

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

214120Orig1s000

**ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS**



IND 074618

MEETING MINUTES

Celgene Corporation
Attention: Mary Vandekauter, M.S., RAC
Director, Regulatory Affairs
9225 Indian Creek Parkway, Suite 900
Overland Park, KS 66210

Dear Ms. Vandekauter:

Please refer to your investigational new drug application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for azacytidine.

We also refer to the meeting between representatives of your firm and the FDA on November 21, 2019. The purpose of the meeting was to discuss a proposed marketing application for oral azacitidine.

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

If you have any questions, call Rachel McMullen, Senior Regulatory Project Manager at (240) 402-4574.

Sincerely,

{See appended electronic signature page}

Donna Przepiorka, MD, PhD
Clinical Team Lead
Division of Hematologic Malignancies 1
Office of Oncologic Diseases
Center for Drug Evaluation and Research

Enclosure:

- Meeting Minutes

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov



MEMORANDUM OF MEETING MINUTES

Meeting Type: B
Meeting Category: Pre-NDA

Meeting Date and Time: November 21, 2019; 10:00 AM to 11:00 AM (ET)
Meeting Location: 10903 New Hampshire Avenue
White Oak Building 22, Conference Room: 1419
Silver Spring, Maryland 20903

Application Number: IND 074618
Product Name: Azacitidine
Indication: [REDACTED] (b) (4)

Sponsor Name: Celgene Corporation

Meeting Chair: Donna Przepiorka, MD, PhD
Meeting Recorder: Suria Yesmin, MS

FDA ATTENDEES

Division of Hematological Malignancies (DHM1)

R. Angelo de Claro, MD, Director (Acting)
Donna Przepiorka, MD, PhD, Clinical Team Leader
Emily Jen, MD, PhD Clinical Reviewer
Patricia Dinndorf, MD, Clinical Reviewer
Suria Yesmin, MS, Senior Regulatory Project Manager

Office of Biostatistics, Division of Biometrics V

Yute Wu, PhD, Acting Biometrics Team Leader
Qing Xu, PhD, Biometrics Reviewer

Office of Clinical Pharmacology

Olanrewaju Okusanya, Pharm D, Clinical Pharmacology Team Lead
Vicky Hsu, Pharm D, Clinical Pharmacology Reviewer

Office of Pharmaceutical Quality

Anamitro Banerjee, PhD, Branch Chief

SPONSOR ATTENDEES

Celgene Corporation

Jay Backstrom, MD, Chief Medical Officer
Paul McNulty, BS Vice President, Regulatory Affairs
Mary Vandekauter, MS, Director, Regulatory Affairs

Carrie Brownstein, MD, Vice President, Clinical R&D
Charles Beach, PharmD, Executive Medical Director, Clinical R&D
Ignazia La Torre, MD, Sr. Medical Director, Clinical R&D
Keshava Kumar, PhD, Principal Clinical Research Scientist, Clinical R&D
Qian Dong, PhD, Associate Director, Biostatistics
Nanxiang Ge, PhD, Executive Director, Biostatistics
Allison Gaudy, PhD, Sr. Scientist, Pharmacokinetics
Rochelle, Bailey, MD, Sr Director, Lead Global Safety Physician
Christine Stuhlmiller, MBA, Sr Director, Global Project Leader
Daniel Lopes de Menezes, PhD, Associate Director, Translational Development

1.0 BACKGROUND

CC-486, an oral formulation of azacitidine, is being developed by Celgene Corporation, the Sponsor, for treatment of AML (b) (4). The Sponsor is planning to submit an NDA for CC-486 in 1Q 2020 (b) (4).

(b) (4)
Advice on the content and format of the NDA was provided in Type C Written Responses issued on October 24, 2019.

On September 27, 2019, the Sponsor requested a Type B meeting to obtain FDA's feedback on the adequacy of the results of Study CC-486-AML-001 to support submission of an NDA.

FDA sent Preliminary Comments to Celgene on November 14, 2019.

2.0 DISCUSSION

Question 1: *Does the Agency agree that the efficacy results for the primary endpoint of OS in conjunction with the results of the key secondary endpoint of RFS demonstrate a statistically significant and meaningful clinical benefit of CC-486 in this patient population?*

FDA Response to Question 1: Your analysis demonstrates statistical significance according to the prespecified plan. Whether the efficacy results are clinically meaningful will be a review issue. We remind you that the data from CC-486-AML-001 should be supported by data from treatment trials of AML (see response to Question 4, Type C WRO dated 10/24/19).

