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Persistence and treatment satisfaction in patients using the AVONEX® PEN™

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BACKGROUND

- Intramuscular interferon beta-1a (IM IFNβ-1a) was first approved in 1996 for treatment of relapsing forms of multiple sclerosis (MS) and is currently approved in more than 80 countries.
  - As of December 31, 2012, approximately 426,300 patients have been treated with IM IFNβ-1a, totaling 1,705,541 cumulative person-years of exposure.[1]
- MS affects the central nervous system and can cause impairment of motor functions.
  - Loss of motor coordination may limit a patient's ability to self-administer parenteral treatments such as IM IFNβ-1a.
- Simplifying the IM injection procedure may enable MS patients to self-administer IM IFNβ-1a more easily and may provide the following benefits:
  - Increased patient persistence and compliance with therapy.
  - More freedom to self-inject and a greater sense of control for patients.
  - Enhanced patient satisfaction and quality of life (QoL) for patients receiving chronic therapy.
- The AVONEX PEN (once-weekly IM IFNβ-1a autoinjector) was approved for the treatment of MS in the United States in 2012.[2]
  - In a phase 3b study of 74 patients with MS treated initially with manual injection and subsequently switched to autoinjection for 4 weeks, patients preferred the AVONEX PEN over manual injection.[3]
- The PERSIST study will provide additional data from a broad range of patients initiating therapy with the AVONEX PEN, may assist clinicians in selecting appropriate patients to receive this device, and may help identify factors that influence compliance.

OBJECTIVE

- Report first interim results of the PERSIST study, which assesses MS patients' experience using the AVONEX PEN in terms of persistence, convenience, compliance, QoL, and fear of injection over 12 months.

METHODS

- PERSIST is a global, prospective, observational, open-label 12-month phase 4 study of MS patients administering IM IFNβ-1a therapy (30 µg once weekly) by autoinjector.
- Patients enrolled in PERSIST were required to meet the following inclusion criteria:
  - Able to understand the purpose and risks of the study and provide signed and dated informed consent and authorization to use protected health information in accordance with national and local patient privacy regulations.
  - Satisfy the locally approved therapeutic indications for the AVONEX PEN.
  - Had the decision to initiate treatment with the AVONEX PEN reached by their physician prior to enrollment.
  - Have made no more than 2 injections with the AVONEX PEN prior to enrollment.
- Physician-reported persistence is assessed at 6 and 12 months; patient-reported compliance data are collected monthly.
- Outcomes evaluated at 3, 6, and 12 months include patient-reported tolerability, ease of use, satisfaction, fear of injection, and QoL. Patient-reported outcomes were measured with the following tools:
  - An injection site pain questionnaire.
  - An injection site reaction (ISR) questionnaire.
  - The EQ-5D questionnaire.
  - The AVONEX PEN instructions grading scale.
  - An ease-of-use grading scale.
  - A patient assessment of injection procedure.
  - A patient satisfaction questionnaire.
  - A fear-of-injection scale.
- Safety data were collected for all patients enrolled.

Statistical analysis

- To determine the sample size for this study, it was assumed that the persistence rate at the end of 12 months would be 68%; enrolling 250 patients would provide a 2-sided 95% confidence interval extending out 5.8% from the assumed persistence rate. Allowing for a 10% dropout rate, approximately 280 patients would be enrolled.
- The efficacy data presented are from a protocol-specified intent-to-treat (ITT) population defined as those who were enrolled in the study and for whom data on the first AVONEX PEN injection were available.
- Data collected at each scheduled time points were tabulated using frequency distributions and/or basic summary statistics (mean and standard deviation [SD]).

RESULTS

Patients

- Enrollment in PERSIST is complete, with a total of 273 MS patients enrolled; 213 (78.0%) had data from the first injection visit and were included in the ITT population.
  - Data analyzed and presented include available 6-month data from the ITT population.
- Baseline demographics and disease characteristics for patients in PERSIST are broadly comparable with contemporary MS trials (Table 1).

Table 1: Baseline demographics and disease characteristics

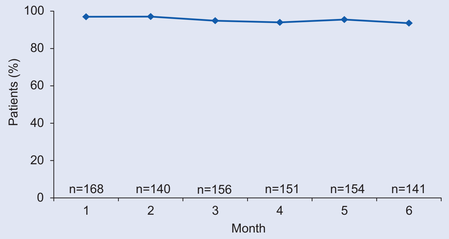
Enrolled	N=273
Age, mean (SD), years	43.0 (10.4)
Female, n (%)	207 (75.8)
White, n (%)	253 (92.7)
Disease duration, mean (SD), years	6.1 (6.2)
Patients with prior DMT use, n (%)	189 (69.2)
Duration of prior DMT use, mean (SD), months	45.8 (41.1)

DMT=disease-modifying therapy.

