4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 14, 2015, from 7:30 a.m. to 5:15 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.

Contact Person: Philip Bautista, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, EMDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously

announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at http://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: During the morning session, the committee will discuss the results of the cardiovascular outcomes trial (CVOT), Saxagliptin Assessment of Vascular Outcomes Recorded in Patients with Diabetes Mellitus, for new drug application (NDA) 22350, Onglyza (saxagliptin) and NDA 200678, Kombiglyze XR (saxagliptin and metformin HCl extended-release) tablets manufactured/marketed by AstraZeneca AB.

During the afternoon session, the committee will discuss the results of the CVOT, Examination of Cardiovascular Outcomes with Alogliptin versus Standard of Care, for NDA 22271, Nesina (ALOGLIPTIN); NDA 022426, Oseni (ALOGLIPTIN and PIOGLITAZONE); and NDA 203414, Kazano (ALOGLIPTIN and METFORMIN) tablets marketed by Takeda Pharmaceutical U.S.A., Inc.

Saxagliptin and ALOGLIPTIN are dipeptidyl peptidase-4 inhibitors, both indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Both CVOTs were submitted in accordance with the 2008 FDA Draft Guidance, "Diabetes Mellitus--Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes," to demonstrate that a new antidiabetic therapy to treat type 2 diabetes is not associated with an unacceptable increase in cardiovascular risk.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior

to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 31, 2015. Oral presentations from the public will be scheduled between approximately 10:10 a.m. to 10:40 a.m., and 3:30 p.m. to 4 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 23, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 24, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Philip Bautista at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 26, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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