DISCUSSION: The Agency agreed that the Sponsor's plan to include three Phase 1 studies along with AZA-AML-001 in the SCE is acceptable. The Agency clarified that the ISE dataset should therefore include all 5 trials. The Agency also reminded the Sponsor that the maximum page limit of the Clinical Summary text (Modules 2.7.1 through 2.7.4) in total is 400 pages.

Question 2: Does the Agency agree that the safety profile of CC-486 observed in the pivotal Phase 3 study, Study CC-486-AML-001 is supportive of an NDA for CC-486 ^(b)₍₄₎

- a) Does the Agency agree that the safety profile of CC-486 observed in the pivotal Phase 3 study, Study CC-486-AML-001 and consistent with the established safety profile for azacitidine is acceptable to enable filing of the proposed NDA?

FDA Response to Question 2a: The safety data from CC-486-AML-001 alone are not sufficient for submission of an NDA; the submission should include safety data from other trials in your development program. See responses to Questions 5-8 in the Type C WRO dated 10/24/19. Whether the totality of the safety data is sufficient for filing the proposed NDA will be a review issue.

DISCUSSION: There was no discussion.

- b) Despite relapse free survival being defined as the key secondary endpoint, per protocol, AML relapse and disease progression were reported as adverse events. Does the Agency agree with the Celgene proposal to present primary safety data for this study excluding AML relapse-associated events to allow for a more informative and clear interpretation of the safety profile of CC-486?

FDA Response to Question 2b: We have no objection to your plan to exclude AML relapse/disease progression preferred terms as adverse events for the review of safety. In your submission, please provide a list of the preferred terms excluded from the analysis.

DISCUSSION: There was no discussion.

- c) Does the Agency have any comments on the overall safety data package presented in this pre-NDA meeting package to support the review of the upcoming NDA?

FDA Response to Question 2c: See response to 2a.

DISCUSSION: There was no discussion.

Question 3: Does the Agency agree that the efficacy and safety data from Study CC-486-AML-001, a Phase 3, Double-blind, Randomized, Placebo-Controlled Study to Compare the Efficacy and Safety of Oral Azacitidine (CC-486) Versus Placebo as Maintenance Therapy in Subjects with Acute Myeloid Leukemia are adequate for filing and review of the NDA for the proposed indication?

FDA Response to Question 3: See responses to Questions 1 and 2.

DISCUSSION: There was no discussion.

Question 4: *Celgene has updated the statistical analysis plan for Study CC-486-AML-001 based on feedback from the Agency provided on 29 Mar 2019. The SAP was finalized on 25 Jul 2019 and submitted to IND 074618 on 31 Jul 2019 (SN0465) prior to database lock and unblinding. However, based on the information presented in this meeting package, does the Agency have any additional statistical comments?*

FDA Response to Question 4: Without reviewing the data from the pivotal study CC-486-AML-001, we are unable to provide comment on the reliability of the estimates from the current statistical analyses. Whether additional statistical analyses would be needed to confirm the robustness of the efficacy results will be a review issue.

DISCUSSION: There was no discussion.

Question 5:

- a) *Based on the efficacy and safety data presented, does the Agency foresee a potential need for an advisory committee for the proposed indication?*

FDA Response to Question 5a: Whether an advisory committee meeting will be needed will be a review issue.

DISCUSSION: There was no discussion.

- b) *Does the Agency foresee requesting an Applicant Orientation Meeting for CC-486?*

FDA Response to Question 5b: Yes.

DISCUSSION: There was no discussion.

Question 6: *Celgene does not plan to prepare a Risk Evaluation and Mitigation Strategy (REMS) for oral azacitidine. Based on the data presented, does the Agency foresee a potential need for a REMS for the proposed indication?*

FDA Response to Question 6: Whether a REMS will be needed will be a review issue.

DISCUSSION: There was no discussion.

Question 7: *Based on the efficacy and safety data presented, does the Agency support the Sponsor's intention to request a Priority Review for this application?*

FDA Response to Question 7: You may request Priority Review, but whether the application is suitable for Priority Review will be determined during the filing review.

DISCUSSION: There was no discussion.

Question 8: Does the Agency have any other comments or advice that may aid in the preparation and submission of the NDA?

