Treatment Guide

KIMMTRAK® Dosing and AE Management

Indication

KIMMTRAK® (tebentafusp-tebn) is a bispecific gp100 peptide-HLA-directed CD3 T cell engager indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.

Important Safety Information Including Boxed Warning

WARNING: CYTOKINE RELEASE SYNDROME
Cytokine Release Syndrome (CRS), which may be serious or life-threatening, occurred in patients receiving KIMMTRAK. Monitor for at least 16 hours following first three infusions and then as clinically indicated. Manifestations of CRS may include fever, hypotension, hypoxia, chills, nausea, vomiting, rash, elevated transaminases, fatigue, and headache.

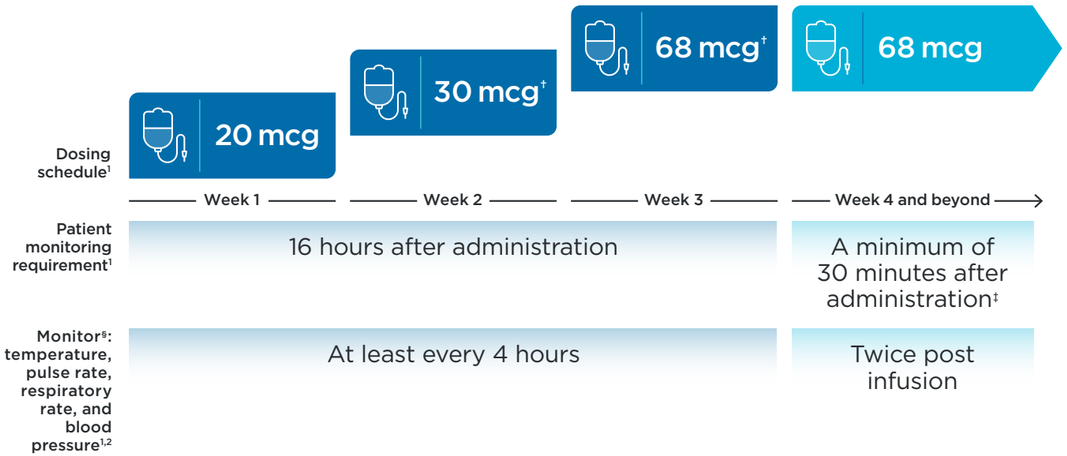
Please see Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** on page 14 and full Prescribing Information.

KIMMTRAK®
(tebentafusp-tebn)
Injection for Intravenous Use 100 mcg/0.5 mL

KIMMTRAK is administered once weekly via continuous intravenous (IV) infusion over 15-20 minutes[1,*]

Adequate hydration/euvolemic status prior to starting KIMMTRAK is advised[1]

KIMMTRAK begins with a step-up dose schedule designed to decrease the risk of adverse events.[1]



The starting dose is 20 mcg for week 1. The dose increases to 30 mcg for week 2 and 68 mcg for week 3 and beyond.[1]

* In clinical trials, patients stopped treatment for disease progression, unless they were otherwise deriving benefit, or for unacceptable toxicity.[1]

† If patient has not had a ≥ grade 2 cytokine release syndrome adverse event with their previous dose.[1]

‡ If patient has not had hypotension requiring medical intervention with their most recent dose.[1]

§ Adjustment in what to monitor and at what frequency can be made using clinical judgment or by institutional standards. Recommendations above based on clinical trial protocol.[3]

Treatment with KIMMTRAK should be continued while patient is deriving clinical benefit and in the absence of unacceptable toxicities.[1]

KIMMTRAK administration[1]

Prior to administering KIMMTRAK:

- No standard premedications are required
- **Ensure patients are euvolemic prior to initiating the infusions**. Administer IV fluids based on clinical evaluation, baseline vital signs, and the volume status of the patient, as assessed by the treating physician, to minimize the risk of hypotension associated with cytokine release syndrome (CRS)
- Patients who may be sensitive to manifestations of CRS, such as hypotension, tachycardia, or hypoxia, or the use of intravenous fluids to manage CRS, should be carefully assessed prior to starting KIMMTRAK
- For patients on maintenance systemic corticosteroids, consider adjusting the corticosteroid dose given the risk of hypotension
- Monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total blood bilirubin prior to and during treatment with KIMMTRAK

