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## Joint Statement of The Endocrine Society and American Thyroid Association

### FDA Guidance on the Use of Liraglutide for Type 2 Diabetes

The U.S. Food and Drug Administration (FDA) recently approved the once daily injectable drug liraglutide (Victoza) for use in the United States. The medication, used as an adjunct to diet and exercise, has been shown in drug trials to improve glycemic control and reduce HbA1c levels in patients with type 2 diabetes. Recently, the FDA has instituted a new program called the Safe Use Initiative. Through this initiative, the FDA routinely schedules briefings to educate medical societies so that they can in turn inform their members about new therapeutic approvals. The Endocrine Society (TES) and the American Thyroid Association (ATA) participated in one of these briefings related to liraglutide on February 18th.

Liraglutide was approved by the FDA in late January. Clinical trials indicate that the medication may be associated with pancreatitis, similar to other diabetes agents. In addition, animal studies show that the drug may increase the risk for medullary thyroid cancer. The risk for these tumors was statistically significant only in animals taking the drug at an eight times greater dose than a human would receive. It is currently unknown what risk these animal test findings may pose to humans because the type of cancer is rare, and no patients treated with the drug during the clinical trial developed medullary thyroid cancer.

Providers are instructed to use caution if the patient has a prior history of pancreatitis. The FDA does not recommend that patients be screened using serum calcitonin levels or thyroid ultrasound. In addition, the FDA has determined that liraglutide should not be used as an initial therapy for diabetes until more studies are complete. The FDA has not precluded that liraglutide may be used as monotherapy; rather, that other drug(s) should be tried first. The FDA is also mandating the development of a registry to track the incidence of medullary thyroid cancer over the next 15 years to help determine if any increase could be associated with the use of liraglutide. Liraglutide was not shown to have an increased risk for cardiovascular events in patients with low risk, though the drug (like all new drugs for treatment of hyperglycemia) will be subject to additional safety studies to show any cardiovascular safety issues in those with higher risk.

Additional information on liraglutide can be found on the FDA website at <http://www.fda.gov/newsevents/newsroom/PressAnnouncements/ucm198638.htm>.

If you have additional questions about the FDA briefing on liraglutide, please contact Holly Whelan, Associate Director of Health Policy at [hwhelan@endo-society.org](mailto:hwhelan@endo-society.org).