A Non-Interventional Post-Authorization Safety Study (NI-PASS) To Check The Effectiveness Of The Patient Card for Enfortumab Vedotin: Insights From Qualitative Interviews With German Patients and Caregivers

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Objective(s)

- Via pre-survey qualitative interviews (planning for the online survey):
  - Thoroughly explore patients'/caregivers' knowledge of enfortumab vedotin (EV)-associated skin reaction risks, awareness and knowledge of Patient Card (PC) content, and reported behaviours to minimise skin reaction risks
- Via cognitive pretesting interviews:
  - Identify unclear draft questionnaire items and confirm translation accuracy
- Via an online survey (results pending):
  - To assess patients'/caregivers' knowledge of EV-associated skin reaction risks, awareness and knowledge of PC content, and reported behaviours to minimise skin reaction risks

Discussion

- The limited qualitative interviews provided evidence of awareness of both the EV treatment risks as well as PC contents
- Participant attitudes were overall positive towards the EV PC
- Participants included both those who reported taking preventative measures to minimize the risk of skin reactions and those who reported taking no actions
- Cognitive pretesting validated that the survey was clear and understandable

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Conflicts of interest

Samantha Kimball-Carroll, Heather Dickerson, Dayna Clark, Kira Lai and Serena Fossati are employees of ICON PLC, contracted by Astellas Pharma Inc. to conduct the study. **Bobby Clark** and **Noah Jamie Robinson** are employees of Astellas Pharma Inc.

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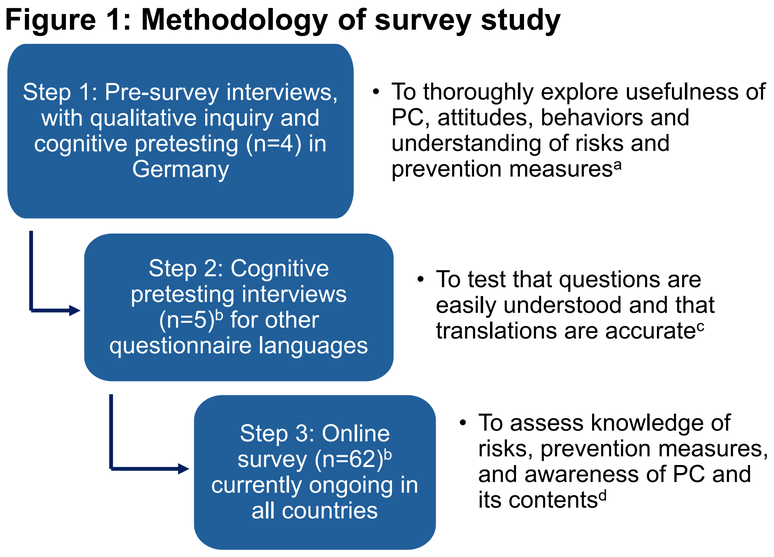
Background

- Risk management plans (RMPs) are required by the European Medicines Agency (EMA) when applying for marketing authorisation in the European Union (EU)[1]
  - The RMP may require additional risk minimisation measures (aRMMs) to mitigate important or potential risks[1,2], including the use of a drug-specific PC
- Evaluation of aRMM effectiveness is often required, and may include qualitative and quantitative methods (e.g. surveys)[1,2]
- EV was first approved as monotherapy by the EMA in April 2022 for adults with previously treated (post-platinum and post-PD1/L1) locally advanced or metastatic urothelial carcinoma (la/mUC)[3]
- A randomized, controlled, phase 3 study found that EV-treated patients with la/mUC who had previously received platinum-containing chemotherapy and PD-1/L1 lived approximately 3.9 months longer than with standard chemotherapy, with no increased incidence of adverse events[4]
- Upon launch of EV in the EU, Astellas Pharma Inc. was required to conduct an effectiveness check of the aRMM implemented
- This effectiveness check is being carried out as a Non-Interventional Post-Authorisation Safety Study (NI-PASS) (Category 3) assessing patients', or their caregivers', knowledge of the risk of skin reactions associated with the use of EV, as well as awareness of the EV PC, knowledge of the content of the PC, and reported behaviours to minimise the risk of skin reactions

Methods

- This study was conducted in three sequential steps: (1) pre-survey interviews (qualitative inquiry and pretesting), (2) cognitive pretest, and (3) online survey (**Figure 1**)
- Patients or caregivers eligible for inclusion in the interviews and survey (**Table 1**) were recruited by a recruitment agency from their database of cancer patients, through social media posts, or referrals from healthcare providers, patient advocacy groups, patient associations or support groups
- Participants were included from 7 European countries (**Figure 2**)

