**BACKGROUND**

Intramuscular interferon beta-1a (IM IFN) 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 IFN-1a, creating 1.783% (1.78%) cumulative patient-years of efficacy data.
- MS affects the central nervous system and can cause impairment of motor functions.

**OBJECTIVE**

- Report final interim results of the PER SIST study, which assesses MS patients’ experience with the AVONEX PEN in terms of persistence, convenience, compliance, QoL, and fear of injection over 12 months.

**METHODS**

- PER SIST is a global, prospective, observational, open-label 12-month phase of a US MS patients administering IM IFN-1a therapy (0.5 µg weekly by subcutaneous injection).
- Patients enrolled in PER SIST 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.
  - Consented to the locally approved spinal cord injury indications for the AVONEX PEN.
  - Had the decision to initiate treatment with the AVONEX PEN reached by their physician prior to enrollment.
  - Had no more than 2 injections sites with the AVONEX PEN prior to enrollment.
  - Physician-reported questions measured at 12 months, patient-reported compliance data 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
  - Injection site pain questionnaire.
  - Injection site reaction (ISR) questionnaire.
  - The ED-50 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.

**RESULTS**

**Persistence, compliance, and adherence**

At 6 months, 92.4% (134 of 145) of patients remained on the AVONEX PEN.

- Overall compliance, defined as not missing any injections from month 1 to month 12, was 87.4% (135 of 155 patients).
- The proportion of patients missing less than 25% of injections over the first 6 months of treatment was 98.4% (136 of 138 patients).
- Patients reported adherence ranged from 93.1% to 97.7% over 4 months (Figure 1).

- Of the 2% of patients who were dosed with the AVONEX PEN, reasons given most often were inconvenience of IM versus subcutaneous injection, concerns about IM injection pain, or inability to work or function without IM injection. One patient (0.7%) withdrew from the study due to an adverse event.

**Tolerance**

- Injection pain was measured on a scale of 0 (no pain at all) to 10 (extremely painful).
- The injection pain level at the first injection visit was low (0-100) mean (SD), 1.5 (1.03) and remained low by month 6 (0-100) mean (SD), 0.3 (0.19) at 6 months.
- At 6 months, 79.5% (116 of 147) patients reported injection-related pain levels ≤ 2.

**Conclusion**

- Of the 2% of patients who were dosed with the AVONEX PEN, reasons given most often were inconvenience of IM versus subcutaneous injection, concerns about IM injection pain, or inability to work or function without IM injection. One patient (0.7%) withdrew from the study due to an adverse event.

- The AVONEX PEN was well tolerated and was preferred by patients as easy to use over the autoinjector for IM injection and was considered easy to use compared to the autoinjector for subcutaneous injection.

- Patients reported being highly satisfied with the AVONEX PEN, fear and anxiety about injection, and compliance with therapy.

- Patients using the AVONEX PEN were less in need of injection assistance from a caregiver.

**Disclosures**

- The authors declare no financial relationships with any commercial companies. Biogen Idec provided funding for editorial support in the development of this poster; Marie Geissler of Infusion Communications wrote the first draft of the poster based on input from authors, and Joshua Safran of Infusion Communications copyedited and styled the poster per congress requirements. Biogen Idec reviewed and provided feedback.

**References**