4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0726]

Antibody Mediated Rejection in Kidney Transplantation; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public workshop regarding new developments and scientific issues related to antibody mediated rejection (AMR) in kidney transplantation. This public workshop is intended to provide information for and gain perspective from individuals, industry, health care professionals, researchers, public health organizations, patients, patient care providers, and other interested persons on various aspects of clinical development of medical products for prophylaxis and/or treatment of AMR in kidney transplant recipients, including clinical trial design and endpoints. The input from this public workshop will also help in developing topics for future discussion.

DATES: The public workshop will be held on April 12, 2017, from 8 a.m. to 6 p.m. and April 13, 2017, from 8:30 a.m. to 1:30 p.m. Submit either electronic or written comments on this public workshop by April 27, 2017. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 27, 2017. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of April 27, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery

service acceptance receipt is on or before that date. See the SUPPLEMENTARY INFORMATION section for registration date and information. Workshop updates and the workshop agenda will be made available at: http://www.fda.gov/Drugs/NewsEvents/ucm532070 prior to the workshop.

ADDRESSES: The public workshop will be held at the Tommy Douglas Conference Center, 10000 New Hampshire Ave., Silver Spring, MD 20903. The conference center's phone number is 240-645-4000.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-0726 for "Antibody Mediated Rejection in Kidney Transplantation." Received comments, those filed in a timely manner (see DATES) will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Division of

Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lori Benner and/or Jessica Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6221, Silver Spring, MD 20993-0002, 301-796-1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public workshop regarding AMR in kidney transplantation. This public workshop will focus on scientific considerations in the clinical development of medical products for prophylaxis and/or treatment of AMR in kidney transplant recipients.

Among the primary goals of this workshop are the discussion of the role of immunosuppressive medication nonadherence in the development of de novo donor specific

antibody (DSA) formation and subsequent AMR, new developments in transplantation and their impact on patient management (such as pretransplant sensitization not manifested by DSA, donor/recipient human leukocyte antigen (HLA) epitope matching, routine posttransplant DSA monitoring), the natural course of the acute-chronic AMR continuum and its temporal association with cellular rejection and changes in glomerular filtration rate (GFR), unmet medical needs and the potential implications of these factors on the design of clinical trials for the prevention and management of AMR.

The Agency encourages individuals, industry, health care professionals, researchers, public health organizations, patients, patient care providers, and other interested persons to attend this public workshop.

II. Participating in the Public Workshop

Registration: Persons interested in attending this public workshop must register by April 6, 2017, midnight Eastern Time. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone to AntibodyMediatedRejectionWorkshop2017@fda.hhs.gov.

Registration is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m. on April 12, 2017, and 8 a.m. on April 13, 2017. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Jessica Barnes or Lori Benner (see FOR FURTHER INFORMATION CONTACT) no later than April 5, 2017.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments and requests to participate in the focused sessions. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. All requests to make oral presentations must be received by the close of registration on April 6, 2017. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by April 7, 2017. If selected for presentation, any presentation materials must be emailed to AntibodyMediatedRejectionWorkshop2017@fda.hhs.gov no later than April 10, 2017. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Division of Dockets Management (see ADDRESSES). A link to the transcript will also be available on the Internet at http://www.fda.gov/Drugs/NewsEvents/ucm532070.htm approximately 45 days after the workshop.

Dated: March 29, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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