To administer KIMMTRAK:

- Administer the diluted solution via IV infusion over 15-20 minutes through a dedicated IV line
  - A sterile, non-pyrogenic, low protein binding 0.2 micron in-line filter infusion set should be used
  - Administer the entire contents of the KIMMTRAK infusion bag to the patient
- Upon completion of KIMMTRAK infusion, flush the infusion line with adequate volume of sterile 0.9% Sodium Chloride Injection, USP to ensure that the entire contents of the infusion bag are administered
  - DO NOT mix KIMMTRAK with drugs other than albumin used during preparation or administer other drugs through the same IV line. Compatibility with other medications and fluids has not been established

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Patient monitoring

For at least the first 3 infusions, patients should be monitored during infusion and at least for 16 hours after infusion is complete[1]

- Based on clinical trials, 16 hours is the likely time frame for presentation of CRS symptoms[4]

- A rise in temperature is generally the first sign of CRS, occurring earlier than drops in blood pressure.[4] Once fever is detected, patients should be monitored more closely for changes in other vital signs like pulse rate, respiratory rate, and blood pressure.[1] Consider managing symptoms early to help prevent CRS from escalating[1]

- Ensure that healthcare providers administering KIMMTRAK have immediate access to medications and resuscitative equipment to manage CRS[1]

- After infusion 3, and once the patient tolerates the most recent infusion without hypotension requiring medical intervention (eg, giving IV fluids), subsequent doses can be administered in appropriate ambulatory care settings (eg, infusion center)[1]

Starting with the 4th infusion of KIMMTRAK, patients should be monitored for a minimum of 30 minutes following each infusion.[1]

Patient monitoring (continued)

Patients should be monitored during and after KIMMTRAK infusion for the following[1,5]:

CRS (T cell activation)

- Fever
- Hypotension
- Hypoxia
- Chills
- Nausea
- Vomiting
- Rash
- Elevated transaminases
- Fatigue
- Headache

Some of these symptoms may be associated with CRS *or* may be isolated events.[1]

Skin reactions (gp100 expression in normal melanocytes)

- Rash
- Pruritus
- Skin hypopigmentation
- Edema
- Dry skin
- Erythema
- Hair color changes

Elevated liver enzymes

- Alanine aminotransferase (ALT)
- Aspartate aminotransferase (AST)
- Total blood bilirubin

Reminders[1,6]

- Discuss with patients the frequency of monitoring and the possible side effects that can occur
- Emphasize to patients the importance of keeping their weekly infusion schedule to maximize the clinical effectiveness of their treatment
- Communication across the care team is important to make sure that KIMMTRAK side effects are recognized and treated as early as possible

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In clinical trials with KIMMTRAK, 1.2% of patients discontinued treatment due to CRS[1]

- **CRS:** KIMMTRAK commonly causes mild to moderate CRS, which if not identified and treated appropriately, may become life-threatening or fatal[1]
- Most patients typically experienced CRS following each of the first few infusions.[5] The majority (84%) of episodes of CRS started the day of infusion[1]
- Ensure adequate hydration/euvolemic status prior to starting KIMMTRAK and immediate access to medications and resuscitative equipment to manage CRS

Discontinuation rate[1]	All grades[1]	Grade 1[5]	Grade 2[5]	Grade 3[1,5]	Grades 4 or 5[5]
1.2%	89%	12%	76%	0.8%	NONE

- A rise in temperature is generally the first sign of CRS, occurring earlier than drops in blood pressure.[4] Once fever is detected, patients should be monitored more closely for changes in other vital signs like pulse rate, respiratory rate, and blood pressure.[1] Consider managing symptoms early to help prevent CRS from escalating
- CRS symptoms were mostly managed with IV fluids, NSAIDs, or systemic corticosteroids[1,5]

Systemic corticosteroids[1,*]	Supplemental oxygen[1,*]	Vasopressor[1,*]
23%	8%	0.8%

- Withhold or discontinue KIMMTRAK based on the persistence and severity of CRS

* For at least one infusion.

