Lonsurf®
(trifluridine and tipiracil) tablets

# PATIENT ACCESS AND DOSING INFORMATION GUIDE

## NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)[1-4]

**CATEGORY 2A**

**Trifluridine and tipiracil (LONSURF) ± bevacizumab** (combination preferred over trifluridine and tipiracil (LONSURF) alone) is recommended by the NCCN Guidelines® as a **third-line or subsequent treatment** for mCRC (Category 2A recommendation)

**CATEGORY 1**

**Trifluridine and tipiracil (LONSURF)** is recommended by the NCCN Guidelines as a **third-line or subsequent treatment** for metastatic GEJ or gastric cancer (Category 1 recommendation)

### INDICATIONS

LONSURF is indicated as a single agent or in combination with bevacizumab for the treatment of adult patients with metastatic colorectal cancer previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if *RAS* wild-type, an anti-EGFR therapy.

LONSURF is indicated for the treatment of adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy.

### IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS

**Severe Myelosuppression:** In the 1114 patients who received LONSURF as a single agent, LONSURF caused severe or life-threatening myelosuppression (Grade 3-4) consisting of neutropenia (38%), anemia (17%), thrombocytopenia (4%) and febrile neutropenia (3%). Three patients (0.3%) died due to neutropenic infection/sepsis; four other patients (0.5%) died due to septic shock. A total of 14% of patients received granulocyte-colony stimulating factors. In the 246 patients who received LONSURF in combination with bevacizumab, LONSURF caused severe or life-threatening myelosuppression (Grade 3-4) consisting of neutropenia (52%), anemia (5%), thrombocytopenia (4%) and febrile neutropenia (0.4%). One patient (0.4%) died due to abdominal sepsis and two other patients (0.8%) died due to septic shock. A total of 29% of patients received granulocyte-colony stimulating factors. Obtain complete blood counts prior to and on Day 15 of each cycle of LONSURF and more frequently as clinically indicated. Withhold LONSURF for severe myelosuppression and resume at the next lower dosage.

GEJ, gastroesophageal junction; mCRC, metastatic colorectal cancer; NCCN, National Comprehensive Cancer Network.

The information provided in this guide is valid as of August 2023 and is subject to change.

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**Please see additional Important Safety Information on page 10 and full Prescribing Information.**

# Dosage and Administration Guidelines[5]

| | |
|---|---|
| **Recommended dosage** | 35 mg/m$^2$ twice daily[a,b] |
| **Active treatment days** | • Days 1 through 5 and days 8 through 12 of each 28-day treatment cycle until disease progression or unacceptable toxicity<br>• In the SUNLIGHT trial, the dose of bevacizumab was 5 mg/kg of body weight given once every 2 weeks (Day 1 and Day 15). Please see the bevacizumab package insert for full Prescribing Information. |
| **BSA-based calculation** | • Round up dose to the nearest 5-mg increment<br>• Do not exceed 80 mg/dose[a] |
| **Administration** | • Taken orally twice daily with food<br>• No restriction on food type |
| **Missed or held doses** | The patient should not make up for these doses; continue with the next scheduled dose |
| **Handling and disposal** | LONSURF is a cytotoxic drug. Follow applicable special handling and disposal procedures |

Refer to the bevacizumab full Prescribing Information for bevacizumab dosing guidance when using LONSURF + bevacizumab.

BSA, body surface area.

[a]Based on the trifluridine component.

[b]In patients with severe renal impairment (creatinine clearance of 15 to 29 mL/min), the recommended dosage is 20 mg/m$^2$.

## 2 tablet strengths for personalized dosing


**15-mg trifluridine/6.14-mg tipiracil tablet**


**20-mg trifluridine/8.19-mg tipiracil tablet**

Tablets may not be shown at actual size.

### Dosage Calculator

**Scan this QR code to calculate the recommended starting dosage of LONSURF**

**IMPORTANT SAFETY INFORMATION** (cont'd)

**WARNINGS AND PRECAUTIONS** (cont'd)

**Embryo-Fetal Toxicity:** LONSURF can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment and for at least 6 months after the final dose.

