

Testimony of the Endocrine Society
Submitted to the
Food and Drug Administration
Endocrinologic and Metabolic Drugs Advisory Committee

The Endocrine Society is the world's largest professional organization of endocrinologists, representing the interests of over 18,500 physicians and scientists engaged in the treatment and research of endocrine disorders, including diabetes and obesity. The Society appreciates the opportunity to provide testimony to the FDA as it considers treatment options, such as VICTOZA (liraglutide) to reduce cardiovascular events in people with diabetes and looks forward to working with the agency as it moves forward in its review of these therapies.

As members of the committee are aware, diabetes is a growing epidemic that affects more than 422 million individuals worldwide¹, 29 million² of whom reside in the United States. Diabetes contributes to the development of many complications, including cardiovascular disease, kidney failure, high blood pressure and cholesterol, retinopathy and neuropathy, which may lead to an increased risk of death if left untreated. For example, people with diabetes and cardiovascular disease are at an increased risk of death. At least 68 percent of people > 65 years of age with diabetes will die of heart disease³. Treatments that reduce or delay these complications experienced by people with diabetes are needed to improve quality of life and increase life expectancy.

¹ Worldwide trends in diabetes since 1980: a pooled analysis of 751 population-based studies with 4.4 million participants. *The Lancet*, Volume 387, Issue 10027, 1513 – 1530.

² National Diabetes Statistics Report, 2014. The Centers for Disease Control and Prevention. <http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf>

³ Seshasai et al. *N Engl J Med* 2011;364:829-41



Despite recent studies, the effect of most diabetes drugs on the development of cardiovascular complications is not known, nor is it clear if any existing treatment options will reduce cardiovascular events and death⁴. The FDA requires new diabetes drugs to demonstrate cardiovascular safety prior to approval, providing a greater understanding of the impact of diabetes drugs on cardiovascular morbidity and mortality. The LEADER outcomes trial found that the use of Victoza (liraglutide) demonstrated reductions in the risk of major cardiovascular events in patients with Type 2 Diabetes who were at high CV risk.⁵ While the Society does not endorse specific therapies or medications undergoing FDA approval, it is encouraged by emerging therapies that have been shown to safely and effectively treat diabetes and reduce life-threatening complications such as cardiovascular disease.

Recent advancements in science have proven effective in reducing co-morbidities associated with the disease and have the potential to reduce the economic burden of diabetes on the healthcare system. Because each person faces unique challenges in the management and severity of their diabetes, it is important that a variety of therapeutic options are available. The Society urges the FDA to give fair consideration of new options in combating this disease and to expedite the approval process for emerging therapies that, based on safety and efficacy data, have the potential to reduce complications and impact the progression of diabetes.

Thank you.

⁴ Zinman, B, et al. N Engl J Med 2015; 373:2117-2128

⁵ Marso, S, et al. N Engl J Med 2016; 375:311-322