FDA Response to Question 8: Yes, we have the following additional comments:

- a. Include an Analysis Data Reviewer's Guide (ADRG) and Study Data Reviewer's Guide (SDRG), an important part of a standards-compliant study and analysis data submission, be prepared and submitted for each data set in the NDA. Please refer to the "Study Data Technical Conformance Guide: Technical Specifications Document," available at: <https://www.fda.gov/media/131872/download>.
- b. Ensure that the define file and/or Reviewer's Guide for the Analysis Data Sets identify the coding dictionary and version for controlled terminology (e.g., MedDRA version, WHO Drug Dictionary version, etc.).
- c. Provide sufficient comments, adequate bookmarks, and hyperlinks in the define file(s) to ensure efficient review.
- d. Submit SAS programs for Study CC-486-AML-001 and ISE. The Sponsors should provide the SAS programs (with adequate comments) used to create all ADaM datasets along with the tables and figures associated with primary and secondary efficacy analyses in order to help reviewers to better understand how the datasets, tables and figures were created. The main purpose of requesting the submission of these programs is to understand the process by which the variables for the respective analyses were created and to confirm the analysis algorithms.

DISCUSSION: The Agency agreed to the Sponsor's proposal to submit the efficacy SAS programs only for the pivotal trial.

- e. Provide documentation of any correspondence (written documents or meeting minutes) with FDA regarding pivotal study of CC-486-AML-001.
- f. Provide the information on the important dates during the development (i.e., database lock date, interim analyses or interim locked dates for the DMC, SAP sign-off dates, protocol sign-off dates, etc).
- g. To assist with the adjudication of efficacy, ensure that all granular results of marrow and peripheral blood testing are included an xpt data file. Please also include in xpt data file(s) with listings of a flag for relapse, date of relapse, flag for HSCT after study enrollment, date of HSCT after study enrollment, date of at least the 1st

poststudy therapy, identity of regimen name or drug(s) used for at least the 1st poststudy therapy, date of last CBC showing continuing remission, and date last known alive.

- h. Regarding the MRD assay used for CC-486-AML-001, please include the following in your submission:
- i. Justification that MRD cutpoint as used is clinically valid for the context of the use.
 - ii. An xpt data file with results of MRD testing. For each result, specify the sample type, date of sample, assay used, input quantity, assay sensitivity, and assay result.
 - iii. The following technical information about the assay:
 - A statement of intended use;
 - The specific test method (including instruments, reagents, and specimen handling);
 - Confirmation that the lab has a process in place for reagent control;
 - A brief discussion of how the test method was validated analytically for each specimen type; and
 - A summary of the performance obtained for accuracy, precision, specificity, and sensitivity

DISCUSSION: The Sponsor noted that they intend to submit the requested information regarding MRD. They stated that additional information on the durability of MRD response may be available after the time of submission. The Agency agreed that it would be useful to receive updated MRD data when available.

- i. To assist with the adjudication of causality of fatal adverse events, the submission should include an xpt data file with the date of death, study day of death, proximate cause of death (usually as reported by the investigator) and the root cause of death as determined by the sponsor for patients in the ISS. The root cause is generally categorized as a) direct effect of active AML, b) an adverse drug reaction or c) an unrelated intercurrent event (such as car accident).

DISCUSSION: The Sponsor proposed to submit cause of death only for patients in the maintenance pool. The Agency indicated that the data for adjudication of on-treatment deaths should include for all subjects in the ISS.

- j. In the ISS, please include an analysis to determine the incidence of prolonged thrombocytopenia (platelets < 50 Gi/L) or neutropenia (ANC < 0.5 Gi/L) past cycle day 42 of therapy in the absence of active leukemia.

DISCUSSION: The Agency agreed that these analyses could be included for the AML maintenance pool only. The Agency will leave a postmeeting note regarding the proposed approach to these analyses.

Postmeeting Note:

Algorithm steps 1 and 2 are reasonable. In step 3, prolonged thrombocytopenia or neutropenia need not be defined from Day 28 onwards. The analysis should determine the incidence of each cytopenia lasting past Cycle Day 42 regardless of start date of the cytopenia.

- k. In your submission, please also address the standard clinical pharmacology pre-NDA comments and other requests/advice sent in the WRO on 10/24/19.

ADDITIONAL CMC DISCUSISON:

The proposed plan as conveyed by the email dated November 19, 2019, appears reasonable. The Sponsor should point out any updates or amendments to the cross-reference information.

3.0 OTHER IMPORTANT MEETING INFORMATION

DISCUSSION OF THE CONTENT OF A COMPLETE APPLICATION

- The content of a complete application was discussed.