**Please see additional Important Safety Information on page 10 and full Prescribing Information.**

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# Dosage and Administration Guidelines (cont'd)[5]

| | LONSURF | | IN COMBINATION WITH BEVACIZUMAB |
|---|---|---|---|
| Week 1 | Twice daily for 5 days with food | 2 days rest | IV dose (Day 1) |
| Week 2 | Twice daily for 5 days with food | 2 days rest | – |
| Week 3 | Rest | | IV dose (Day 15) |
| Week 4 | Rest | | – |

Obtain complete blood cell counts prior to and on Day 15 of each cycle.

# Dosage Modifications[5]

## When to delay the dose:

**At treatment initiation, delay the cycle start of LONSURF until:**

- ANC ≥1500/mm$^3$ or febrile neutropenia is resolved
- Platelet count ≥75,000/mm$^3$
- Grade 3 or 4 non-hematological AEs are resolved to Grade 0 or 1

**During treatment, withhold LONSURF for any of the following:**

- ANC <500/mm$^3$ or febrile neutropenia
- Platelet count <50,000/mm$^3$
- Grade 3 or 4 non-hematological AEs

## When to reduce the dose:

**After recovery, resume LONSURF after reducing the dose by 5 mg/m$^2$/dose from the previous dose level for[c]:**

- Febrile neutropenia
- Uncomplicated Grade 4 neutropenia (which has recovered to ≥1500/mm$^3$) or thrombocytopenia (which has recovered to ≥75,000/mm$^3$) that results in more than 1-week delay in start of next cycle
- Non-hematologic Grade 3 or 4 AEs, except for Grade 3 nausea and/or vomiting controlled by antiemetic therapy or Grade 3 diarrhea responsive to antidiarrheal medication

**A maximum of 3 dose reductions are permitted to a minimum dose of 20 mg/m$^2$ twice daily**

- Do not escalate LONSURF dose after it has been reduced
- Permanently discontinue treatment with LONSURF if patient cannot tolerate reduced dose
- In patients with severe renal impairment who are unable to tolerate a dose of 20 mg/m$^2$ twice daily, reduce dose to 15 mg/m$^2$ twice daily

**For LONSURF + bevacizumab combination treatment in mCRC,** modify the dosage of LONSURF as above and/or modify bevacizumab administration as appropriate. Refer to the bevacizumab Prescribing Information for bevacizumab dosage administration.

AE, adverse event; ANC, absolute neutrophil count; IV, intravenous.

[c]These are the only AEs that require a dose reduction. Refer to the bevacizumab Prescribing Information for dose modifications for adverse reactions associated with bevacizumab.

**IMPORTANT SAFETY INFORMATION** (cont'd)

**USE IN SPECIFIC POPULATIONS**

**Lactation:** It is not known whether LONSURF or its metabolites are present in human milk. There are no data to assess the effects of LONSURF or its metabolites on the breastfed child or the effects on milk production. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with LONSURF and for 1 day following the final dose.

**Please see additional Important Safety Information on page 10 and full Prescribing Information.**

Lonsurf® (trifluridine and tipiracil) tablets

# Packaging Information[5]

| Formulation | Packaging | 11-Digit NDC[a] |
|---|---|---|
| LONSURF<br>15-mg trifluridine/6.14-mg tipiracil tablets | 20-count bottle | 64842-1025-**0**1 |
| | 40-count bottle | 64842-1025-**0**2 |
| | 60-count bottle | 64842-1025-**0**3 |
| LONSURF<br>20-mg trifluridine/8.19-mg tipiracil tablets | 20-count bottle | 64842-1020-**0**1 |
| | 40-count bottle | 64842-1020-**0**2 |
| | 60-count bottle | 64842-1020-**0**3 |

NDC, National Drug Code.
[a]The **red zero** converts the 10-digit NDC to the 11-digit NDC. Payer requirements regarding the use of NDCs may vary. Electronic data exchange generally requires use of the 11-digit NDC.