CRS grading and management guidance

No dosage reduction for KIMMTRAK is recommended. For specific dosage modifications please refer to Section 2.3, Table 1 in full Prescribing Information.[1]

			Next dose	
Criteria:	**ASTCT grade***	**Acute management**	**Dexamethasone 4 mg or equivalent premedication 30 min prior to next dose?**	**Escalate to next dose level?**
Temperature ≥38 °C (100.4 °F) with:				
• No hypotension or hypoxia	**≤ Grade 1**	IV fluids, symptomatic support	**NO**	**YES**
• Hypotension that responds to fluids (does not require vasopressors) • Or hypoxia requiring low flow nasal cannula (≤6 L/min) or blow-by oxygen	**Grade 2** lasting <2 hours	IV fluids, symptomatic support	**NO**	**YES**
	lasting 2-3 hours or recurrent	**Above + corticosteroids†**	**YES**	**YES**
	lasting >3 hours & not responding to therapy	**Above + corticosteroids†**	**YES**	**NO‡**
• Hemodynamic instability requiring vasopressor (with or without vasopressin) • Or worsening hypoxia or respiratory distress requiring high flow nasal cannula (≥6 L/min) or face mask	**Grade 3**	**Above + corticosteroids†**	**YES**	**NO‡**
• Hemodynamic instability requiring multiple vasopressors (excluding vasopressin) • Worsening hypoxia or respiratory distress despite oxygen administration requiring positive pressure	**Grade 4**	**Permanently discontinue KIMMTRAK and treat with corticosteroids†**		

* Based on ASTCT consensus grading of CRS criteria (Lee et al. 2019).[1]

† If hypotension is not rapidly resolved (ie, within 2–3 hours of onset) with intravenous crystalloid therapy, intravenous corticosteroid therapy of methylprednisolone 2 mg/kg initial dose or equivalent and/or tocilizumab 8 mg/kg IV (not to exceed 800 mg/infusion) per institutional guidelines should be administered until symptoms (eg, hypotension) resolve.[1,3]

‡ Do not escalate if severe CRS occurred during initial dose escalation; resume escalation once dosage is tolerated.[1]

Grade 1 = Mild
Grade 2 = Moderate
Grade 3 = Severe
Grade 4 = Potentially life threatening

Please see Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** on page 14 and full Prescribing Information.

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No patients discontinued therapy for skin reactions[7]

Skin reactions: Typically occurred following each of the first few infusions.[5] Median time to onset was one day, with most resolved to ≤ grade 1 between doses.[1]

Discontinuation rate[7]	All grades[1]	Grade 2[1]	Grade 3[1]	Grades 4 or 5[1]
0%	91%	44%	21%	NONE

- **Rash occurred in 83% of patients[1,*]**; a red rash can appear on all or part of the body, causing the skin to itch, peel, and become painful; it can manifest differently in different patients[8]
- Monitor patients for skin reactions.[1] If skin reactions occur, treat with antihistamines and topical or systemic steroids based on persistence and severity of symptoms[1]
- Majority of symptoms resolved without any long-term sequelae.[1] Withhold or permanently discontinue KIMMTRAK depending on the severity of skin reactions[1]
- No cases of Stevens-Johnson syndrome or toxic epidermal necrolysis were reported within the phase 3 clinical trial[9]

* See rash management guidance on adjacent page.

Skin reaction management and dose modifications[1,3]

Severity	KIMMTRAK dosage modifications
Grade 1[a]	• Treat symptomatically with antihistamines, oral analgesics, and topical steroids, as needed
Grade 2 or 3[a]	• Withhold KIMMTRAK until ≤ grade 1 or baseline • Resume KIMMTRAK at same dose level (ie, do not escalate if grade 3 skin reactions occurred during initial dose escalation; resume escalation once dosage is tolerated) • For persistent reactions not responding to oral steroids, consider intravenous corticosteroid (eg, 2 mg/kg/day methylprednisolone or equivalent)
Grade 4[a]	• Permanently discontinue KIMMTRAK • Administer intravenous corticosteroid (eg, 2 mg/kg/day methylprednisolone or equivalent)

[a] Based on National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) version 4.03 (NCI CTCAEv4.03).