Persistence, compliance, and adherence

- At 6 months, 92.6% (126 of 136) of patients remained on the AVONEX PEN.
- Overall compliance, defined as not missing any injections from month 1 to month 6, was 81.6% (155 of 190 patients).
  - The proportion of patients missing less than 20% of injections over the first 6 months of PERSIST was 96.8% (184 of 190).
- Patient-reported adherence ranged from 93.6% to 97.1% over 6 months (Figure 1).
  - Reasons given by most patients for missed injections included forgetting to administer the injection, flu-like symptoms, and injection fatigue.

Figure 1: Patient-reported adherence in PERSIST



Tolerability

- Injection pain was measured on a scale of 0 (no pain) to 10 (extremely painful).
- The injection pain level at the first injection visit was low (n=205; mean [SD], 1.5 [1.93]) and remained low to month 6 (n=139; mean [SD], 1.7 [1.95]).
- At 6 months, 75.7% (106 of 140) patients reported injection-related pain levels ≤2.
- Most patients (71.9% [97 of 135]) reported no ISRs at month 6. Table 2 shows the incidence of ISRs experienced by patients in PERSIST.

Table 2: Incidence of ISRs in PERSIST at month 6

ISR	No. (%) of patients (n=135)
Any ISR	38 (28.1)
Bruising	22 (16.3)
Pain	18 (13.3)
Redness	11 (8.1)
Swelling	4 (3.0)
Inflammation	1 (0.7)
Itching	1 (0.7)
Rash	1 (0.7)

Patient satisfaction

- The overwhelming majority of patients (97.2% [138 of 142]) reported being very satisfied or satisfied with the AVONEX PEN at 6 months. Patient ratings of the reasons for satisfaction with the PEN, assessed at 6 months, are listed in Table 3.

Table 3: Reasons for satisfaction with the AVONEX PEN

Key feature of injection experience	No. (%) of patients (n=142)
Ease of use	119 (83.8)
Ease of preparation	114 (80.3)
Convenience	94 (66.2)
Injection comfort	91 (64.1)
Time required	83 (58.5)
Reduces fear about taking injections	79 (55.6)
Instructions for use	46 (32.4)

- Of the 2.8% of patients who were dissatisfied with the AVONEX PEN, the reasons given most often included the device's being too difficult to use or not working as expected.
- Autoinjection with the AVONEX PEN was reported to be easy or very easy by 82.0% (150 of 183) of patients at their first injection visit and 88.5% (116 of 131) of patients at month 6.
  - Few patients (15.3% [20 of 131]) reported difficulties using the AVONEX PEN at month 6; of these 20 patients, 16 had difficulty with injecting, 4 had difficulty in preparing the injection, and 2 had difficulty re-capping the device prior to disposal.
- The number of patients requiring injection assistance from a caregiver decreased from the first injection visit to month 6 (Figure 2).
- The proportion of patients reporting fear of injection decreased over 6 months, as did the proportion of patients reporting anxiety about the injection (Figure 3).
- Of the patients who read the directions for use at their first injection visit (n=118), the majority reported that the directions were helpful or very helpful (83.9% [99 of 118]) and/or easy or very easy to understand (78.8% [93 of 118]); 86.4% (102 of 118) were satisfied or very satisfied with the level of detail provided.

Figure 2: PERSIST patients who required injection assistance by a caregiver

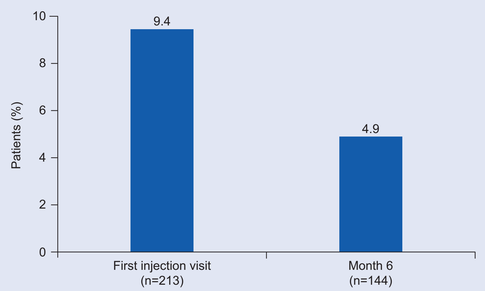
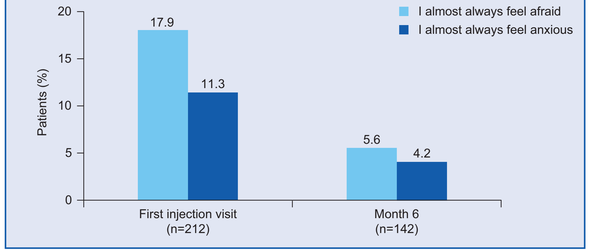


Figure 3: Injection fear and anxiety reported by patients in PERSIST



CONCLUSIONS

- Interim data for PERSIST patients at 6 months demonstrate a high level of compliance and persistence and thus adherence to medication administered with the AVONEX PEN.
- The AVONEX PEN was well tolerated and was perceived by patients as easy to use over the first 6 months.
- Patients reported being highly satisfied with the AVONEX PEN; fear and anxiety about injection decreased over time.
- Patients using the AVONEX PEN were less in need of injection assistance from a caregiver.
- These data support findings from previous studies evaluating the AVONEX PEN.[3]

References

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Disclosures

BS, SS, XY: employees of Biogen Idec Inc. CG: former employee of Biogen Idec Inc.

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