**IMPORTANT SAFETY INFORMATION** (cont'd)

**USE IN SPECIFIC POPULATIONS** (cont'd)

**Male Contraception:** Because of the potential for genotoxicity, advise males with female partners of reproductive potential to use condoms during treatment with LONSURF and for at least 3 months after the final dose.

**Please see additional Important Safety Information on page 10 and full Prescribing Information.**

Lonsurf® (trifluridine and tipiracil) tablets

# Specialty Pharmacies and Distributors

| Specialty Pharmacy | Website | Telephone | Fax |
|---|---|---|---|
| Accredo | accredo.com | (877) 732-3431 | (877) 329-4605 |
| AllianceRx Walgreens Prime | alliancerxwp.com | (855) 244-2555 | (877) 231-8302 |
| Biologics by McKesson | biologics.mckesson.com | (800) 850-4306 | (800) 823-4506 |
| CVS Specialty | cvsspecialty.com | (800) 237-2767 | (800) 323-2445 |
| Onco360 | onco360.com | (877) 662-6633 | (877) 662-6355 |
| Optum Specialty Pharmacy | specialty.optumrx.com | (855) 427-4682 | (877) 342-4596 |

| Specialty Distributor | Website | Telephone | Fax |
|---|---|---|---|
| AmerisourceBergen Oncology Supply | oncologysupply.com | (800) 633-7555 | (800) 248-8205 |
| AmerisourceBergen Specialty Distribution | asdhealthcare.com | (800) 746-6273 | (800) 547-9413 |
| Cardinal Health SPD Hospital | orderexpress.cardinalhealth.com | (800) 926-3161 | (614) 553-6301 |
| Cardinal Health SPD Physician Office and Clinic | specialtyonline.cardinalhealth.com | (877) 453-3972 | (877) 274-9897 |
| McKesson Plasma and Biologics | connect.mckesson.com | (877) 625-2566 | (888) 752-7626 |
| McKesson Specialty Health | mscs.mckesson.com | (800) 482-6700 | (800) 289-9285 |

Please contact an authorized distributor or one of the specialty pharmacies listed for the average wholesale price (AWP) and wholesale acquisition cost (WAC) pricing.

**Please see additional Important Safety Information on page 10 and full Prescribing Information.**

# Diagnosis Codes[6]

## Metastatic colorectal cancer

| ICD-10-CM | Description |
|---|---|
| C18.0 | Malignant neoplasm of cecum |
| C18.2 | Malignant neoplasm of ascending colon |
| C18.3 | Malignant neoplasm of hepatic flexure |
| C18.4 | Malignant neoplasm of transverse colon |
| C18.5 | Malignant neoplasm of splenic flexure |
| C18.6 | Malignant neoplasm of descending colon |
| C18.7 | Malignant neoplasm of sigmoid colon |
| C18.8 | Malignant neoplasm of overlapping sites of colon |
| C18.9 | Malignant neoplasm of colon, unspecified |
| C19 | Malignant neoplasm of rectosigmoid junction |
| C20 | Malignant neoplasm of rectum |
| C21.8 | Malignant neoplasm of overlapping sites of rectum, anus and anal canal |
| C78.5 | Secondary malignant neoplasm of large intestine and rectum |
| C78.6 | Secondary malignant neoplasm of retroperitoneum and peritoneum |
| D37.4 | Neoplasm of uncertain behavior of colon |
| D37.5 | Neoplasm of uncertain behavior of rectum |

ICD-10-CM, *International Classification of Diseases, Tenth Revision, Clinical Modification.*

**IMPORTANT SAFETY INFORMATION** (cont'd)

**USE IN SPECIFIC POPULATIONS** (cont'd)

**Geriatric Use:** Patients 65 years of age or older who received LONSURF as a single agent had a higher incidence of the following hematologic laboratory abnormalities compared to patients younger than 65 years: Grade 3 or 4 neutropenia (46% vs 32%), Grade 3 anemia (20% vs 14%), and Grade 3 or 4 thrombocytopenia (6% vs 3%). Patients 65 years of age or older who received LONSURF in combination with bevacizumab had a higher incidence of the following hematologic laboratory abnormalities compared to patients younger than 65 years: Grade 3 or 4 neutropenia (60% vs 46%) and Grade 3 or 4 thrombocytopenia (5% vs 4%).