Rash grading and management guidance

Medications used by ≥10% of KIMMTRAK-treated patients[7]		CTCAE Grade[1]	Hold KIMMTRAK until ≤ grade 1 or baseline?[1,3]	Treat with corticosteroids?[1,3]	Can escalate to next dose?[1,3]
Medication class/name	**KIMMTRAK (n = 203)**				
Systemic antihistamines	65%	**Grade 1**	NO	**YES** with antihistamines, oral analgesics, and topical steroids, as needed	**YES**
Topical corticosteroids	45%	**Grade 2 or 3**	**YES**	**YES** with topical or oral steroids, as needed	**NO** Do not escalate if Grade 3 skin reactions occurred during initial dose escalation; resume escalation once dosage is tolerated
Emollients and protectives	12%				
Systemic corticosteroids	10%	**Persistent grade 2 or 3** not responding to oral steroids	**YES**	**YES** consider IV corticosteroids (eg, 2 mg/kg/day methylprednisolone or equivalent)	
		Grade 4	Permanently discontinue KIMMTRAK and treat with IV corticosteroids (eg, 2 mg/kg/day methylprednisolone or equivalent)		

Grade 1 = Mild
Grade 2 = Moderate
Grade 3 = Severe
Grade 4 = Potentially life threatening

- Rash is thought to be due to on-target off-tumor activity of KIMMTRAK against gp100-expressing healthy melanocytes in skin, consistent with the mechanism of action[1,5]

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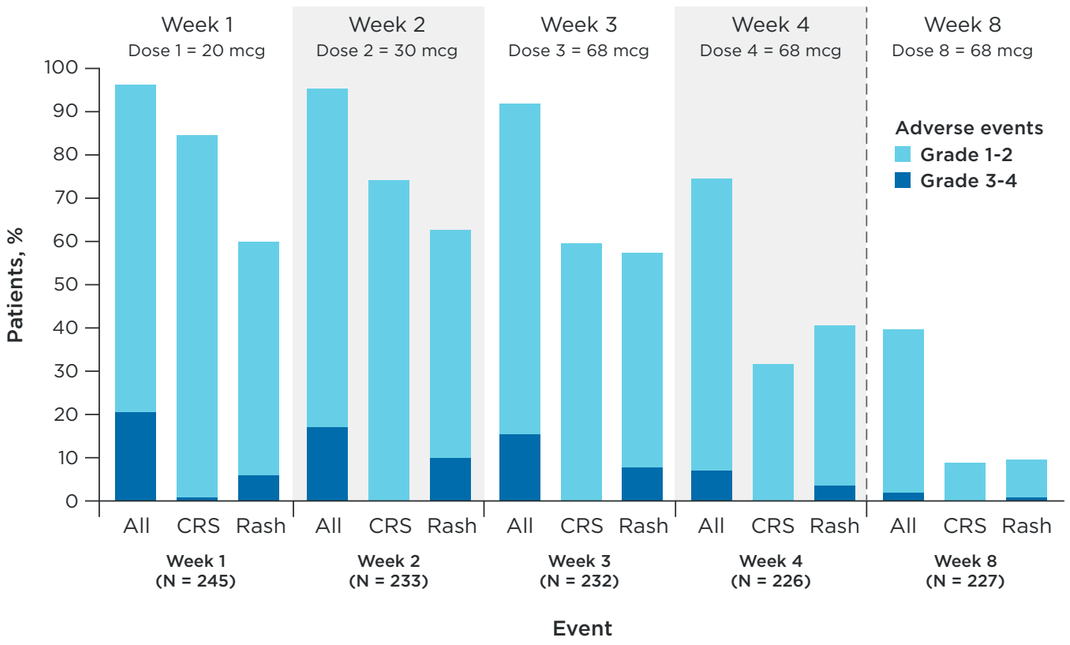
Low 3.3% discontinuation rate with KIMMTRAK due to treatment-emergent adverse events[1]

The most common adverse reactions (≥30%) in patients who received KIMMTRAK were cytokine release syndrome, rash, pyrexia, pruritus, fatigue, nausea, chills, abdominal pain, edema, hypotension, dry skin, headache, and vomiting. The most common (≥50%) laboratory abnormalities were decreased lymphocyte count, increased creatinine, increased glucose, increased AST, increased ALT, decreased hemoglobin, and decreased phosphate.[1]

Treatment-related adverse events decreased in frequency and severity following each subsequent KIMMTRAK infusion[1,5]

Incidence of select treatment-related adverse events by week during treatment with KIMMTRAK in the primary analysis[5]



CRS represents algorithmic identification of cases based on American Society for Transplant and Cellular Therapy (ASTCT) grading criteria (Lee et al. 2019).[1] Rash represents a composite of multiple related terms.[1]

