CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

211192Orig1s000

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

IND 119341

MEETING MINUTES

Agios Pharmaceuticals, Inc.
Attention: Shane A. McGann, PharmD, RPh
Manager, Regulatory Affairs
88 Sidney Street
Cambridge, MA 02139

Dear Dr. McGann:

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for AG-120.

We also refer to the meeting between representatives of your firm and the FDA on May 25, 2016. The purpose of the meeting was to obtain guidance on the (b) (4)

A copy of the official minutes of the meeting is enclosed for your information. Please notify us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions, call Laura Wall, Regulatory Project Manager at (301) 796-2237.

Sincerely,

{See appended electronic signature page}

Donna Przepiorka, MD, PhD
Acting Clinical Team Leader
Division of Hematology Products
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

Enclosure:
Meeting Minutes

FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

MEMORANDUM OF MEETING MINUTES

Meeting Type:	Type B
Meeting Category:	Pre-Phase 3
Meeting Date and Time:	May 25, 2016 from 2:00 PM to 3:00 PM (ET)
Meeting Location:	White Oak Building 22, Conference Room: 1313
Application Number:	IND 119341
Product Name:	AG-120
Proposed Indication:	Treatment of patients with acute myelogenous leukemia (AML) harboring an isocitrate dehydrogenase-1 (IDH1) mutation: • As a single agent for the treatment of adult patients with relapsed or refractory (R/R) AML [redacted] (b) (4)
Sponsor/Applicant Name:	Agios Pharmaceuticals, Inc.
Meeting Chair:	Donna Przepiorka, MD, PhD, Acting Clinical Team Leader
Meeting Recorder:	Laura Wall, MS, Regulatory Project Manager

FDA ATTENDEES

Division of Hematology Products (DHP)
Ann Farrell, MD, Division Director
Albert Deisseroth, MD, PhD, Clinical Team Leader
Donna Przepiorka, MD, PhD, Acting Clinical Team Leader
Pat Dinndorf, MD, Clinical Reviewer
Ashley Ward, MD, Clinical Reviewer,
Laura Wall, MS, Regulatory Project Manager

Office of Clinical Pharmacology, Division of Pharmacometrics
Olanrewaju Okusanya, PharmD, MS, Clinical Pharmacology Reviewer

Office of Biostatistics, Division of Biometrics V
Lei Nie, PhD, Team Leader
Kallappa Koti, PhD, Statistical Reviewer

Division of Hematology Oncology Toxicology (DHOT)
Christopher Sheth, PhD, Supervisory Pharmacologist/Toxicologist
Matthew Thompson, PhD, MPH, Pharmacology/Toxicology Reviewer

Office of Translational Sciences
Sarah Dorff, PhD, Genomics Reviewer

SPONSOR ATTENDEES
Chris Bowden, MD, Agios, Chief Medical Officer
Sam Agresta, MD, MPH & TM, MS CI & TR, Agios, Vice-President, Clinical Development
Ann Cahill, PA, Agios, Senior Director, Clinical Development
Eyal Attar, MD, Agios, Medical Director, Clinical Development
Meredith Goldwasser, ScD, Agios, Senior Director, Head of Biometrics and Data Management
Hua Liu, PhD, Agios, Associate Director of Biostatistics
Jacqueline Cinicola, MS, Agios, Senior Director, Regulatory Affairs
Shane McGann, PharmD, RPh, Agios, Manager, Regulatory Affairs
Annie Estrella, MS, Agios, Director, Head of Medical Writing
Katharine Yen, PhD, Agios, Director, Clinical Science
Paul McInulty, Celgene, Executive Director, Global Regulatory Affairs
Krishnan Viswanadhan, PharmD, MBA, Celgene, Global Project Leadership, Alliance Partner
(b) (4)

1.0 BACKGROUND

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(b) (4)

3.0 OTHER IMPORTANT MEETING INFORMATION

PREA REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for this indication has an orphan drug designation, you are exempt from these requirements. Please include a statement that confirms this finding, along with a reference to this communication, as part of the pediatric section (1.9 for eCTD submissions) of your application. If there are any changes to your development plans that would cause your application to trigger PREA, your exempt status would change.

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