FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
Endocrinologic and Metabolic Drugs Advisory Committee Meeting
The Inn and Conference Center, University of Maryland University College
3501 University Boulevard East, Adelphi, MD
May 27, 2010

Questions to the Advisory Committee

1) Please comment on the findings of glucose intolerance and development of diabetes associated with Egrifta (tesamorelin) therapy and its impact on long-term cardiovascular risk.

2) Please comment on the increase in IGF-1 levels associated with Egrifta (tesamorelin) therapy and concerns associated with chronic use of Egrifta (tesamorelin) with respect to long-term cancer and cardiovascular risk.

3) Please comment on the clinical relevance of Visceral Adipose Tissue (VAT) reduction with Egrifta (tesamorelin) in the HIV population with respect to cardiovascular risk reduction.

4) Please comment on the clinical relevance of Visceral Adipose Tissue (VAT) reduction with Egrifta (tesamorelin) in the HIV population with respect to patient-perceived benefits

5) Please comment on the clinical relevance of Visceral Adipose Tissue (VAT) reduction with Egrifta (tesamorelin) in the HIV population with respect to adherence to anti-retroviral therapies.

6) Does the overall risk-benefit assessment of a fixed-dose regimen of Egrifta (tesamorelin) 2 mg/day support its approval for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy?

Vote: Yes/No/Abstain

If voting yes:

- please discuss basis for this recommendation
- please discuss whether any recommendations should be made to duration of use, targeted population, and safety monitoring
- please discuss whether any additional studies, including cardiovascular outcomes trials, should be conducted post-approval

If voting no:

- please discuss basis for this recommendation
- please discuss what additional studies, including cardiovascular outcomes trials, would be necessary to address deficiency/deficiencies