From *New England Journal of Medicine*, Nathan P, et al, Overall survival benefit with tebentafusp in metastatic uveal melanoma, Volume 385, Page 1204. Copyright © 2021 Massachusetts Medical Society. Adapted with permission from Massachusetts Medical Society.[5]

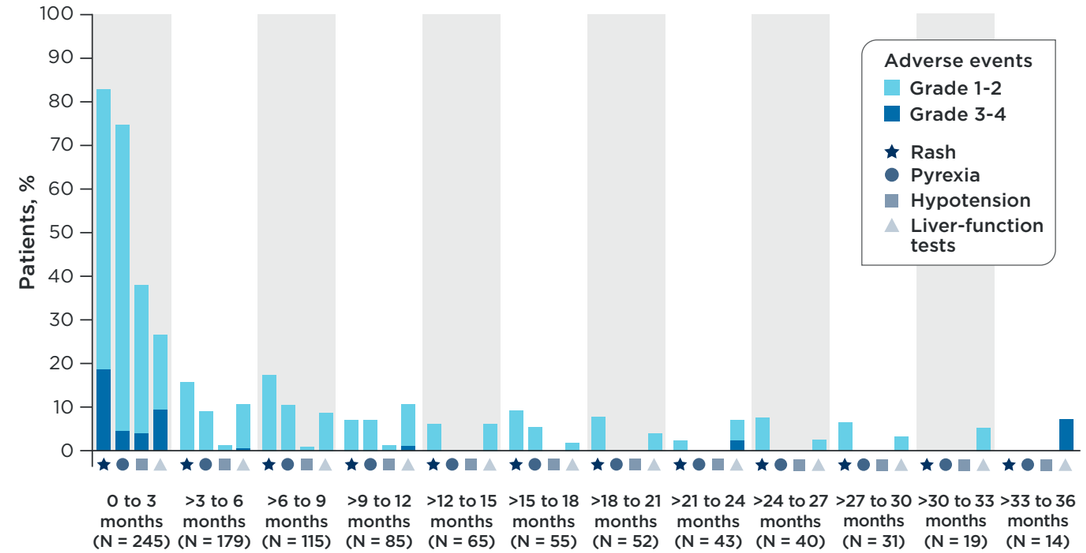
No treatment-related deaths were reported[5]; 1 treatment-emergent death was reported with KIMMTRAK.[10]

No new safety signals were identified at the **3-YEAR** follow-up analysis[11]

KIMMTRAK treatment-related adverse events were predictable and manageable,* decreasing in frequency and severity after the first few doses[1,11]

- Low 3.2% discontinuation rate with KIMMTRAK due to treatment-emergent adverse events[12]

Long-term frequency and severity of selected treatment-related adverse events with KIMMTRAK (minimum follow-up 36 months)[11]



The numbers of patients at risk for each time interval are indicated. Rash, hypotension, and liver-function tests (ie, elevated liver-function values) are composite terms for a list of related adverse events of any grade.

From *New England Journal of Medicine*, Hassel JC, et al, Three-year overall survival with tebentafusp in metastatic uveal melanoma, Volume 389, Page 9. Copyright © 2023 Massachusetts Medical Society. Adapted with permission from Massachusetts Medical Society.

Treatment with KIMMTRAK should be continued while patient is deriving clinical benefit and in the absence of unacceptable toxicities.[1]

No treatment-related deaths were reported[11]; 3 treatment-emergent deaths were reported with KIMMTRAK.[13]

* CRS symptoms were mostly managed with IV fluids, NSAIDs, corticosteroids, oxygen, and rarely, a vasopressor.[1,5] Monitor fluid status, vital signs, and oxygenation level and provide appropriate therapy.

