Iowa PDL New Drug Review

Proprietary Name: Romvimza®
Common Name: vimseltinib
PDL Category: Antineoplastic Agents

Pharmacology/Usage: Vimseltinib, the active ingredient of Romvimza®, is a kinase inhibitor. It is a kinase inhibitor that inhibits colony-stimulating factor 1 receptor (CSF1R). In vitro, vimseltinib inhibited CSF1R autophosphorylation, signaling induced by CSF1 ligand binding, and proliferation of cells expressing CSF1R.

Indication: For treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity.

There is no pregnancy category for this medication; however, the risk summary indicates that based on data from animal studies and its mechanism of action, Romvimza® can cause fetal harm when administered to a pregnant woman. There are no available data on vimseltinib use in pregnant women to assess for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Advise pregnant women of the potential risk to a fetus. Verify pregnancy status in females of reproductive potential prior to the start of treatment. Advise females of reproductive potential and males that are partnered with females of reproductive potential to use effective contraception during treatment with Romvimza® and for 1 month after the last dose. The safety and efficacy of use in the pediatric population have not been established.

Dosage Form: Capsules: 14mg, 20mg, 30mg.

Swallow whole; do not open, break, or chew the capsules.

Recommended Dosage: The recommended dosage is 30mg PO twice weekly, with a minimum of 72 hours between doses, as directed on the blister package. Instruct patients to follow the schedule on the blister package and to Romvimza® on the same days each week. Take with or without food.

If a dose is missed by 48 hours or less, take the missed dose as soon as possible and take the next dose on its regularly scheduled day. If a dose is missed by more than 48 hours, skip the missed dose, and take the next dose on its regularly scheduled day.

If vomiting occurs within 30 minutes of taking a dose, repeat that dose. Otherwise, take the next dose on its regularly scheduled day.

Dose modifications for adverse reactions may be needed. Refer to the prescribing information for additional information.

Dose adjustments are not required with mild hepatic impairment. Romvimza® has not been studied in patients with moderate or severe hepatic impairment.

Drug Interactions: Vimseltinib is a P-gp inhibitor in vitro. Concomitant use of Romvimza® with P-gp substrates may increase exposure of these substrates; however, this has not been studied clinically. Avoid concomitant use with P-

gp substrates while taking Romvimza®. If concomitant use cannot be avoided, take Romvimza® at least 4 hours prior to P-gp substrates unless otherwise recommended in the substrate prescribing information.

Vimseltinib is a breast cancer resistance protein (BCRP) inhibitor in vitro. Concomitant use of Romvimza® with BCRP substrates may increase exposure of these substrates; however, this has not been studied clinically. Avoid concomitant use with BCRP substrates while taking Romvimza®. Refer to the prescribing information of the BCRP substrate for dose modifications if concomitant use cannot be avoided.

Vimseltinib is an organic cation transporter 2 (OCT2) inhibitor in vitro. Concomitant use of Romvimza® with OCT2 substrates may increase exposure of these substrates; however, this has not been studied clinically. Avoid concomitant use with OCT2 substrates while taking Romvimza®. Refer to the prescribing information of the OCT2 substrate for dose modifications if concomitant use cannot be avoided.

Box Warning: This product does not have a box warning.

Common Adverse Drug Reactions: *Listed % incidence for adverse drug reactions= reported % incidence for drug (Romvimza®) minus reported % incidence for placebo for all grades. Please note that an incidence of 0% means the incidence was the same as or less than placebo.* The most frequently reported adverse events included periorbital edema (39%), lacrimation increased (12%), dry eye (10%), fatigue (21%), peripheral edema (25%), face edema (23%), rash (42%), pruritus (21%), hypertension (7%), and neuropathy (9.4%).

Laboratory abnormalities included AST increased (81%), cholesterol increased (27%), ALT increased (8%), creatinine increased (14.4%), ALP increased (6%), magnesium increased (10.4%), calcium decreased (10.4%), neutrophils decreased (28.4%), and leukocytes decreased (21%).

Cases of serious and fatal liver injury have occurred with the use of another kinase inhibitor that targets CSF1R. Serious and fatal liver injury have not been observed with Romvimza®. Avoid Romvimza® in patients with preexisting increased serum transaminases; total bilirubin or direct bilirubin (> upper limit of normal [ULN]); or active liver or biliary tract disease, including ALP. Monitor liver tests, including AST, ALT, total bilirubin, direct bilirubin, ALP, and gamma-glutamyl transferase (GGT) prior to the start of treatment, twice a month for the first two months and once every 3 months for the first year of therapy and as clinically indicated thereafter. Withhold and reduce the dose or permanently discontinue Romvimza® based on the severity of the hepatotoxicity.