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# Diagnosis Codes (cont'd)[6]

## Metastatic gastric cancer

| ICD-10-CM | Description |
|---|---|
| C16.0 | Malignant neoplasm of cardia |
| C16.1 | Malignant neoplasm of fundus of stomach |
| C16.2 | Malignant neoplasm of body of stomach |
| C16.3 | Malignant neoplasm of pyloric antrum |
| C16.4 | Malignant neoplasm of pylorus |
| C16.5 | Malignant neoplasm of lesser curvature of stomach, unspecified |
| C16.6 | Malignant neoplasm of greater curvature of stomach, unspecified |
| C16.8 | Malignant neoplasm of overlapping sites of stomach |
| C16.9 | Malignant neoplasm of stomach, unspecified |

This information is not intended as coverage or coding advice and does not guarantee reimbursement. You should verify the appropriate reimbursement information for services or items you provide. Each healthcare professional is responsible for ensuring all coding is accurate and appropriate.

**IMPORTANT SAFETY INFORMATION** (cont'd)

**USE IN SPECIFIC POPULATIONS** (cont'd)

**Renal Impairment:** No adjustment to the starting dosage of LONSURF is recommended in patients with mild or moderate renal impairment (CLcr of 30 to 89 mL/min). Reduce the starting dose of LONSURF for patients with severe renal impairment (CLcr of 15 to 29 mL/min) to a recommended dosage of 20 mg/m$^2$.

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# Taiho Oncology Co-Pay Assistance Program

## Making access easier for patients

TAIHO ONCOLOGY PATIENT SUPPORT
*Supporting your treatment journey*

**CO-PAY ASSISTANCE PROGRAM**

***Potential***

**$0 CO-PAY***

If you are eligible, the Taiho Oncology Co-Pay Program may help reduce your co-pay responsibility to $0

TAIHO ONCOLOGY

TAIHO ONCOLOGY PATIENT SUPPORT
*Supporting your treatment journey*

**TO DETERMINE PATIENT ELIGIBILITY**

**GO TO: TaihoOncologyCopay.com**

**OR CALL: 1-844-TAIHO-4U**
**(1-844-824-4648)**

## Eligible patients may pay $0 per treatment cycle

### PATIENTS MAY BE ELIGIBLE IF THEY:

- Have commercial prescription insurance coverage
- Use a specialty pharmacy
- Use a hospital outpatient pharmacy
- Receive medicine from a doctor's office

### PATIENTS MAY NOT BE ELIGIBLE IF THEY:

- Are reimbursed under Medicaid, a Medicare drug benefit program, TRICARE, or other state or federal programs
- Reside outside of the US, Puerto Rico, or US territories

*Restrictions and eligibility: Offer valid in the US, Puerto Rico, and US territories only. Only valid for patients with private insurance. Offer not valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, TRICARE, or other federal or state programs (such as medical assistance programs). If the patient is eligible for drug benefits under any such program, this offer is not valid and the patient cannot use this offer. By presenting or accepting this benefit, patient and pharmacist agree not to submit claim for reimbursement under the above programs. Patient further agrees to comply with any and all terms of his or her health insurance contract requiring notification to his or her payer of the existence and/or value of this offer. It is illegal to or offer to sell, purchase, or trade this benefit. Maximum reimbursement limits apply; patient out-of-pocket expense may vary. Taiho Oncology, Inc., reserves the right to rescind, revoke, or amend this offer at any time without notice.

NCCN, National Comprehensive Cancer Network® (NCCN®).