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Elevated liver enzymes and other adverse reactions management and dose modifications

Elevated liver enzymes: The majority (73%) of ALT or AST elevations occurred within the first few infusions.[1] Most patients experiencing grade 3 or 4 ALT/AST elevations had improvement to ≤ grade 1 within 7 days.[1]

Discontinuation rate[1]	All grades[1]	Grades 3 or 4[1]
0.4%	65%	8%

- More than 90% of patients with ALT/AST elevation were able to continue treatment.[14] Elevations in bilirubin have been reported in 27% of patients[1]
- Majority of the elevations in bilirubin were temporarily associated with an increase in size of liver metastasis[14]
- Monitor ALT, AST, and total blood bilirubin prior to the start of and during treatment with KIMMTRAK.[1] Withhold KIMMTRAK according to severity[1]

Elevated liver enzymes management and dose modifications[1]

Severity	KIMMTRAK dosage modifications
Grade 3 or 4[a]	• Withhold KIMMTRAK until ≤ grade 1 or baseline • Resume KIMMTRAK at same dose level if the elevated liver enzymes occur in the setting of grade 3 CRS; resume escalation if next administration is tolerated • If the elevated liver enzymes occur outside the setting of grade 3 CRS - resume escalation if the current dose is less than 68 mcg, - or resume at same dose level if dose escalation has completed • Administer intravenous corticosteroids if no improvement within 24 hours

[a] Based on National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) version 4.03 (NCI CTCAEv4.03).

Other adverse reactions* management and dose modifications[1]

Severity	KIMMTRAK dosage modifications
Grade 3[a]	• Withhold KIMMTRAK until ≤ grade 1 or baseline • Resume KIMMTRAK at same dose level (ie, do not escalate if other grade 3 adverse reaction occurred during initial dose escalation; resume escalation once dosage is tolerated)
Grade 4[a]	• Permanently discontinue KIMMTRAK

* Other adverse reactions as found in Section 6.1, Table 4 of full Prescribing Information.
[a] Based on National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) version 4.03 (NCI CTCAEv4.03).

Reminders for patients

Consider discussing with patients the frequency of monitoring and the possible side effects that can occur. Remind the patient to alert the provider or nursing staff if they have[1]:

- Fever
- Tiredness or weakness
- Vomiting
- Chills
- Nausea
- Low blood pressure
- Dizziness and light headedness
- Headache
- Right-sided abdominal pain or yellowing of the skin or eyes (ie, abnormal liver blood tests)
- Wheezing and trouble breathing
- Rash
- Patchy or extensive redness, pain, itching or swelling of skin (rash)
- Redness, pain, or swelling around the eye, eyelid, or inner lining of the eyelid
- Dry skin and skin peeling

Importance of patients keeping their infusion appointments

- Emphasize to patients the importance of keeping their weekly infusion schedule. To maximize the patient's opportunity to experience the overall survival benefit seen in clinical trials, patients must receive KIMMTRAK weekly, as prescribed[1,6]
- Breaks in treatment, if needed, were allowed in the clinical trials for up to 2 weeks.[6] Breaks for more than 2 weeks are not recommended[6]
  - Side effects may occur at the same frequency and severity as a patient who is initiating treatment (first few infusions)[6]
  - The impact on outcomes for breaks longer than 2 weeks has not been evaluated

If KIMMTRAK is well tolerated during the first 3 infusions, the patient may be able to continue weekly treatments in an appropriate healthcare setting closer to home[1]

- KIMMTRAK CONNECT® can help the patient find options closer to home

KIMMTRAK CONNECT®

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Indication and Important Safety Information Including Boxed Warning

Indication

KIMMTRAK is a bispecific gp100 peptide-HLA-directed CD3 T cell engager indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.

Important Safety Information Including Boxed Warning

WARNING: CYTOKINE RELEASE SYNDROME
Cytokine Release Syndrome (CRS), which may be serious or life-threatening, occurred in patients receiving KIMMTRAK. Monitor for at least 16 hours following first three infusions and then as clinically indicated. Manifestations of CRS may include fever, hypotension, hypoxia, chills, nausea, vomiting, rash, elevated transaminases, fatigue, and headache. CRS occurred in 89% of patients who received KIMMTRAK with 0.8% being grade 3 or 4. Ensure immediate access to medications and resuscitative equipment to manage CRS. Ensure patients are euvolemic prior to initiating the infusions. Closely monitor patients for signs or symptoms of CRS following infusions of KIMMTRAK. Monitor fluid status, vital signs, and oxygenation level and provide appropriate therapy. Withhold or discontinue KIMMTRAK depending on persistence and severity of CRS.