The contents were discussed. The Agency and Sponsor reached agreement on the content of a complete application.

- All applications are expected to include a comprehensive and readily located list of all clinical sites and manufacturing facilities included or referenced in the application.
- A preliminary discussion was held on the need for a REMS, other risk management actions and, where applicable, the development of a Formal Communication Plan

The Agency indicated that at the present time they were unaware of any safety issues that would require a REMS or special risk management action. The final determination will be a review issue.

- Major components of the application are expected to be submitted with the original application and are not subject to agreement for late submission. You stated you intend to submit a complete application and therefore, there are no agreements for late submission of application components.

In addition, we note the chemistry pre-submission meeting on October 17, 2018, and refer you to the minutes of that meeting for any additional agreements that may have been reached.

PREA REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (codified at section 505B of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 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 or deferred (see section 505B(a)(1)(A) of the FD&C Act). Applications for drugs or biological products for which orphan designation has been granted that otherwise would be subject to the requirements of section 505B(a)(1)(A) are exempt pursuant to section 505B(k)(1) from the PREA requirement to conduct pediatric assessments.

Title V of the FDA Reauthorization Act of 2017 (FDARA) amended the statute to create section 505B(a)(1)(B), which requires that any original marketing application for certain adult oncology drugs (i.e., those intended for treatment of an adult cancer and with molecular targets that FDA has determined to be substantially relevant to the growth or progression of a pediatric cancer) that are submitted on or after August 18, 2020, contain reports of molecularly targeted pediatric cancer investigations. See link to list of relevant molecular targets below. These molecularly targeted pediatric cancer investigations must be “designed to yield clinically meaningful pediatric study data, gathered using appropriate formulations for each age group for which the study is required, regarding dosing, safety, and preliminary efficacy to inform potential pediatric labeling” (section 505B(a)(3)). Applications for drugs or biological products for which orphan designation has been granted and which are subject to the requirements of section 505B(a)(1)(B), however, will not be exempt from PREA (see section 505B(k)(2)) and will be required to include plans to conduct the molecularly targeted pediatric investigations as required, unless such investigations are waived or deferred.

Under section 505B(e)(2)(A)(i) of the FD&C Act, you must submit an Initial Pediatric Study Plan (iPSP) within 60 days of an End of Phase 2 (EOP2) meeting, or such other time as agreed upon with FDA. (In the absence of an EOP2 meeting, refer to the draft guidance below.) The iPSP must contain an outline of the pediatric assessment(s) or molecularly targeted pediatric cancer investigation(s) that you plan to conduct (including, to the extent practicable study objectives and design, age groups, relevant endpoints, and statistical approach); any request for a deferral, partial waiver, or waiver, if applicable, along with any supporting documentation; and any previously negotiated pediatric plans with other regulatory authorities. The iPSP should be submitted in PDF and Word format. Failure to include an Agreed iPSP with a marketing application could result in a refuse to file action.

For additional guidance on the timing, content, and submission of the iPSP, including an iPSP Template, please refer to the draft guidance for industry *Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans*.

For the latest version of the molecular target list, please refer to FDA.gov.¹

FDARA REQUIREMENTS

Sponsors planning to submit original applications on or after August 18, 2020 or sponsors who are uncertain of their submission date may request a meeting with the Oncology Center of Excellence Pediatric Oncology Program to discuss preparation of the sponsor's initial pediatric study plan (iPSP) for a drug/biologic that is intended to treat a serious or life-threatening disease/ condition which includes addressing the amendments to PREA (Sec. 505B of the FD & C Act) for early evaluation in the pediatric population of new drugs directed at a target that the FDA deems substantively relevant to the growth or progression of one or more types of cancer in children. The purpose of these meetings will be to discuss the Agency's current thinking about the relevance of a specific target and the specific expectations for early assessment in the pediatric population unless substantive justification for a waiver or deferral can be provided. Meetings requests should be sent to the appropriate review division with the cover letter clearly stating "**MEETING REQUEST FOR PREPARATION OF iPSP MEETING UNDER FDARA.**" These meetings will be scheduled within 30 days of meeting request receipt. The Agency strongly advises the complete meeting package be submitted at the same time as the meeting request. Sponsors should consult FDA's Guidance on Formal Meetings Between the FDA and Sponsors or Applicants² to ensure open lines of dialogue before and during their drug development process.

