4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-4996]

Advancing Drug Development for the Prevention of Spontaneous Preterm Birth; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled "Advancing Drug Development for the Prevention of Spontaneous Preterm Birth." The meeting will be convened by Duke University's Robert J. Margolis, MD, Center for Health Policy (Duke-Margolis) and supported by a cooperative agreement with FDA. The meeting is intended to gather industry, family, clinician, researcher, ethicist, professional society, and other stakeholder input on the impact of preterm birth on families and on society, as well as on the ethical, regulatory, and clinical trial considerations surrounding the drug development for the prevention of spontaneous preterm birth.

DATES: The public meeting will be held on January 23 and 24, 2024, from 1 p.m. to 4:30 p.m. Eastern Time each day. See the SUPPLEMENTARY INFORMATION section for registration information.

ADDRESSES: The public meeting will be held virtually via Zoom.

FOR FURTHER INFORMATION CONTACT: Luke Durocher, Duke-Margolis Center for Health Policy, margolisevents@duke.edu, 202-621-2800; or Christina Chang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-2078.

SUPPLEMENTARY INFORMATION:

I. Background Information

In the United States in 2021, 1 in every 10 infants was born prematurely (before 37 weeks of pregnancy). Infants born too early have higher rates of death and disability, resulting in a significant public health concern. The exact mechanisms and risk factors associated with spontaneous preterm birth are not fully understood, resulting in a dearth of interventions demonstrated to be effective and safe.

FDA endorses an informed and balanced approach to gathering data supporting the safe and effective use of drugs and biological products for the prevention of spontaneous preterm birth. Currently, there is a significant medical need for such therapies, as there are no FDA approved therapies for reducing the risk of neonatal morbidity/mortality resulting from spontaneous preterm birth. Input from this meeting will help provide guidance on the development of therapies for the prevention of spontaneous preterm birth.

II. Topics for Discussion at the Public Meeting

The meeting will allow participants (including clinicians, patients, family, researchers, ethicists, professional societies, and other stakeholders) to provide input on key topics, including:

- The current understanding of spontaneous preterm birth, including the epidemiology of the condition, etiologies, and pathophysiology
- Ethical and regulatory considerations and challenges associated with the development of therapeutics for the prevention of spontaneous preterm birth
- Impact of preterm birth on families and society
- Assessing efficacy and safety in clinical programs for therapeutics for spontaneous preterm birth prevention
- Dose-finding and clinical trial design considerations

For more information on the meeting topics and discussion questions, visit https://duke.is/g/gde6. Duke-Margolis will publish a discussion guide outlining background information and current thinking on the topic areas to this website approximately 2 weeks before

the meeting date. FDA will also post the agenda and other meeting materials to this website approximately 5 business days before the meeting.

The format of the public meeting will consist of a series of presentations, panel discussions, and open discussion.

III. Participating in the Public Meeting

Registration: To register for the virtual public meeting, please visit the following website: https://duke.is/g/gde6. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free. Persons interested in attending this virtual public meeting must register. Early registration is recommended. Registrants will receive confirmation once they have been accepted. If you need special accommodations due to a disability, please contact Luke Durocher, Duke-Margolis Center for Health Policy, at margolisevents@duke.edu or at 202-621-2800.

Streaming Webcast of the Public Meeting: This virtual public meeting will be webcast via Zoom and the archived video footage will be available at the event website. The link for registration is the same as above: https://duke.is/g/gde6. Registered webcast participants will be sent technical system requirements in advance of the event. It is recommended that you review these technical system requirements prior to joining the streaming webcast of the public meeting. Although FDA has verified the website addresses in this document, please note that websites are subject to change over time.

Transcripts: Please be advised that transcripts of the public meeting will not be available.

Dated: November 16, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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