinue STIVARGA in patients who develop RPLS.

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PFS results from CONCUR[11]

- Median PFS of 3.2 months (95% CI, 2.0-3.7) with STIVARGA® (regorafenib) + BSC (n=136) vs 1.7 months (95% CI, 1.6-1.8) with placebo + BSC (n=68)
- STIVARGA reduced the risk of disease progression or death by 69% in CONCUR (HR: 0.31 [95% CI, 0.22-0.44]; *P*<0.0001)

DCR results from CONCUR[11]

- 51% DCR with STIVARGA included 47% stable disease rate and 4% partial response rate (n=70/136)
- 7% DCR with placebo included 7% stable disease rate and 0% partial response rate (n=5/68)
  - Disease control is defined as a proportion of patients with a best response of complete or partial response or stable disease; assessment of stable disease had to be made at least 6 weeks after randomization

In CONCUR, patients were able to receive cytotoxic therapy following treatment with STIVARGA[12]

29% of patients in the CONCUR trial received cytotoxic therapy after STIVARGA

Systemic anticancer treatment during CONCUR trial follow-up	STIVARGA, n (%) (n=136)	Placebo, n (%) (n=68)
Patients with ≥1 medication	42 (30.9)	29 (42.6)
Any antineoplastic or immunomodulation agent	39 (28.7)	27 (39.7)

Important Safety Information (continued)

Wound Healing Complications: Impaired wound healing complications can occur in patients who receive drugs that inhibit the VEGF signaling pathway. Therefore, STIVARGA has the potential to adversely affect wound healing. Withhold STIVARGA for at least 2 weeks prior to elective surgery. Do not administer for at least 2 weeks following major surgery and until adequate wound healing. The safety of resumption of STIVARGA after resolution of wound healing complications has not been established.

Embryo-Fetal Toxicity: STIVARGA can cause fetal harm when administered to a pregnant woman. There are no available data on STIVARGA use in pregnant women. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with STIVARGA and for 2 months after the final dose.

Nursing Mothers: Because of the potential for serious adverse reactions in breastfed infants from STIVARGA, do not breastfeed during treatment with STIVARGA and for 2 weeks after the final dose.

STIVARGA® (regorafenib) safety profile in CONCUR

Drug-related AEs occurring at any grade in ≥10% of patients or at Grade 3 or higher[11]

AEs	STIVARGA (160 mg) + BSC (n=136), n (%)				Placebo + BSC (n=68), n (%)			
	Grades 1-2	Grade 3	Grade 4	Grade 5	Grades 1-2	Grade 3	Grade 4	Grade 5
Any event	58 (43)	67 (49)	5 (4)	2 (1)	21 (31)	9 (13)	1 (1)	0
HFSR	78 (57)	22 (16)	NA	NA	3 (4)	0	NA	NA
Hyperbilirubinemia	41 (30)	6 (4)	3 (2)	NA	4 (6)	1 (1)	0	NA
ALT concentration increased	23 (17)	9 (7)	0	NA	5 (7)	0	0	NA
AST concentration increased	24 (18)	7 (5)	1 (1)	NA	6 (9)	0	0	NA
Hypertension	16 (12)	15 (11)	0	0	1 (1)	2 (3)	0	0
Hoarseness	27 (20)	1 (1)	NA	NA	0	0	NA	NA
Diarrhea	23 (17)	1 (1)	0	0	1 (1)	1 (1)	0	0
Fatigue	19 (14)	4 (3)	NA	NA	4 (6)	1 (1)	NA	NA
Proteinuria	11 (8)	2 (1)	NA	NA	0	1 (1)	NA	NA

ALT=alanine aminotransferase; AST=aspartate aminotransferase.

- AEs occurred in 100% of patients receiving STIVARGA (n=136) and 88% of patients receiving placebo (n=60) during treatment (or up to 30 days after end of treatment)[11]
- Treatment-related AEs occurred in 97% of STIVARGA patients (n=132) and 46% of placebo patients (n=31)[11]
- Grade 3 or higher treatment-related AEs were reported in 54% of patients receiving STIVARGA (n=74) and 15% of those receiving placebo (n=10)[11]
- 32% of STIVARGA patients (n=43) experienced a serious AE vs 26% of placebo patients (n=18)[11]
- 14% of patients (n=19) discontinued STIVARGA due to an AE vs 6% of placebo patients (n=4)[11]

Important Safety Information (continued)

Most Frequently Observed Adverse Drug Reactions in mCRC (≥30%): The most frequently observed adverse drug reactions (≥30%) in STIVARGA-treated patients vs placebo-treated patients in mCRC, respectively, were: asthenia/fatigue (64% vs 46%), pain (59% vs 48%), decreased appetite and food intake (47% vs 28%), HFSR/PPE (45% vs 7%), diarrhea (43% vs 17%), mucositis (33% vs 5%), weight loss (32% vs 10%), infection (31% vs 17%), hypertension (30% vs 8%), and dysphonia (30% vs 6%).

