Swiss Summary of the Risk Management Plan (RMP)

ELAHERE®

(Mirvetuximab soravtansine)

5 mg/ml (20 mg/100 ml)

Concentrate for solution for infusion

Version 1 (08 May 2025)

Based on EU RMP, version 0.3, dated August 2024

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Disclaimer

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimize them.
The RMP summary of ELAHERE® is a concise document and does not claim to be exhaustive. As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g., by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of ELAHERE® in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. AbbVie AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of ELAHERE®.

PART VI SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF RISK MANAGEMENT PLAN FOR ELAHERE (MIRVETUXIMAB SORAVTANSINE)

This is a summary of the risk management plan (RMP) for ELAHERE. The RMP details important risks of ELAHERE, how these risks can be minimised, and how more information will be obtained about ELAHERE's risks and uncertainties (missing information).

ELAHERE's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how ELAHERE should be used.

This summary of the RMP for ELAHERE should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of ELAHERE's RMP.

I THE MEDICINE AND WHAT IT IS USED FOR

ELAHERE is authorised as monotherapy for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens (see SmPC for the full indication). It contains mirvetuximab soravtansine as the active substance and it is given intravenously.

Further information about the evaluation of ELAHERE's benefits can be found in ELAHERE's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage < link to the EPAR summary landing page >

II RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

Important risks of ELAHERE, together with measures to minimise such risks and the proposed studies for learning more about ELAHERE's risks, are outlined below.

- Measures to minimise the risks identified for medicinal products can be:
- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g., with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including periodic safety updated report (PSUR) assessment –so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of ELAHERE is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of ELAHERE are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of ELAHERE. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g., on the long-term use of the medicine).

Table 19: Lists of Important Risks and Missing Information

List of Important Risks and Missing Information	
Important identified risks	Ocular disorders
Important potential risks	None
Missing information	Use in patients with moderate hepatic impairment

II.B Summary of Important Risks

Important identified risk: Ocular disorders	
Evidence for linking the risk to the medicine	As mirvetuximab soravtansine is a DM4 (payload) tubulin-directed compound and corneal effects were observed in nonclinical studies, ocular disorders were expected adverse reactions in clinical studies. Across clinical studies, 405 of 682 patients (59%) treated with mirvetuximab soravtansine developed ocular adverse reactions. The majority were of mild or moderate severity; 75 patients (11%) had a severe (≥ Grade 3) ocular adverse reaction. The most common adverse reactions were vision blurred in 43% of patients and keratopathy in 29% of patients. The ocular adverse reactions typically occurred 6 weeks after the start of treatment and in most cases completely or partially improved. The use of lubricating and corticosteroid eye drops together with dose modifications and supportive treatment helped to minimise the severity of the adverse reactions and assisted the recovery of patients. Clinical studies can provide an estimation of the frequency and nature of an adverse reaction that is expected to occur in clinical practice.

Important identified risk: Ocular disorders	
Risk factors and risk groups	No specific risk factors have been identified.
Risk minimisation measures	Routine risk minimisation measures: • Warning for severe ocular adverse reactions and to monitor patients in SmPC section 4.4 • Recommendation for ophthalmic exams in SmPC sections 4.2 and 4.4, and PL section 3 • Guidance for the patient to report any new or worsening eye problems before the start of each treatment cycle in PL sections 2 and 3 • Recommendation to use lubricating eye drops during treatment in SmPC sections 4.2 and 4.4, and PL sections 2 and 3 • Recommendation to use ophthalmic topical steroids for moderate or severe corneal adverse reactions in SmPC sections 4.2 and 4.4, and PL sections 2 and 3 • Warning for the patient to talk to their doctor or nurse before they are given ELAHERE if they have vision or eye problems in PL section 2 • Dose modifications for keratitis/keratopathy by severity grade in SmPC section 4.2 • Warning for the patient to seek urgent medical attention if they experience severe eye problems in PL section 2 • Recommendation to avoid use of contact lenses during treatment unless directed by a healthcare professional in SmPC section 4.4 and PL sections 2 and 3 • Guidance for driving and using machinery in SmPC section 4.7 and PL section 2 • Adverse reactions in SmPC section 4.8 and PL section 4 • Restricted medical prescription Additional risk minimisation measures: • None

Missing information: Use in patients with moderate hepatic impairment	
Risk minimisation measures	Routine risk minimisation measures: • Guidance that ELAHERE should be avoided in patients with moderate to severe hepatic impairment in SmPC section 4.2 • Information that the pharmacokinetics of mirvetuximab soravtansine in patients with moderate to severe hepatic impairment is unknown in SmPC section 5.2 • Restricted medical prescription Additional risk minimisation measures:

Missing information: Use in patients with moderate hepatic impairment	
	• None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: • Study IMGN853-0425 See section II.C of this summary for an overview of the post-authorisation development plan.

II.C Post-Authorisation Development Plan

II.C.1 Studies Which Are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of ELAHERE.

II.C.2 Other Studies in Post-Authorisation Development Plan

Study IMGN853-0425

A randomized Phase 2, open-label study of mirvetuximab soravtansine in patients with platinum-resistant advanced high-grade epithelial ovarian, primary peritoneal, or fallopian tube cancers with high folate receptor-alpha expression testing 2 schedules of administration for dose optimization, with a separate cohort to determine starting dose in patients with moderate hepatic impairment

Purpose of the study: To evaluate the safety and pharmacokinetics (PK) of mirvetuximab soravtansine, unconjugated DM4, and S-methyl DM4 in patients with moderate hepatic impairment, according to National Cancer Institute Organ Dysfunction Working Group (NCI-ODWG) criteria.