Skin Reactions
Skin reactions, including rash, pruritus, and cutaneous edema occurred in 91% of patients treated with KIMMTRAK. Monitor patients for skin reactions. If skin reactions occur, treat with antihistamine and topical or systemic steroids based on persistence and severity of symptoms. Withhold or permanently discontinue KIMMTRAK depending on the severity of skin reactions.

Elevated Liver Enzymes
Elevations in liver enzymes occurred in 65% of patients treated with KIMMTRAK. Monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total blood bilirubin prior to the start of and during treatment with KIMMTRAK. Withhold KIMMTRAK according to severity.

Embryo-Fetal Toxicity
KIMMTRAK may cause fetal harm. Advise pregnant patients of potential risk to the fetus and patients of reproductive potential to use effective contraception during treatment with KIMMTRAK and 1 week after the last dose.

The most common adverse reactions (≥30%) in patients who received KIMMTRAK were cytokine release syndrome, rash, pyrexia, pruritus, fatigue, nausea, chills, abdominal pain, edema, hypotension, dry skin, headache, and vomiting. The most common (≥50%) laboratory abnormalities were decreased lymphocyte count, increased creatinine, increased glucose, increased AST, increased ALT, decreased hemoglobin, and decreased phosphate.

Please see full Prescribing Information, including BOXED WARNING for CRS.

For more information or to report suspected adverse reactions, contact the Immunocore Medical Information Center at 1-844-IMMUNO-1 (1-844-466-8661).

For patient assistance, contact:

KIMMTRAKCONNECT®

KIMMTRAKCONNECT.com
844-775-CARE (2273)

References: 1. Kimmtrak. Package insert. Immunocore Ltd; 2022. **2.** Data on file. Immunocore. [2024-C004]. **3.** Protocol for: Nathan P, Hassel JC, Rutkowski P, et al; IMCgp100-202 Investigators. Overall survival benefit with tebentafusp in metastatic uveal melanoma. *N Engl J Med.* 2021;385:1196-1206. doi:10.1056/NEJMoa2103485 **4.** Hassel JC, Berking C, Forschner A, Gebhardt C, et al. Practical guidelines for the management of adverse events of the T cell engager bispecific tebentafusp. *Eur J Cancer.* 2023;191:112986. doi:10.1016/j.ejca.2023.112986 **5.** Nathan P, Hassel JC, Rutkowski P, et al; IMCgp100-202 Investigators. Overall survival benefit with tebentafusp in metastatic uveal melanoma. *N Engl J Med.* 2021;385(13):1196-1206. doi:10.1056/NEJMoa2103485 **6.** Schlaak M, Dummer R, Kirkwood JM, et al. 821P. Safety and efficacy of infrequent tebentafusp treatment omissions in patients with metastatic uveal melanoma. *Ann Oncol.* 2022;33(supplement 7):S923. doi.org/10.1016/j.annonc.2022.07.947 **7.** Hassel JC, Rutkowski P, Baurain JF, et al. Co-primary endpoint of overall survival for tebentafusp-induced rash in a phase 3 randomized trial comparing tebentafusp vs. investigator's choice in first line metastatic uveal melanoma. Poster presented at: ASCO General Meeting; June 4-8, 2021; Virtual Meeting. **8.** Data on file. Immunocore. [2024-C017]. **9.** Carvajal RD, Nathan P, Sacco JJ, et al. Phase I study of safety, tolerability, and efficacy of tebentafusp using a step-up dosing regimen and expansion in patients with metastatic uveal melanoma. *J Clin Oncol.* 2022;40(17):1939-1948. doi:10.1200/JCO.21.01805 **10.** Data on file. Immunocore. [2024-C001]. **11.** Hassel JC, Piperno-Neumann S, Rutkowski P, et al. Three-year overall survival with tebentafusp in metastatic uveal melanoma. *N Engl J Med.* 2023;389(24):2256-2266. doi:10.1056/NEJMoa2304753 **12.** Data on file. Immunocore. [2024-C002]. **13.** Data on file. Immunocore. [2024-C003]. **14.** Chmielowski B, Kapiteijn E, Ascierto PA, et al. Characterization of liver function tests following tebentafusp in phase 3 randomized trial comparing tebentafusp with investigator's choice in first line metastatic uveal melanoma (mUM). Poster presented at: ESMO Congress; September 16-21, 2021; Virtual Meeting.

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CM-US-TEBE-2200003 v6.0 February 2025

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