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Stivarga®
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The power of patient support and expert assistance

Access Services by Bayer is a support program available to patients who have been prescribed STIVARGA® (regorafenib). Access Services by Bayer offers a range of services to help patients access STIVARGA.

Services available through Access Services by Bayer

Access Services by Bayer Nurse Counselors:
Monday-Friday, 9 AM-6 PM ET

Access Services by Bayer Financial Support Counselors:
Monday-Friday, 9 AM-6 PM ET

A resource for patient education and support	A resource for access and reimbursement support	A resource for financial support
• Provide information and answer questions for patients and caregivers • Educate on potential AEs • Supply patient educational materials – Starter kits – Refill reminders	• Perform benefits investigation • Assist with prior authorization denials and appeals process • Conduct alternative coverage research for uninsured or underinsured patients • Coordinate with specialty pharmacy providers (SPPs), self-dispensing practices, and outpatient pharmacies	• Oncology $0 Co-Pay Program assistance for commercially insured patients* • Refer qualified patients to independent organizations that may assist with out-of-pocket expenses† • Refer eligible patients to the Bayer US Patient Assistance Foundation

For more information, call us by phone: 1-800-288-8374

Qualifying patients may be eligible for $0 Co-Pay

$0 CO-PAY
NO monthly cap and up to $25,000 per year for privately insured patients. Annual enrollment is required.

- Once enrolled, eligible patients may pay as little as $0
  – Eligible patients will be automatically re-enrolled every January
- Maximum co-pay program benefit of $25,000 per calendar year
- No monthly cap

3 WAYS TO ENROLL IN $0 CO-PAY

1. Directly via www.zerocopaysupport.com or call 1-647-245-5622
2. Call Access Services by Bayer: 1-800-288-8374
3. Contact the SPP Network

*Patients who are enrolled in any type of government insurance or reimbursement programs are not eligible. As a condition precedent of the co-payment support provided under this program, e.g., co-pay refunds, participating patients and pharmacies are obligated to inform insurance companies and third-party payors of any benefits they receive and the value of this program, and may not participate if this program is prohibited by or conflicts with their private insurance policy, as required by contract or otherwise. Void where prohibited by law, taxed, or restricted. Patients enrolled in Bayer's Patient Assistance Program are not eligible. Bayer may determine eligibility, monitor participation, equitably distribute product and modify or discontinue any aspect of the Access Services by Bayer program at any time, including but not limited to this commercial co-pay assistance program.

†Access Services by Bayer provides referrals to third party organizations; eligibility criteria apply.

REFERENCES

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Stivarga® (regorafenib) tablets

For your previously treated patients with mCRC

HARNESS THE CLINICALLY PROVEN POWER OF STIVARGA® (regorafenib)

Demonstrated potential to maximize OS potential

23% **REDUCTION IN RISK OF DEATH WITH STIVARGA[1]**
HR: 0.77 [95% CI, 0.64-0.94]; *P*=0.0102)[1]

- There were 275 deaths out of 505 patients treated with STIVARGA (55%) vs 157 deaths out of 255 patients treated with placebo (62%)[1]
- STIVARGA improved OS in CORRECT, which included patients with historically collected *KRAS* status (N=729)[1]
  – Historical *KRAS* status was assessed (59% mutant, 41% wild-type *KRAS*)

26% **PATIENTS WERE ABLE TO RECEIVE CYTOTOXIC THERAPY** following treatment with STIVARGA in the CORRECT trial[2]

- During the CORRECT trial follow-up[5]:
  – 26% (131) and 30% (76) of patients received ≥1 systemic anticancer treatment in the STIVARGA and placebo groups, respectively
  – 26% (130) of patients and 29% (74) of patients received an antineoplastic or immunomodulation agent in the STIVARGA and placebo groups, respectively

- The most frequently observed adverse drug reactions (≥30%) in STIVARGA-treated patients vs placebo-treated patients in mCRC, respectively, were: asthenia/fatigue (64% vs 46%), pain (59% vs 48%), decreased appetite and food intake (47% vs 28%), HFSR/PPES (45% vs 7%), diarrhea (43% vs 17%), mucositis (33% vs 5%), weight loss (32% vs 10%), infection (31% vs 17%), hypertension (30% vs 8%), and dysphonia (30% vs 6%)[1]

Indication

STIVARGA is indicated for the treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type, an anti-EGFR therapy.

Important Safety Information

WARNING: HEPATOTOXICITY

- **Severe and sometimes fatal hepatotoxicity has occurred in clinical trials.**
- **Monitor hepatic function prior to and during treatment.**
- **Interrupt and then reduce or discontinue STIVARGA for hepatotoxicity as manifested by elevated liver function tests or hepatocellular necrosis, depending upon severity and persistence.**

Please see additional Important Safety Information throughout this brochure. For important risk and use information, please click here for the full Prescribing Information, including the Boxed Warning.

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PP-STI-US-1267-1 03/21

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(regorafenib) tablets