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

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
May 24, 2016

QUESTIONS

---

1. **DISCUSSION:** Discuss the benefit(s) of starting the fixed-combination drug product containing liraglutide and insulin degludec in patients with type 2 diabetes mellitus not treated with either a basal insulin or a GLP-1 agonist (i.e., starting two new drugs at once). In your discussion, identify the patient population in whom this use would be useful and address why you would select the fixed-combination product over use of an available GLP-1 agonist or basal insulin in these patients. Explain your rationale using data from the briefing materials and presentations, or from your own clinical experience.

2. **DISCUSSION:** Discuss the benefit(s) of using the combination product containing liraglutide and degludec in patients with type 2 diabetes previously treated with either a basal insulin or a GLP-1 agonist (i.e., adding a single new drug to an existing regimen). In your answer, identify the patient population in whom use of the combination product in this manner would be useful. Explain your rationale using data from the briefing materials and presentations, or from your own clinical experience.

3. **DISCUSSION:** Discuss clinical concerns related to the use of the fixed-combination product which combines a drug that, when used alone, has a wide effective dose range and is titrated to effect on a continuous scale (i.e., insulin degludec) with a drug that, when used alone, has one or two recommended effective dose(s) (i.e., liraglutide).

   Specifically discuss:

   a. Issues related to loss of dosing flexibility including but not limited to: Use of potentially ineffective doses of one agent in populations with low insulin requirements, inability to dose the two drugs independently with the device presentation proposed, inability to increase the insulin dose beyond 50 units.

   b. Issues related specifically to product presentation/device including but not limited to: use errors that may occur in the care setting related to a lack of clarity on the amount of each product delivered with each given dose, insufficient understanding that, unlike insulin products, the maximum dose for the combination is capped.

4. **VOTE:** Based on data in the briefing materials and presentations at today's meeting, do you recommend approval of the liraglutide/degludec fixed-combination drug, delivered using the proposed device, for the treatment of adult patients with type-2 diabetes mellitus?

   a. If you voted yes, explain your rationale and discuss whether use of the combination should be approved for patients who have never been treated with a basal insulin product or a GLP-1 product, for patients who are inadequately controlled on either a basal insulin product or a GLP-1 product or for both populations. Recommend additional post-approval studies if you think these are needed.

   b. If you voted no, explain your rationale and recommend additional pre-approval studies if you think these are needed.