Mepolizumab Prefilled Autoinjector and Prefilled Syringe Real World Use: The Patient Experience

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Background

- Mepolizumab is approved for the treatment of severe eosinophilic asthma in the US, EU, Japan, and other countries, and for eosinophilic granulomatosis with polyangiitis in several countries, including the US and Japan.
- Mepolizumab is currently delivered as a lyophilized powder requiring reconstitution and is administered in clinical settings by health care professionals (HCPs).
- To improve the convenience and ease of treatment with mepolizumab, a liquid drug product in a ready-to-use prefilled autoinjector (AI) and prefilled syringe (PFS) has been developed to enable at-home, self-administration, in addition to in-clinic HCP administration.

Objective

- To capture the patient experience of self-administering mepolizumab treatment via AI and PFS.

Methods

- Two open-label, single-arm, repeat-dose, multicenter, international Phase IIIa studies that included patients aged ≥12 years, diagnosed with severe eosinophilic asthma were conducted to evaluate the real-word use (RWU) of mepolizumab administered via an AI [204959 (N=159; NCT03099096)] and PFS [205667 (N=56; NCT03021304)].
- Mepolizumab (100mg SC) was administered by the patient/caregiver Q4W with a 12 week treatment period. The first and third dose (Weeks 0 and 8, respectively) were self-administered under observation in-clinic, while the second dose (Week 4) was self-administered, unobserved at home.
- To capture the patient experience of self-administering treatment, quantitative questionnaires were administered to participants at the end of study assessment or following study withdrawal (AI: n=153; PFS: n=56 completed questionnaires), and in a subset, additional semi-structured, qualitative exit interviews over the phone were completed within 6 weeks after end of study visit or early withdrawal visit (AI: n=25; PFS: n=7). Interviews were digitally recorded and transcribed, translated, if not in English originally, and qualitative data analyzed in ATLAS.ti. Both data collection methods were embedded directly into the clinical study and were predefined clinical endpoints.
- The structure and content of the quantitative questionnaires and qualitative exit interviews were similar to allow the interviews to bring depth, context, and allow for improved interpretation of the quantitative results.
- Exit Interviews were conducted between September and November 2017 (204959) and May and August 2017 (205667).

Results

- Approximately 60% of the patients in each study were female with a mean age of approximately 50 years (**Table 1**).
- A total of 25 patients in the AI study (Germany=8; US=7; Canada=6 and Australia=4) and a total of 7 patients participated in the exit interviews for the PFS study (US=6; Russia=1).

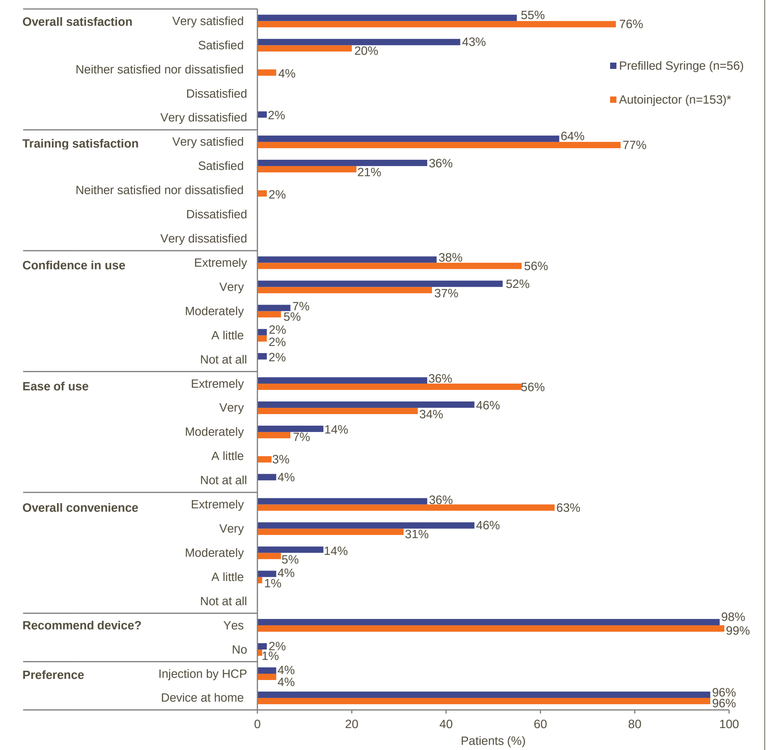
Table 1. Demographic and clinical characteristics of patients included in the quantitative interview

	Autoinjector (N=159)	Pre-filled syringe (n=56)
Female, n (%)	98 (62)	33 (59)
Age (years), mean (SD)	49.3 (16.18)	50.8 (12.98)
Disease duration (years), mean (SD)	23.3 (16.47)	22.3 (14.67)
Current mepolizumab use, n (%)	84 (53)	23 (41)
Prior experience with self-injection of medication, n (%)	43 (27)	16 (29)

Device Training

- For both the AI and PFS, quantitative (**Figure 1**) and qualitative results demonstrated that the vast majority of patients were satisfied with the level of training received.

