

Final Summary Minutes of the Antimicrobial Drug Advisory Committee Meeting April 26, 2019

The Antimicrobial Drug Advisory Committee of the Food and Drug Administration, Center for Drug Evaluation and Research met on April 26, 2019, at the Tommy Douglas Conference Center 10000 New Hampshire Ave. Silver Spring, Maryland. Prior to the meeting, the members and temporary voting members were provided the briefing materials from the FDA and Industry. The meeting was called to order by Lindsey R. Baden, MD (Chairperson). The conflict of interest statement was read into the record by Lauren Tesh Hotaki, PharmD, BCPS (Designated Federal Officer). Approximately 75 people in attendance. There were two (2) Open Public Hearing speaker presentations.

A verbatim transcript will be available, in most instances, approximately ten to twelve weeks following the meeting date.

Agenda: The committee discussed the safety and effectiveness of bacitracin for intramuscular injection for the treatment of infants with pneumonia and empyema caused by staphylococci shown to be susceptible to the drug, which is the only approved indication for bacitracin for intramuscular injection. The committee also considered whether there are other uses for bacitracin for intramuscular injection that could be studied. FDA presented background information on the regulatory history of bacitracin for intramuscular injection and information on the current use of bacitracin for intramuscular injection.

Attendance:

Antimicrobial Drug Advisory Committee Members Present (Voting): Lindsey R. Baden, MD (Chairperson); CAPT Timothy H. Burgess, MD, MPH, FACP; Nina M. Clark, MD; Dean A. Follmann, PhD; Michael Green, MD, MPH; Barbara M. Gripshover, MD; Ighovwerha Ofotokun, MD, MSc; George K. Siberry, MD, MPH; Sankar Swaminathan, MD; Peter Joseph Weina, PhD, MD

Antimicrobial Drug Advisory Committee Members Not Present (Voting): Jennifer Le, PharmD, MAS; Joanna M. Schaenman, MD, PhD; Roblena E. Walker, PhD (Consumer Representative)

Antimicrobial Drug Advisory Committee Member Present (Non-Voting): Nicholas A. Kartsonis, MD (Industry Representative)

Temporary Members (Voting): Gregory Burger, PharmD, CPPS, FASHP, NREMT; Michael D. Caldwell, MD, PhD, FACS; Maureen A. Finnegan, MD; Susan L. Krug (Patient Representative); Steven B. Meisel, PharmD, CPPS; Joy McVey Hugick, BA (Acting Consumer Representative); Deborah Saine, MS, RPh, FASHP; Stephanie H. Stovall, MD

FDA Participants (Non-Voting): John Farley, MD, MPH; Sumathi Nambiar, MD, MPH; Thomas Smith, MD; Caroline J. Jjingo, MD, MPH; Katherine Schumann, MS

Designated Federal Officer (Non-Voting): Lauren Tesh Hotaki, PharmD, BCPS

Open Public Hearing Speakers: Varuna Srinivasan, MD MPH (National Center for Healthcare Research); Hua Wang, PhD (The Ohio State University)

The agenda was as follows:

Call to Order and Introduction of
Committee

Lindsey Baden, MD
Chairperson, AMDAC

Conflict of Interest Statement

Lauren Tesh Hotaki, PharmD, BCPS
Designated Federal Officer, AMDAC

FDA Opening Remarks

Thomas Smith, MD
Clinical Team Leader
Division of Anti-Infective Products (DAIP)
Office of Antimicrobial Products (OAP)
Office of New Drugs (OND), CDER, FDA

FDA PRESENTATION

Bacitracin for Intramuscular Injection
Labeled Indication and Current Uses

Caroline J. Jjingo, MD, MPH
Clinical Reviewer
DAIP, OAP, OND, CDER, FDA

Clarifying Questions

INDUSTRY PRESENTATION

Xellia Pharmaceuticals USA, LLC

Safety and Effectiveness of Bacitracin
for Intramuscular Injection

Tatjana Anic-Milic, MD
Director, Medical Affairs
Xellia Pharmaceuticals USA, LLC

Clarifying Questions

BREAK

OPEN PUBLIC HEARING

Questions to the Committee/Committee Discussion

ADJOURNMENT

Questions to the Committee:

1. **VOTE:** Do the benefits of bacitracin for intramuscular injection outweigh the risks for its approved indication of the treatment of infants with pneumonia and empyema caused by staphylococci shown to be susceptible to the drug?

- If yes, please provide any recommendations concerning labeling.
- If no, please provide your rationale.
- Please provide any additional comments or thoughts on your vote.

Vote Result: Yes: 0 No: 17 Abstain: 1

***Committee Discussion:** The majority of the committee agreed that the benefits of bacitracin for intramuscular injection do not outweigh the risks for its approved indication of the treatment of infants with pneumonia and empyema caused by staphylococci shown to be susceptible to the drug, citing such associated risks as nephrotoxicity and anaphylactic reactions. Of those who voted no, there was consensus on the lack of available data (new and old) to assess safety and efficacy of the drug for this indication. It was further noted that there is no evidence of current use for its labeled indication and a lack of susceptibility criteria (breakpoints) to guide clinicians. Many of those who voted no stated that there are multiple safe and effective alternatives to treat pneumonia and empyema caused by staphylococci in this patient population. Many members cited the lack of recommendations from professional medical and surgical societies supporting the use of bacitracin for intramuscular injection for either its labeled indication or for off-label uses. The single committee member who abstained from voting commented that it is difficult to assess the efficacy of bacitracin given the historical nature of the data and the lack of modern data assessing the activity of bacitracin. This member thought it would be useful to survey the Infectious Diseases community broadly to more fully understand if there are clinically important uses of bacitracin today given increasing antimicrobial resistance. This member thought great care is required before limiting options to treat antimicrobial resistant organisms given the limited antimicrobial drug development pipeline. Please see the transcript for details of the committee discussion.*

2. **DISCUSSION:** Are there uses for bacitracin for intramuscular injection other than for treatment of infants with pneumonia and empyema caused by staphylococci that could be studied?

***Committee Discussion:** The committee noted that there are potential uses for bacitracin for intramuscular injection other than for the treatment of infants with pneumonia and empyema caused by staphylococci that could be studied. These include irrigation for surgical procedures, irrigation of central lines to disrupt biofilms, and treatment of resistant *Neisseria gonorrhoeae* and other sexually transmitted infections such as syphilis. All of these potential uses require proper studies. Please see the transcript for details of the committee discussion.*

The meeting was adjourned at approximately 1:00 p.m.