In addition, you may contact the OCE Subcommittee of PeRC Regulatory Project Manager by email at OCEPERC@fda.hhs.gov. For further guidance on pediatric product development, please refer to FDA.gov.³

PRESCRIBING INFORMATION

In your application, you must submit proposed prescribing information (PI) that conforms to the content and format regulations found at 21 CFR 201.56(a) and (d) and 201.57 including the Pregnancy and Lactation Labeling Rule (PLLR) (for applications submitted on or after June 30, 2015). As you develop your proposed PI, we encourage you to review the labeling review resources on the PLR Requirements for Prescribing

¹ <https://www.fda.gov/about-fda/oncology-center-excellence/pediatric-oncology>

² See the guidance for industry "*Formal Meetings Between the FDA and Sponsors or Applicants.*"

³ <https://www.fda.gov/drugs/development-resources/pediatric-and-maternal-health-product-development>

Information⁴ and Pregnancy and Lactation Labeling Final Rule⁵ websites, which include:

- The Final Rule (Physician Labeling Rule) on the content and format of the PI for human drug and biological products.
- The Final Rule (Pregnancy and Lactation Labeling Rule) on the content and format of information related to pregnancy, lactation, and females and males of reproductive potential.
- Regulations and related guidance documents.
- A sample tool illustrating the format for Highlights and Contents, and
- The Selected Requirements for Prescribing Information (SRPI) – a checklist of important format items from labeling regulations and guidances.
- FDA's established pharmacologic class (EPC) text phrases for inclusion in the Highlights Indications and Usage heading.

Pursuant to the PLLR, you should include the following information with your application to support the changes in the Pregnancy, Lactation, and Females and Males of Reproductive Potential subsections of labeling. The application should include a review and summary of the available published literature regarding the drug's use in pregnant and lactating women and the effects of the drug on male and female fertility (include search parameters and a copy of each reference publication), a cumulative review and summary of relevant cases reported in your pharmacovigilance database (from the time of product development to present), a summary of drug utilization rates amongst females of reproductive potential (e.g., aged 15 to 44 years) calculated cumulatively since initial approval, and an interim report of an ongoing pregnancy registry or a final report on a closed pregnancy registry. If you believe the information is not applicable, provide justification. Otherwise, this information should be located in Module 1. Refer to the draft guidance for industry *Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products – Content and Format*.

Prior to submission of your proposed PI, use the SRPI checklist to ensure conformance with the format items in regulations and guidances.

After initiation of all trials planned for the phase 3 program, you should consider requesting a Type C meeting to gain agreement on the safety analysis strategy for the

⁴ <https://www.fda.gov/drugs/laws-acts-and-rules/plr-requirements-prescribing-information>

⁵ <https://www.fda.gov/drugs/labeling/pregnancy-and-lactation-labeling-drugs-final-rule>

Integrated Summary of Safety (ISS) and related data requirements. Topics of discussion at this meeting would include pooling strategy (i.e., specific studies to be pooled and analytic methodology intended to manage between-study design differences, if applicable), specific queries including use of specific standardized MedDRA queries (SMQs), and other important analyses intended to support safety. The meeting should be held after you have drafted an analytic plan for the ISS, and prior to programming work for pooled or other safety analyses planned for inclusion in the ISS. This meeting, if held, would precede the Pre-NDA meeting. Note that this meeting is optional; the issues can instead be addressed at the pre-NDA meeting.

To optimize the output of this meeting, submit the following documents for review as part of the briefing package:

- Description of all trials to be included in the ISS. Please provide a tabular listing of clinical trials including appropriate details.
- ISS statistical analysis plan, including proposed pooling strategy, rationale for inclusion or exclusion of trials from the pooled population(s), and planned analytic strategies to manage differences in trial designs (e.g., in length, randomization ratio imbalances, study populations, etc.).
- For a phase 3 program that includes trial(s) with multiple periods (e.g., double-blind randomized period, long-term extension period, etc.), submit planned criteria for analyses across the program for determination of start / end of trial period (i.e., method of assignment of study events to a specific study period).
- Prioritized list of previously observed and anticipated safety issues to be evaluated, and planned analytic strategy including any SMQs, modifications to specific SMQs, or sponsor-created groupings of Preferred Terms. A rationale supporting any proposed modifications to an SMQ or sponsor-created groupings should be provided.

When requesting this meeting, clearly mark your submission “**DISCUSS SAFETY ANALYSIS STRATEGY FOR THE ISS**” in large font, bolded type at the beginning of the cover letter for the Type C meeting request.

