4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Rechanneling the Current Cardiac Risk Paradigm: Arrhythmia Risk Assessment During Drug Development Without the Thorough QT Study; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), the Cardiac Safety Research Consortium, and the International Life Sciences Institute's Health and Environmental Sciences Institute (HESI) will cosponsor a public workshop entitled "Rechanneling the Current Cardiac Risk Paradigm: Arrhythmia Risk Assessment During Drug Development Without the Thorough QT Study." The workshop will introduce for discussion a new nonclinical paradigm for assessing Torsade de Pointes (TdP) risk and explore the parameters for an appropriate, strong, nonclinical proarrthymia screening method as an alternative to clinical Thorough QT studies. The workshop, which will seek input from all attendees, is intended to provide a forum for stakeholders, including experts and opinion leaders from academia, industry, and regulatory agencies in the United States, the European Union, Canada, and Asian countries, to discuss what a new framework might look like, the benefits and limitations of the current guidelines, and the importance of a uniform assay schema.

Date and Time: The public workshop will be held on July 23, 2013, from 8 a.m. to 6 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993.

Contact Person: Devi Kozeli, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4183, Silver Spring, MD 20993, 301-796-1128, email: devi.kozeli@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

This workshop will introduce for discussion a new nonclinical paradigm for assessing TdP risk and explore the parameters for an appropriate, strong, nonclinical proarrthymia screening method as an alternative to clinical Thorough QT studies. The workshop, which will seek input from all attendees, is intended to provide a forum for stakeholders, including experts and opinion leaders from academia, industry, and regulatory agencies in the United States, the European Union, Canada, and Asian countries, to discuss what a new framework might look like, the benefits and limitations of the current guidelines, and the importance of a uniform assay schema.

A description of the planned activities for the workshop can be found at: http://www.hesiglobal.org/i4a/pages/index.cfm?pageID=3620 (FDA has verified this online address but is not responsible for subsequent changes to the Web site where it is located after this document publishes in the Federal Register.)

Registration and Accommodations: Registration for non-FDA attendees should be performed online at the following address: https://evm.auxserv.duke.edu/iebms/reg/reg_p1_form.aspx?oc=10&ct=DCRIHBD09&eventid=5

0715. (FDA has verified this online address but is not responsible for subsequent changes to the Web site where it is located after this document publishes in the Federal Register.)

Registration for FDA attendees is also online, at the following address: https://duke.qualtrics.com/SE/?SID=SV_bmv7T8GPm4IAPd3.

The registration deadline for paying attendees is July 15, 2013. With the exception of FDA employees and a limited number of speakers or organizers, registrants must pay a registration fee covering the cost of facilities, materials, and food. The registration fees for different categories of attendee are as follows:

Category	Cost
Commercial Entity or Industry, Not Members of HESI	$950
Commercial Entity or Industry, HESI Members	$600
Academia, Professional Society, or Nonprofit Organization	$250
Government (non-FDA)	$150

Seats are limited, and conference space will be filled in the order in which registrations are received. Attendees are responsible for their own accommodations.

If you need special accommodations due to a disability, please contact Devi Kozeli (see Contact Person) at least 7 days in advance.

Dated: June 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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