**References: 1.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Rectal Cancer V.5.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed September 21, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Colon Cancer V.3.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed August 3, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Gastric Cancer V.2.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed August 10, 2023. To view the most recent and complete version of the guidelines, go online to NCCN.org. **4.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Esophageal and Esophagogastric Junction Cancers V.3.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed August 10, 2023. To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. **5.** LONSURF. Prescribing Information. Taiho Oncology Inc; 2023. **6.** National Center for Health Statistics. *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM). Centers for Disease Control and Prevention. Accessed June 5, 2023. https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2023/ **7.** Bevacizumab Prescribing Information. Genentech Inc; 2009.

**Please see additional Important Safety Information on page 10 and full Prescribing Information.**

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# Taiho Oncology Patient Support™

Taiho Oncology Patient Support offers personalized services to help patients, caregivers, and healthcare professionals access Taiho Oncology products. This includes insurance coverage determination and help with medication affordability.

TAIHO ONCOLOGY PATIENT SUPPORT
*Supporting your treatment journey*

## HOW TO ENROLL

We offer 3 convenient ways to enroll in Taiho Oncology Patient Support services:

### Via the HCP Portal

- **Enroll online**, directly through our HCP portal at TaihoPatientSupport.com
- **NOTE:** Login required. Please register prior to enrolling

OR

### Download, Print, and Fax

- Download and fill in the **Enrollment Form**, and print it out to complete
- Fax the completed form to **1-844-287-2559**

OR

### By Phone

- Call **1-844-TAIHO-4U** (1-844-824-4648) for help with enrollment

## Taiho Oncology Patient Support can assist with:

### Insurance Coverage Support

- Benefits investigation
- Prior authorization assistance
- Appeals assistance
- Coordination of prescriptions with pharmacies


### Patient Affordability Assistance[a]

- $0 co-pay program enrollment for eligible commercially insured patients
- Patient assistance program designed to provide free medication to eligible patients who are uninsured or underinsured
- Referrals to third-party foundations for co-pay or other assistance based on eligibility and additional criteria
- Referrals to Medicare Part D Low-Income Subsidy (LIS)/Extra Help Program

### Personalized Nurse Support[b]

- One-on-one nurse educational support for patients, available via opt-in

HCP, healthcare professional.
[a]Visit TaihoPatientSupport.com to see full eligibility criteria.
[b]If this option is selected on the Patient Enrollment Form, a Nurse Navigator will be assigned to provide telephone support and will address general inquiries about LONSURF treatment.

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# INDICATIONS AND IMPORTANT SAFETY INFORMATION

## INDICATIONS

LONSURF is indicated as a single agent or in combination with bevacizumab for the treatment of adult patients with metastatic colorectal cancer previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if *RAS* wild-type, an anti-EGFR therapy.

LONSURF is indicated for the treatment of adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy.

## IMPORTANT SAFETY INFORMATION

## WARNINGS AND PRECAUTIONS

**Severe Myelosuppression:** In the 1114 patients who received LONSURF as a single agent, LONSURF caused severe or life-threatening myelosuppression (Grade 3-4) consisting of neutropenia (38%), anemia (17%), thrombocytopenia (4%) and febrile neutropenia (3%). Three patients (0.3%) died due to neutropenic infection/sepsis; four other patients (0.5%) died due to septic shock. A total of 14% of patients received granulocyte-colony stimulating factors. In the 246 patients who received LONSURF in combination with bevacizumab, LONSURF caused severe or life-threatening myelosuppression (Grade 3-4) consisting of neutropenia (52%), anemia (5%), thrombocytopenia (4%) and febrile neutropenia (0.4%). One patient (0.4%) died due to abdominal sepsis and two other patients (0.8%) died due to septic shock. A total of 29% of patients received granulocyte-colony stimulating factors. Obtain complete blood counts prior to and on Day 15 of each cycle of LONSURF and more frequently as clinically indicated. Withhold LONSURF for severe myelosuppression and resume at the next lower dosage.

**Embryo-Fetal Toxicity:** LONSURF can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment and for at least 6 months after the final dose.