Romvimza® 20mg capsule contains FC&C Yellow No. 5 (tartrazine) which may cause allergic reactions in certain susceptible patients. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin sensitivity. Romvimza® 14mg and 20mg capsules contain FD&C Yellow No. 6 (Sunset Yellow FCF), which may cause allergic reactions.

In the phase 3 study (MOTION), serum creatinine increased and reached a maximum mean increase by 10.4 weeks compared to baseline. These increases in serum creatinine may not be associated with changes in renal function. Increases in creatinine reversed upon discontinuation of Romvimza®. The increases in serum creatinine may be due to inhibition of renal tubular secretion transporters. During Romvimza® treatment, use alternative measures that are not based on serum creatinine to assess renal function.

Contraindications: There are no contraindications listed with this product.

Manufacturer: Deciphera Pharmaceuticals

Analysis: The efficacy of Romvimza® was assessed in MOTION, a phase 3, double-blind, multicenter, randomized, placebo-controlled study that included patients with TGCT for whom surgical resection may cause worsening functional limitation or severe morbidity. Eligible patients had a confirmed diagnosis of TGCT with measurable disease per the Response Evaluation Criteria in Solid Tumors (RECIST v1.1) with at least one lesion having a minimum size of 2cm. Patients were randomized to placebo or Romvimza® 30mg twice weekly for 24 weeks. At week 25, patients who completed the double-blind, randomized part of the trial were eligible to advance to an ongoing, open-label extension study where all patients received Romvimza®.

The median age of included patients (N=123) was 44 years (range 20 to 78 years), while 59% were female, 65% were white, 74% had prior surgery, 69% had diffuse TGCT, and 23% were previously treated with systemic therapy. Disease locations were knee (67%), ankle (12%), hip (10%), other (5%), foot (3.3%), and wrist (2.4%).

The main efficacy outcome measure was overall response rate (ORR) as assessed by blinded independent radiological review (IRR) per RECIST v1.1 at week 25. Additional efficacy outcomes measured at week 25 included ORR as assessed using tumor volume score (TVS), mean change from baseline in active range of motion (ROM) of the affected joint at week 25 measured by goniometry assessments, change from baseline in the Patient-Reported Outcomes Measurement Information System- Physical Function (PROMIS-PF) 15-item score (upper and lower extremity items), and response of at least a 30% improvement in the mean Brief Pain Inventory (BPI) Worst Pain numeric rating scale (NRS) score without a 30% or greater increase in narcotic analgesic use.

Results suggested that a statistically significant improvement in ORR was demonstrated in patients randomized to Romvimza® as compared with placebo. Results are presented in the table below, which was adapted from the prescribing information.

Efficacy Parameter	Romvimza® (N=83)	Placebo (N=40)
Overall Response Rate (ORR) per RECIST v1.1		
ORR	40%	0%
Complete Response (CR)	5%	0%
Partial Response (PR)	35%	0%
p-value	<0.0001	
Duration of Response (DOR)		
Median (Range in months)	Not reached (2.5+, 19.4+)	Not applicable
DOR ≥6 months	28 (85%)	-
DOR ≥9 months	19 (58%)	-
Active ROM		
Patients with data at baseline & week 25, n	73	33
Baseline mean	63.0	62.9
Mean change from baseline	18.4	3.8
Difference in Least Squares means; p-value	14.6%; p=0.0077	
PROMIS-PF (15-item score; ranges from 0-100)		
Patients with data at baseline & week 25, n	63	30
Baseline mean	39.0	38.5
Mean change from baseline	4.6	1.3

Efficacy Parameter	Romvimza® (N=83)	Placebo (N=40)
Difference in Least Squares means; p-value	3.3; p=0.0007	
BPI-30 Response		
Patients with data at baseline & week 25, n	68	31
Responders, n (%)	40 (48.2%)	9 (22.5%)
Difference in responder rate; p-value	26.2%; p=0.0056	

ORR by TVS was 67% in patients randomized to Romvimza® and 0% in patients randomized to placebo (p<0.0001).

Place in Therapy: Romvimza® is a kinase inhibitor indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity. It is to be taken orally twice weekly. The efficacy of Romvimza® was assessed in a phase 3, randomized, double-blind, placebo-controlled study that included patients with TGCT for whom surgical resection may cause worsening functional limitation or severe morbidity. The main efficacy outcome measure was ORR, and results suggested a statistically significant improvement in ORR was demonstrated in the Romvimza® group as compared with the placebo group (p<0.0001; NNT 3).

Summary

It is recommended that Romvimza® should be non-preferred in order to confirm the appropriate diagnosis and clinical parameters for use.

PDL Placement: ☐ **Recommended**
☒ **Non-Recommended with Conditions**

References

[1] Romvimza [package insert]. Waltham, MA: Deciphera Pharmaceuticals LLC; 2025.

Prepared By: Iowa Medicaid Date: 06/23/2025