Figure 1. Patient reported experience of the mepolizumab autoinjector and safety syringe - quantitative questionnaire results



*Two versions of injection guidance on the device were incorporated into the trial, providing information to the patient in pictogram form on how to inject, alongside the common IFU: 'standard IFU + pictogram label' (i.e. Quick Reference Guide) (IFU+P), and 'standard IFU' without a pictogram label on the device (IFU). Combined results are presented. Numbers of patients indicate the number of patients who completed the questionnaire.

Confidence in self-administration

- 98% of patients using the AI and 96% of patients using the PFS were at least moderately confident in self-administering mepolizumab based on the IFU (**Figure 1**).
  - AI – Patient 7: *So the first time you used the pen on your own outside of the doctor's office, how confident did you feel in your ability to use it? "Very confident. Very confident, very. No problem whatsoever. I took the medicine out, set it for half an hour, cleaned my thigh with a little bit of alcohol and I injected myself."*
- Within the exit interviews 15/25 and 5/7 of patients in the AI and PFS groups respectively reported that their confidence improved over the course of the study. Most of the patients who did not report an improvement reported during the exit interview that they were "extremely"/ "very" confident at study start.
  - AI – Patient 15: *Did your level of confidence change over the course of the study? So, let's say from the first time to the third injection? "Oh, yes, definitely because by that injection you knew what to expect and how to do it, so you felt more comfortable on the third one. Because, you've already had two and the second one you did, and the third one you felt more comfortable, yeah, definitely."*

Satisfaction with using the device at home & ease of administration

- Most patients reported that it was easy to self-administer using the AI or PFS at home and were generally "satisfied" or "very satisfied" with using the devices at home (**Figure 1**). Within the exit interviews, patients voiced that their satisfaction was driven by ease of use, safety and convenience. One PFS patient reported the device to be "moderately easy" to use during the exit interview due to having to find the right angle for administration.

Convenience of using the device at home

- 94% of patients using the AI and 82% of patients using the PFS reported that it was "very"/"extremely" convenient to use the device at home (**Figure 1**). The exit interviews revealed the predominant reason being time saved.
  - AI – Patient 15: *Did you find the pen convenient to use? "Very convenient. Extremely so, I mean I, I wouldn't mind just giving that at home, every month or whatever if it comes to market which will be very, very good thing to do, because at the moment what I have to is get the injection from my pharmacy, and I have to go to my GP and the GP does the injection for me. This will save me doing that every month and you just do it at home."*
- One PFS patient stated "a little-to-moderately convenient," explaining that it was not as easy as injections where the needle retracts. An additional patient provided a rating of "a little convenient" as administration involved more steps than using an inhaler.

Preference of at-home self-administration or in-clinic administration by HCP

- In patients who had previously received mepolizumab 96% preferred self-administration at home using the autoinjector or prefilled syringe, over in clinic administration by a HCP.
- Within the qualitative interviews convenience was reported as the main reason for this preference.
  - PFS – Patient 3: *Would you prefer to receive the injection from a safety syringe given at the doctor's office or an injection that you give yourself at home? "An injection I give myself at home … because I don't have to drive to the doctor's office and take part of their day … It would be more convenient for everybody … It's one more thing that I don't have to add to their day. I don't have to waste the gas or the time to leave the house and go do it."*

Conclusions

- The real-world use studies for the mepolizumab prefilled AI and PFS show that for the majority of patients, both devices provide a convenient, easy route of administration. 94% of patients using the AI and 82% using the PFS reported that it was "very"/"extremely" convenient to use the device at home. 90% of patients using the AI and 82% using the PFS reported that it was "very"/"extremely" easy to use the device at home
- In the subset of patients asked (those who had previously received mepolizumab), self-administration at home was preferred by most patients compared to in-clinic injection by a HCP. The results of the qualitative interviews provide complementary details to the results from the quantitative questionnaires

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