Introduction

• IFN β-1a SC tiw has been shown to be efficacious and well tolerated in patients with RRMS. 3–6 months

• The long-term safety profile of IFN β-1a SC tiw is well established, with considerable clinical trial and post-marketing data available. 3–6 months

• In the 2-year, double-blind, placebo-controlled PRISMS (Phosphorus of Relapse and stability by interferon beta) Substudy in Multiple Sclerosis trial, IFN β-1a SC tiw significantly reduced relapse rates and the number of active T2 lesions, and allowed disease progression compared with placebo, in patients with relapsing-remitting MS (RRMS). 3–6 months

Safety results from PRISMS demonstrated that flu-like symptoms (FLS) were common in all groups, and that injection-site reactions (ISRs) were frequent in both IFN β-1a SC tiw groups, with no apparent dose effect. 3–6 months

• During the PRISMS study, ISRs (n=182) and FLS (n=216) led to four patients discontinuing IFN β-1a SC tiw, highlighting these adverse events (AEs) as a possible tolerability issue for IFN β-1a SC tiw. 3–6 months

• The frequency of ISRs and FLS appear to reduce with increased time on IFN β-1a SC tiw; however, detailed analysis of the frequency of IFN β-1a SC tiw tolerability issues at early time points remains limited.4

Methods

• Patients enrolled in the PRISMS study (n=560) were IFN-naïve adults with RRMS who were randomized to receive IFN β-1a SC tiw doses in the incidence of difference between the two IFN β-1a 22 μg SC tiw (31.2%) and placebo (26.7%) was seen during the PRISMS study, ISRs (n=2) and FLS (n=2) led to four patients discontinuing IFN β-1a SC tiw. 3–6 months

• To evaluate tolerability data by timing and severity of AEs during the first year of therapy, Table 1 provides data on injection-site reactions and flu-like symptoms. 3–6 months

• The percentage of patients who experienced injection-site erythema, unspecified ISRs, or injection-site pain declined sharply after the first 3 months of IFN β-1a SC tiw treatment and decreased further during the subsequent 9 months of IFN β-1a SC tiw treatment and decreased during the first 12 months of treatment. 3–6 months

• Very few patients discontinued IFN β-1a SC tiw due to injection-site erythema, unspecified ISRs, injection-site pain, or FLS. 3–6 months

• This percentage of patients experiencing injection-site erythema, unspecified ISRs, injection-site pain, or FLS decreased considerably after 3 months of IFN β-1a SC tiw treatment and remained low during Months 3–12. 3–6 months

• This analysis suggests that tolerability issues with IFN β-1a SC tiw are greatest during the first 3 months of treatment, and that patients who continue treatment after this early time period may experience considerably fewer tolerability issues. 3–6 months

Objective

• To evaluate tolerability data by timing and severity of AEs during the first year of PRISMS in order to further characterize the safety profile of IFN β-1a SC tiw. 6–12 months

Results

• More patients treated with IFN β-1a SC tiw than with placebo experienced injection-site erythema, unspecified ISRs, and injection-site pain during the first year of PRISMS (Table 1). 6–12 months

• Over the cumulative 0–12-month period, treatment discontinuation due to tolerability-associated AEs was rare, exceeding 1% only for unspecified ISRs in the (n=184) IFN β-1a 44 μg SC tiw group (52.9%, n=98). 6–12 months

• The majority of these AEs were mild, with severe AEs occurring rarely during the first 12 months of treatment. 6–12 months

• No serious AEs, FLS, unspecified ISRs, injection-site pain, or injection-site erythema AEs were reported in any group. 6–12 months

Conclusions

• AEs likely to affect the tolerability of IFN β-1a SC tiw, including injection-site erythema, unspecified ISRs, injection-site pain, and FLS, occurred more frequently in patients treated with IFN β-1a SC tiw than in patients treated with placebo. 6–12 months

• The majority of these AEs were mild, with severe AEs occurring rarely during the first 12 months of treatment. 6–12 months

• Ve very few patients discontinued IFN β-1a SC tiw due to injection-site erythema, unspecified ISRs, injection-site pain, or FLS. 6–12 months

• This percentage of patients experiencing injection-site erythema, unspecified ISRs, injection-site pain, or FLS decreased considerably after 3 months of IFN β-1a SC tiw treatment and remained low during Months 3–12. 6–12 months

• This analysis suggests that tolerability issues with IFN β-1a SC tiw are greatest during the first 3 months of treatment, and that patients who continue treatment after this early time period may experience considerably fewer tolerability issues. 6–12 months

References

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Disclosures

• The incidence of FLS was greatest during the first 3 months of treatment and decreased during the subsequent 3 months of IFN β-1a SC tiw treatment (Figure 2D).

• In the IFN β-1a 44 μg SC tiw group, 9.7% and 3.2% of patients experienced FLS during Months 3–6 and 6–12 of the PRISMS study, respectively, compared with 23.9% during Months 0–3. Similarly, 4.6% and 7.9% of patients in the IFN β-1a 22 μg SC tiw group experienced FLS during Months 3–6 and 6–12, respectively, versus 23.8% during Months 0–3 (Figure 2B).

• The incidence of moderate or severe FLS in the IFN β-1a 44 and 22 μg SC tiw groups remained low (<3.2%) during Months 3–6 and 6–12, and was comparable with that in the placebo group (Figure 2A–C).