FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Dermatologic and Ophthalmic Drugs Advisory Committee Meeting

HILTON, SILVER SPRING MD
JUNE 18, 2008
QUESTIONS

This application proposes the first biologic product for the treatment of pediatric plaque psoriasis.

Please discuss the adequacy of the assessments of efficacy for the pediatric population:

1. Has the applicant provided sufficient information to demonstrate efficacy of etanercept in the pediatric population?

2. Has the applicant provided sufficient information concerning the maintenance of treatment effect with this therapy?

3. Has the applicant provided sufficient information regarding stopping/withdrawal of treatment with this therapy?

4. Are there additional informational needs? If so, what are they?

Please discuss the adequacy of the assessment of safety for this target population:

5. Has the applicant provided sufficient information regarding the risk of infection in the target pediatric population?

6. Has the applicant provided sufficient information regarding the risk of malignancy in the target pediatric population?

7. The applicant has agreed to conduct post-marketing safety study 20040210. This long term study is intended to provide safety information regarding the use of etanercept in adult patients. Does the committee recommend approval of etanercept in pediatric patients prior to the completion of this safety study?

Please discuss the relative benefits and risks for the use of etanercept in pediatric patients:

8. Do the benefits of etanercept therapy in the treatment of children with moderate to severe plaque psoriasis outweigh the risks?

9. Should etanercept be approved for the treatment of moderate to severe plaque psoriasis in children?

    a. If the answer is no, what informational needs should be addressed prior to approval?

    b. If the answer is yes:

        - In what age groups should etanercept be approved for use?

        - Are there informational needs that should be addressed prior or following approval?

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Dermatologic and Ophthalmic Drugs Advisory Committee Meeting

HILTON, SILVER SPRING MD
JUNE 18, 2008
QUESTIONS

10. Is labeling, by itself, an adequate vehicle to educate physicians and patients concerning the benefits and risk of initiating and continuing treatment with etanercept in pediatric patients?

    a. If the answer is no, please provide a discussion of other mechanisms

Please discuss in general, the following aspects of pediatric studies of psoriasis with systemic therapies:

11. Is there a degree and severity of psoriasis that should be set as a minimum for study enrollment?

12. Discuss the optimal study design (sample size, length of study, evaluation of treatment effect) in order to provide a sufficient safety database pre-approval?

13. In general, should post-marketing commitments and post-marketing requests for adult safety studies be completed prior to approval of products intended to treat pediatric patients?