## USE IN SPECIFIC POPULATIONS

**Lactation:** It is not known whether LONSURF or its metabolites are present in human milk. There are no data to assess the effects of LONSURF or its metabolites on the breastfed child or the effects on milk production. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with LONSURF and for 1 day following the final dose.

**Male Contraception:** Because of the potential for genotoxicity, advise males with female partners of reproductive potential to use condoms during treatment with LONSURF and for at least 3 months after the final dose.

**Geriatric Use:** Patients 65 years of age or older who received LONSURF as a single agent had a higher incidence of the following hematologic laboratory abnormalities compared to patients younger than 65 years: Grade 3 or 4 neutropenia (46% vs 32%), Grade 3 anemia (20% vs 14%), and Grade 3 or 4 thrombocytopenia (6% vs 3%). Patients 65 years of age or older who received LONSURF in combination with bevacizumab had a higher incidence of the following hematologic laboratory abnormalities compared to patients younger than 65 years: Grade 3 or 4 neutropenia (60% vs 46%) and Grade 3 or 4 thrombocytopenia (5% vs 4%).

**Renal Impairment:** No adjustment to the starting dosage of LONSURF is recommended in patients with mild or moderate renal impairment (CLcr of 30 to 89 mL/min). Reduce the starting dose of LONSURF for patients with severe renal impairment (CLcr of 15 to 29 mL/min) to a recommended dosage of 20 mg/m$^2$.

**Hepatic Impairment:** Do not initiate LONSURF in patients with baseline moderate or severe (total bilirubin > 1.5 times ULN and any AST) hepatic impairment. Patients with severe hepatic impairment (total bilirubin > 3 times ULN and any AST) were not studied. No adjustment to the starting dosage of LONSURF is recommended for patients with mild hepatic impairment.

## ADVERSE REACTIONS

**Serious adverse reactions** occurred in 25% of patients. The most frequent serious adverse reactions (≥2%) were intestinal obstruction (2.8%), and COVID-19 (2%). Fatal adverse reactions occurred in 1.2% of patients who received LONSURF in combination with bevacizumab, including rectal fistula (0.4%), bowel perforation (0.4%) and atrial fibrillation (0.4%).

**The most common adverse reactions or laboratory abnormalities (≥10% in incidence) in patients treated with single-agent LONSURF** at a rate that exceeds the rate in patients receiving placebo in mCRC: anemia (77% vs 33%), neutropenia (67% vs 0.8%), asthenia/fatigue (52% vs 35%), nausea (48% vs 24%), thrombocytopenia (42% vs 8%), decreased appetite (39% vs 29%), diarrhea (32% vs 12%), vomiting (28% vs 14%), abdominal pain (21% vs 19%), and pyrexia (19% vs 14%). In metastatic gastric cancer or gastroesophageal junction (GEJ): neutropenia (66% vs 4%), anemia (63% vs 38%), nausea (37% vs 32%), thrombocytopenia (34% vs 9%), decreased appetite (34% vs 31%), vomiting (25% vs 20%), infections (23% vs 16%) and diarrhea (23% vs 14%).

Pulmonary emboli occurred more frequently in LONSURF-treated patients compared to placebo: in mCRC (2% vs 0%) and in metastatic gastric cancer and GEJ (3% vs 2%).

Interstitial lung disease (0.2%), including fatalities, has been reported in clinical studies and clinical practice settings in Asia.

**The most common adverse reactions or laboratory abnormalities (≥20% in incidence) in patients treated with LONSURF in combination with bevacizumab** vs LONSURF alone were neutropenia (80% vs 68%), anemia (68% vs 73%), thrombocytopenia (54% vs 29%), fatigue (45% vs 37%), nausea (37% vs 27%), increased aspartate aminotransferase (34% vs 28%), increased alanine aminotransferase (33% vs 23%), increased alkaline phosphate (31% vs 36%), decreased sodium (25% vs 20%), diarrhea (21% vs 19%), abdominal pain (20% vs 18%), and decreased appetite (20% vs 15%).

**Please see full Prescribing Information.**

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12/2023 LON-PM-US-1757 v2

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