



FDA approves lovance's Amtagvi, a first-in-class autologous cell therapy

Market Event Summary

Thomas Pataillot-Meakin | March 2024

Amtagvi offers valuable treatment regardless of *BRAF*-mutation-status

Key details

- **Industry norm**

Treatment of second-line and above unresectable or metastatic melanoma is primarily immune checkpoint inhibitors, or BRAF/MEK inhibitors, dependent on *BRAF*-mutation-status. Amtagvi's *BRAF*-mutation-agnosticism allows for cross-patient application and expands the currently limited treatment options.

- **Patient behavior**

Patients prefer fewer clinical visits; Amtagvi's single infusion will likely appeal to patients and help guarantee compliance.

- **Pharma perception**

KOLs are concerned that Amtagvi's reach could be limited to high-traffic treatment centers due to manufacturing complexity but are excited by the response rates and efficacy (which are greatly superior to those for existing options) in multiple-treatment-resistant patients.

- **Pharma reaction**

Approval of Amtagvi defines a regulatory pathway to approval for TIL-based therapies and will likely generate further investment in other cell-based therapies.

Strategic implications

Which centers will be able to deliver Amtagvi?

What proportion of patients would be eligible?

How does Amtagvi's efficacy and response rate compare to other emerging therapies?

Will the price limit accessibility in the United States?

Factors for Consideration



Pooled analysis showed 48-month OS rate was 47.3%, ORR 45%, and median DOR was not reached.



82% of patients had grade 3/4 thrombocytopenia. No treatment-related discontinuations.



The price of \$515,000 is higher than CAR-T therapies. An MAA for the EU has not yet been filed.

About the Author



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Clarivate coverage of malignant melanoma

- [Malignant melanoma disease landscape & forecast \(G7\)](#).
- [Malignant melanoma current treatment: physician insights: US](#) - explores the current prescribing trends of medical oncologists treating malignant melanoma.
- [Malignant melanoma current treatment: treatment sequencing: US](#) - presents surveyed medical oncologist's most frequent treatment sequences for malignant melanoma.
- [Malignant melanoma unmet need](#) - detail expanded analysis on *BRAF*-mutation-positive unresectable or metastatic malignant melanoma (US/EU).

Author Bio

Thomas Pataillot-Meakin, M.Sc., Ph.D. has several years of experience in cancer research. Prior to joining Clarivate, he worked in research laboratories developing immunotherapies for neuroblastoma, and optimizing and integrating next-generation sequencing into the National Health Service. As a Ph.D. candidate, he studied the use of circulating DNA as a predictive biomarker for prostate and breast cancer. In addition to his Ph.D. from Imperial College London, Dr. Pataillot-Meakin holds a master of science degree in cancer from University College London and a bachelor of science degree in natural sciences, with a major in pharmacology, from the University of Bath.



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