File 157

Memo

To: Ms. Kimberly Topper

From: Eric J. Schenkel, MD

Subject: Oral Presentation at the Wed, April 26th FDA Meeting

Date: April 17, 2000

Dear Ms. Topper,

I would like to be placed on the list of oral presenters for the meeting at the FDA on the afternoon of Wednesday April 26, 2000. I am a clinical investigator who has been intimately involved with growth issues in children taking nasal corticosteroids (see reference below). My presentation, which should last ten minutes, addresses concerns about growth effects of nasal steroids in children, and differences among the different steroid preparations.

I am the Director of Valley Clinical Research Center in Easton, Pennsylvania, and can be reached via phone at (610)252-7388, via fax at (610)253-7058 and/or e-mail at Eschenkelm@aol.com

Thank you for considering me for an oral presentation.

Sincerely,

Eric J. Schenkel, MD
Director

Ref.-

Schenkel, E., Skoner, D., Bronsky, E., Miller, D., Pearlman, D., Rooklin, A., Rosen, J., Ruff, M., Vandewalker, M., Wanderer, A., Damaraju, C., Nolop, K., Mesarina-Wicki, B., Absence of Growth Retardation in Children With Perennial Allergic Rhinitis After One Year of Treatment With Mometasone Furoate Aqueous Nasal Spay. Pediatrics(electronic), Vol. 105 No.2p.e22, 2000

Overview - Nasal Steroids & Childhood Growth

- Joint PADAC/MEDAC meeting, July 30-31, 1998, to review proposed class labeling for oral and intranasal corticosteroids regarding growth suppression
- FDA announced new pediatric labeling, November 9, 1998

Skoner DP, Rachelefsky GS, Meltzer EO, et al. Detection of growth suppression in children during treatment with Joint PADAC/MEDAC meeting, July 30-31 1998intranasal beclomethasone dipropionate. *Pediatrics* [serial

Results of the Literature Review (All Studies)

- Intranasal corticosteroids:
  - 2 "well designed" studies were reviewed, 1 of which showed a growth-suppressive effect
- Oral inhaled corticosteroids:
  - 5 "well designed" studies were reviewed, 4 showed a growth suppressive effect

Intranasal Beclomethasone (BDP)

Study Design

- 12-month, double-blind, placebo-controlled
- 100 prepubescent children aged 6 to 9.5 years with allergic rhinitis
- Children randomized to receive one of two treatments:
  - Beclomethasone dipropionate (168 mcg bid; n=51)
  - Placebo bid (n=49)

Skoner DP, Rachelefsky GS, Meltzer EO, et al. Detection of growth suppression in children during treatment with intranasal beclomethasone dipropionate. *Pediatrics* [serial online]. February 1, 2000.

Intranasal Beclomethasone (BDP)

- Results (Mean Change in Standing Height)
  - BDP: 5.0 cm/yr
  - Placebo: 5.9 cm/yr
  - Delta: 0.9 cm/yr ($P<0.01$)
- After 12 months, mean overall rate of growth was 0.014 cm/day for BDP vs 0.016 cm/day for placebo ($P<0.01$)

Skoner DP, Rachelefsky GS, Meltzer EO, et al. Detection of growth suppression in children during treatment with intranasal beclomethasone dipropionate. *Pediatrics* [serial online]. February 1, 2000.

Intranasal Beclomethasone (BDP)

Conclusion

- A small but statistically significant effect of beclomethasone dipropionate on growth was observed

Skoner DP, Rachelefsky GS, Meltzer EO, et al. Detection of growth suppression in children during treatment with intranasal beclomethasone dipropionate. *Pediatrics* [serial online]. February 1, 2000.

One-Year, Double-Blind Study of the Effects of Mometasone Furoate Nasal Spray Versus Placebo on Growth of Children With Perennial Rhinitis

Objective

- To evaluate whether MFNS has an effect in 98 children with perennial allergic rhinitis aged 3 to 9 years on (1) growth or (2) HPA-axis function

Schenkel EJ, Skoner DP, Bronsky EA, et al. Absence of growth retardation in children with perennial allergic rhinitis after one year of treatment with mometasone furoate aqueous nasal spray. *Pediatrics* [serial online]. February 1, 2000.

One-Year, Double-Blind Study of the Effects of Mometasone Furoate Nasal Spray Versus Placebo on Growth of Children With Perennial Rhinitis

Study Design

- 1 year, randomized, placebo-controlled, double-blind, multicenter
- 98 children aged 3-9 years
- Positive skin test within previous year to one or more clinically significant perennial allergens
- Children randomly assigned to receive the following:
  - MFNS 100 mcg qd (n=49) or Placebo qd (n=49)
- Standing height assessed with stadiometer

Schenkel EJ, Skoner DP, Bronsky EA, et al. Absence of growth retardation in children with perennial allergic rhinitis after one year of treatment with mometasone furoate aqueous nasal spray. *Pediatrics* [serial online]. February 1, 2000.

One-Year, Double-Blind Study of the Effects of Mometasone Furoate Nasal Spray Versus Placebo on Growth of Children With Perennial Rhinitis

Study Conclusions

- One year treatment with MFNS 100 mcg daily did not suppress growth in young children (aged 3 to 9 years)
- One year treatment with MFNS 100 mcg daily was well tolerated by young children
- One year treatment with MFNS 100 mcg daily did not alter HPA-axis function (n=17)

Schenkel EJ, Skoner DP, Bronsky EA, et al. Absence of growth retardation in children with perennial allergic rhinitis after one year of treatment with mometasone furoate aqueous nasal spray. *Pediatrics* [serial online]. February 1, 2000.