

Exubera® Advisory Committee Draft Questions

1. Has the efficacy of Exubera® been adequately assessed in patients with Type 1 diabetes? Specifically, is there sufficient clinical trial evidence that Exubera® can be effectively applied to an “intensive” glycemic control regimen?
2. Has the efficacy of Exubera® been adequately assessed in patients with Type 2 diabetes, in regimens of :
 - a. short-acting insulin alone
 - b. basal-bolus insulin
 - c. combinations of short-acting insulin with oral hypoglycemic agents?
3. Has the safety of Exubera® regarding hypoglycemia been adequately assessed
 - a. In Type 1 diabetes in “intensive” control regimens?
 - b. In Type 2 diabetes
4. Have the effects of respiratory infection, asthma, and smoking on the kinetics of Exubera® inhaled insulin been adequately assessed? Please comment on recommendations about the use of Exubera® in these settings.
5. Are there sufficient data to assess the pulmonary safety of Exubera® in patients without underlying lung disease?
 - a. If yes, do the data suggest an acceptable pulmonary safety profile in patients without underlying lung disease?
 - b. If no, what additional information is needed?
6. Are there sufficient data to assess the pulmonary safety of Exubera® in patients with underlying lung disease?
 - a. If yes, do the data suggest an acceptable pulmonary safety profile in patients with underlying lung disease?
 - b. If no, what additional information is needed?
7. Should Exubera® be approved for the proposed indications?
 - a. Type 1 diabetes
 - b. Type 2 diabetes as monotherapy, in combination with basal insulin, in combination with oral agents
8. What, if any, recommendations does the committee have for additional investigations of Exubera®?