SUBMISSION FORMAT REQUIREMENTS

The Electronic Common Technical Document (eCTD) is CDER and CBER’s standard format for electronic regulatory submissions. The following submission types: **NDA, ANDA, BLA, Master File** (except Type III) and **Commercial INDs** must be submitted in eCTD format. Submissions that do not adhere to the requirements stated in the eCTD

Guidance will be subject to rejection. For more information please visit FDA.gov.⁶

The FDA Electronic Submissions Gateway (ESG) is the central transmission point for sending information electronically to the FDA and enables the secure submission of regulatory information for review. Submissions less than 10 GB must be submitted via the ESG. For submissions that are greater than 10 GB, refer to the FDA technical specification *Specification for Transmitting Electronic Submissions using eCTD Specifications*. For additional information, see FDA.gov.⁷

OFFICE OF SCIENTIFIC INVESTIGATIONS (OSI) REQUESTS

The Office of Scientific Investigations (OSI) requests that the items described in the draft guidance for industry *Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions* (February 2018) and the associated *Bioresearch Monitoring Technical Conformance Guide Containing Technical Specifications* be provided to facilitate development of clinical investigator and sponsor/monitor/CRO inspection assignments, and the background packages that are sent with those assignments to the FDA ORA investigators who conduct those inspections. This information is requested for all major trials used to support safety and efficacy in the application (i.e., phase 2/3 pivotal trials). Please note that if the requested items are provided elsewhere in submission in the format described, the Applicant can describe location or provide a link to the requested information.

Please refer to the draft guidance for industry *Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions* (February 2018) and the associated *Bioresearch Monitoring Technical Conformance Guide Containing Technical Specifications*.⁸

4.0 ISSUES REQUIRING FURTHER DISCUSSION

There were no issues requiring further discussion.

5.0 ACTION ITEMS

NA

6.0 ATTACHMENTS AND HANDOUTS

A copy of the Sponsor's responses is attached for reference.

⁶ <http://www.fda.gov/ectd>

⁷ <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway>

⁸ <https://www.fda.gov/media/85061/download>

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DONNA PRZEPIORKA
11/25/2019 11:35:35 AM



FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

MEMORANDUM OF MEETING MINUTES (Sponsor)

Meeting Type: Type B
Meeting Category: End of Phase 1/2
Meeting Date and Time: September 6, 2011; 1:00PM, EST
Meeting Location: Bldg. #22, Room 1415

Application Number: 074618
Product Name: Oral Azacitidine
Indication: [REDACTED] (b) (4)

Sponsor/Applicant Name: Celgene
Meeting Request Date: June 23, 2011
Meeting BGP date: August 9, 2011

Meeting Chair: Edvardas Kaminskas, M.D.
Meeting Recorder: Kim J. Robertson

FDA ATTENDEES:

Edvardas Kaminskas, M.D., Acting Deputy Director DHP
Albert Deisseroth, M.D., Ph.D., Medical Officer, DHP
Bahru Habtemariam, Pharm.D., Reviewer, Office of Clinical Pharmacology, DCP5
Julie Bullock, Pharm.D., Team Leader, Office of Clinical Pharmacology, DCP5
Mark Rothmann, Ph.D., Statistical Team Leader, DBV
Kyung Y. Lee, Ph.D., Statistical Reviewer, DBV
Kim J. Robertson, Regulatory Project Manager, DDOP

SPONSOR ATTENDEES:

Jay Backstrom, MD, MPH – Corporate Vice President, Clinical Research and Development
Benton Brown, MD – Senior Director, Drug Safety
Adrienne Farid, PhD – Executive Director, Project Leadership
Eric Laille, MS – Senior Scientist, Clinical Pharmacology
Lela Lucy, MS – Principal Statistician, Biostatistics
Paul McNulty – Director, Regulatory Affairs
Penny Ng, MSc, MBA, RAC – Senior Manager, Regulatory Affairs
Kaushik Datta, PhD, DABT – Senior Principal Scientist, Toxicology

Meeting Minutes
Type B, EOP 1/2
September 6, 2011

OODP
DDOP

Barry Skikne, MD, FACP, FCP (SA) – Executive Director, Clinical Research and
Development
Ann Tanner, RPh, MPH, RAC – Senior Director, Regulatory Affairs

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/s/

KIM J ROBERTSON

09/09/2011

06September11 IND 074618; Oral Azacitidine Sponsor Meeting Minutes; Celgene; MDS

EDVARDAS KAMINSKAS

09/15/2011