Figure 1: Methodology of survey study

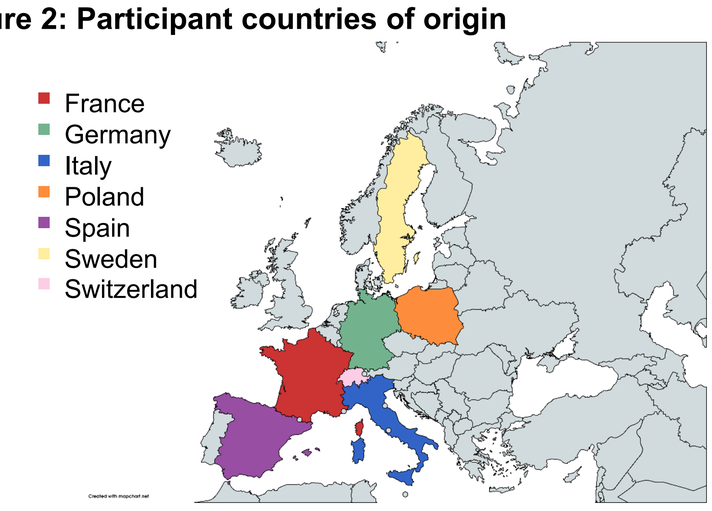


[a]Pre-survey interviews were conducted remotely in Germany by trained moderators, according to a structured interview guide, over 45-60 minutes
[b]The 'n' value corresponds to the total number of patients or caregivers across all countries
[c]The questionnaire underwent cognitive pretesting in each of the other languages (French, Italian, Polish, Spanish, Swedish) prior to survey launch in each country
[d]Effectiveness of the PC will be assessed based on the primary endpoint with a target of 80% or more patients/caregivers providing correct responses to question about the risk of skin reactions associated with the use of EV

Table 1. Eligibility criteria

Inclusion Criteria	Exclusion Criteria
– Patients (or caregivers of patients) who have received or are currently receiving EV therapy	– Participated in the qualitative interviews or cognitive pretesting (survey only)
– Residing in a participating European country (Germany only for qualitative interviews)	– Caregiver of a deceased patient that received EV therapy
– 18 years of age or older	– Have themselves (or have immediate family members who have) worked for Astellas Pharma Inc., ICON Commercial Solutions (coordinating investigator), EMA, or the National Competent Authorities of the participating countries within the past 5 years
– Agree to participate	

Figure 2: Participant countries of origin

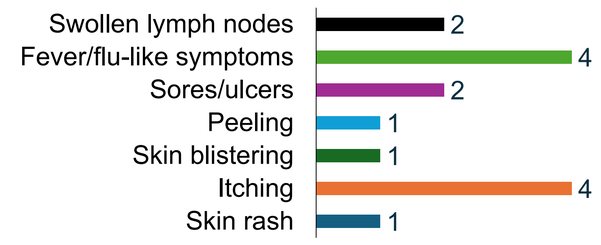


Results

Qualitative Inquiry Summary

- Participants had wide general awareness of treatment risks associated with the use of EV
- All participants (4 of 4) described experience with or awareness of at least one of the key major skin-specific reaction risks (skin rash, itching, skin blistering and/or peeling) (**Figure 3**)
- All participants described experience with or awareness of at least one of the other key major treatment risks (sores/ulcers, fever/flu-like symptoms, swollen lymph nodes, or other symptoms) (**Figure 3**)

Figure 3: Participant (n=4) awareness of symptoms



Knowledge of EV treatment risks

- The majority of the participants indicated that they had prior awareness of the PC (3 of 4) and its contents; one participant expressed that they had not received the PC prior to study participation
- All participants demonstrated an ability to summarize the contents and purpose of the PC when prompted

Understanding of EV PC

- Of patients and caregivers (3 of 4) who expressed awareness of the PC, all further endorsed that the patient needs to keep the PC on them at all times (**Table 2**)
  - Similarly, three participants reported that the patient had carried the PC to a past healthcare professional (HCP) visit

Understanding of EV PC (cont.)

- Two participants reported using prevention measures to minimize the risk of skin reactions and two reported taking no preventative measures
- The participants' attitudes towards the PC were overall positive, with the majority of participants describing the PC as useful (3 of 4); all participants indicated that they would carry the PC on them in future and would take it to future HCP visits

Table 2: Understanding of EV PC

Role	Sample Quote
Patient	I get indications of what I have to pay attention to, what the reactions of the medication can be... mostly skin irritations and even fever and flu-like symptoms. These are the things I should pay attention to and how I should behave when something happens.
Caregiver	I guess it would be in case my father is found somewhere you can find it in your wallet and look who the person is...if he wasn't able to articulate himself, for example, because of pain or similar then anyone would at least know what illness he has, the medication he is on and where he is treated
Caregiver	I think this card offers a certain level of security. No matter where you go, even if you are travelling and so on… everybody knows that this patient receives this treatment and has to be treated accordingly.

Cognitive Pretesting Summary

- Participants in both Germany (n=4) and for other languages (n=5) unanimously found the survey to be clear and easy to understand.
- The participants provided overall positive feedback, noting that the survey was concise and a good questionnaire
- There were minor suggestions and notes throughout the survey that did not result in substantial changes to question content; there were also updates made to the translations for one word/phrase in each of the French, German and Polish versions

Pending results

- As of September 2024, the main online survey had been launched in 4 of 7 countries with 4 countries having met the target number of completed surveys (50% of the overall target of 62 responses).
  - It is planned that the survey will have launched in all countries by Q4 2024 and will close by Q2 2025 (**Table 3**)
- Effectiveness of the EV PC will be assessed based on the results of the survey

Table 3: Survey Summary

Country	Survey Launch[a]	Target number	Number completed[b]
France	Pending	14	0
Germany	27 March 2024	16	16
Italy	Pending	12	0
Poland	27 March 2024	5	5
Spain	30 August 2024	5	5
Sweden	Pending	5	0
Switzerland	24 May 2024	5	5

[a]Dependent on product availability, regulatory and ethics committee approvals where applicable. [b]As of 23 September 2024