Taiho Oncology, Inc. Announces Comprehensive Access Support Program for LONSURF® (trifluridine and tipiracil)

Taiho Oncology strives to meet the LONSURF® (trifluridine and tipiracil) access needs of all patients, regardless of insurance status, and has created a customized one-stop, comprehensive, and fully integrated patient support program called Taiho Oncology Patient Support. The program's intent is to remove financial barriers and ensure LONSURF is available to every appropriate patient. Additionally, Taiho Oncology donates significant dollars to independent third-party administered patient assistance programs to support their missions of helping patients in financial need.

"We recognize that the delivery of care is becoming increasingly expensive and Taiho Oncology is committed to easing the financial burden on patients, their families and society," states Timothy Wert, Senior Director of Market Access at Taiho Oncology. "Our goal is for Taiho Oncology Patient Support to be recognized as a top tier program for ensuring appropriate access to care for patients."

Taiho Oncology Patient Support reimbursement specialists are available to patients and their providers Mon – Fri from 8am – 8pm EST. The program may be reached by calling (844) TAIHO-4U – or – (844)-824-4648 or by visiting us on the web at www.TaihoPatientSupport.com.

Services offered are:

CoPay Support for eligible, privately insured patients. The Taiho Oncology Patient Support Co-pay Card can help to reduce LONSURF out-of-pocket expenses to no more then $30/per cycle.

Alternate Funding Support Referrals for eligible, publicly insured patients to nonprofit foundations for co-pay assistance.

Patient Assistance to provide LONSURF at no cost, for eligible patients who have insufficient or no prescription insurance coverage for LONSURF, including Medicaid, Medicare, or any other public or private insurance program, and who have insufficient personal financial resources to pay for their treatment.

For more information on Taiho Oncology, Inc., please visit us on the web www.taihooncology.com/us/ or call (609) 750-3500.

About LONSURF
LONSURF is indicated for the treatment of patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy.[1]

LON-PM-US-0299

Important Safety Information[1]

WARNINGS AND PRECAUTIONS

Severe Myelosuppression: In Study 1, LONSURF caused severe and life-threatening myelosuppression (Grade 3-4) consisting of anemia (18%), neutropenia (38%), thrombocytopenia (5%), and febrile neutropenia (3.8%). One patient (0.2%) died due to neutropenic infection. In Study 1, 9.4 percent of LONSURF-treated 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 febrile neutropenia, Grade 4 neutropenia, or platelets less than 50,000/mm^3. Upon recovery, resume LONSURF at a reduced dose.

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 with LONSURF.

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 infant or the effects on milk production. Because of the potential for serious adverse reactions in breastfeeding infants, advise women not to breastfeed during treatment with LONSURF and for one day following the final dose.

Male Contraception: 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: Grade 3 or 4 neutropenia and thrombocytopenia and Grade 3 anemia occurred more commonly in patients 65 years old or older who received LONSURF.

Renal Impairment: Patients with moderate renal impairment may require dose modifications for increased toxicity. No patients with severe renal impairment were enrolled in Study 1.

Hepatic Impairment: Patients with moderate or severe hepatic impairment were not enrolled in Study 1.

ADVERSE REACTIONS

Most Common Adverse Drug Reactions in Patients Treated with LONSURF (≥ 5 percent): The most common adverse drug reactions in LONSURF-treated patients vs

placebo-treated patients with refractory mCRC, respectively, were: asthenia/fatigue (52% vs 35%), nausea (48% vs 24%), decreased appetite (39% vs 29%), diarrhea (32% vs 12%), vomiting (28% vs 14%), abdominal pain (21% vs 18%), pyrexia (19% vs 14%), stomatitis (8% vs 6%), dysgeusia (7% vs 2%), and alopecia (7% vs 1%).

Additional Important Adverse Drug Reactions: The following occurred more frequently in LONSURF-treated patients compared to placebo: infections (27% vs 15%), and pulmonary emboli (2% vs 0%).

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

Laboratory Test Abnormalities in Patients Treated with LONSURF: Laboratory test abnormalities in LONSURF-treated patients vs placebo-treated patients with refractory mCRC, respectively, were: anemia (77% vs 33%), neutropenia (67% vs 1%), and thrombocytopenia (42% vs 8%).

Please see Full Prescribing Information.
www.taihooncology.com/us/prescribing-information.pdf

References

1. LONSURF [prescribing information]; Princeton, NJ: Taiho Oncology, Inc.; 2015.
