OBSTETRICS & GYNECOLOGY

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- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)*

**The corresponding author has opted to make this information publicly available.*

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Date: Jan 28, 2022
To: "Christine Mauck" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-21-2456

RE: Manuscript Number ONG-21-2456

A Phase 3 Randomized Trial of a Single-Dose Bioadhesive Clindamycin 2% Gel for Bacterial Vaginosis

Dear Dr. Mauck:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. Although it is judged not acceptable for publication in Obstetrics & Gynecology in its present form, we would be willing to give further consideration to a revised version.

If you wish to consider revising your manuscript, you will first need to study carefully the enclosed reports submitted by the referees and editors. Each point raised requires a response, by either revising your manuscript or making a clear and convincing argument as to why no revision is needed. To facilitate our review, we prefer that the cover letter include the comments made by the reviewers and the editor followed by your response. The revised manuscript should indicate the position of all changes made. We suggest that you use the "track changes" feature in your word processing software to do so (rather than strikethrough or underline formatting).

Please be sure to address the Editor comments (see "EDITOR COMMENTS" below) in your point-by-point response.

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Feb 18, 2022, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

Comments/Clarifications

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page 12 line 228 What treatment was given to these women and what was the interval from the clindamycin treatment?

page 13 line 238 What about percentage of those who had burning/stinging Clinda vs placebo and vulvovaginal pain clinda vs placebo ? these are symptoms that are clnically significant

page 13 line 242 Whats the location of the edema?

page 15 line 279 What about oral metronidazole? does this statement include that? What are the advantages over oral metronidazole.

Thank you

Reviewer #2: This is a randomized controlled trial comparing 1 day clindamycin therapy with novel adhesive properties to placebo for treatment of bacterial vaginosis. The study followed FDA guidelines for approval studies.

1. Methods: It is not clear to me why subjects with + yeast (which could have been a rapid Affirm test) and gonorrhea and chlamydia were not excluded from the trial. Similarly, why not exclude those with Nugent Scores less than 7 from the beginning?

2. Methods: Did the FDA require a placebo arm? I am just wondering why this novel treatment wasn't compared to an existing treatment given that the patients had a diagnosis that was left untreated in the placebo arm.

3. Methods: What was the definition of a clinical cure? Why the large difference between clinical cure and bacteriological cure?

4. Results: I may have missed it but I don't see reported how many women required additional BV therapy in each arm.

5. Discussion: How is the product any better than other products on the market to treat BV? Without a comparator arm, we don't really know. Lines 277-281 are inadequate and need more citations and data on the other treatments. What about cost?

Reviewer #3: This is a double blind randomized trial of a single dose bioadhesive clindamycin 2% gel, assessing the efficacy and safety for bacterial vaginosis treatment.

Line 61 Is this product different from the currently available single dose clindamycin products. If so, how is it different?

Line 134 Were there any restrictions on vaginal intercourse or douching for participants in the study?

Lines 142 -143 Consider providing more details explaining your sequential approach.

Line 210-217 Also report the CMH test statistics in addition to the p-values.

Lines 230 - 232 In your modified ITT population, you had excluded those with other vaginal or cervical infections at baseline (also described in Lines 97-102), which population do you describe here that had positive yeast cultures prior to dosing?

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

Abstract: Needs to conform to our RCT template.

Table 2: Should round all wgts (means, SD etc) to nearest 0.1 kg, all heights to nearest 0.1cm and all BMI to nearest 0.1 kg/m².

Fig 1: Need to provide primary outcome etc for the ITT population of n = 306 patients, in addition to Tables 3, 4 (the mITT).

lines 226-233 and Appendix 4: Should include in main text in Table format, either separately or in Table 5, the most frequent TEAEs (vulvovaginal candidiasis or pruritus) among the treatment and placebo groups.

EDITOR COMMENTS:

1. The Editors of Obstetrics & Gynecology have increased transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:

A. OPT-IN: Yes, please publish my point-by-point response letter.
B. OPT-OUT: No, please do not publish my point-by-point response letter.

2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:

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* Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and in the body text. For industry-sponsored studies, the Role of the Funding Source section should be included in the body text of the manuscript.
* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
* Name the IRB or Ethics Committee institution in the Methods section (if applicable).
* Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

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4. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, the reasons that race/ethnicity were assessed in the study also should be described (eg, in the Methods section and/or in table footnotes). Race/ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases, missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race.

Use "Black" and "White" (capitalized) when used to refer to racial categories. The nonspecific category of "Other" is a convenience grouping/label that should be avoided, unless it was a prespecified formal category in a database or research instrument. If you use "Other" in your study, please add detail to the manuscript to describe which patients were included in that category.

5. Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. The statement should indicate 1) whether individual deidentified participant data (including data dictionaries) will be shared; 2) what data in particular will be shared; 3) whether additional, related documents will be available (eg, study protocol, statistical analysis plan, etc.); 4) when the data will become available and for how long; and 5) by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Responses to the five bullet points should be provided in a box at the end of the article (after the References section).

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(1) Adherence to the GPP3 guideline should be noted in the cover letter.

(2) For publication purposes, the portions of particular importance to industry-sponsored research are below. In your cover letter, please indicate whether the following statements are true or false, and provide an explanation if necessary:
(2a) All authors had access to relevant aggregated study data and other information (for example, the study protocol) required to understand and report research findings.
(2b) All authors take responsibility for the way in which research findings are presented and published, were fully involved at all stages of publication and presentation development and are willing to take public responsibility for all aspects of the work.
(2c) The author list accurately reflects all substantial intellectual contributions to the research, data analyses, and publication or presentation development. Relevant contributions from persons who did not qualify as authors are disclosed in the acknowledgments.
(2d) The role of the sponsor in the design, execution, analysis, reporting, and funding (if applicable) of the research has been fully disclosed in all publications and presentations of the findings. Any involvement by persons or organizations with an interest (financial or nonfinancial) in the findings has also been disclosed.
(2e) All authors have disclosed any relationships or potential competing interests relating to the research and its publication or presentation.

(3) The abstract should contain an additional heading, "Funding Source," and should provide an abbreviated listing of the funder(s).

*From Battisti WP, Wager E, Baltzer L, Bridges D, Cairns A, Carswell CI, et al. Good publication practice for communicating company-sponsored medical research: GPP3. Ann Intern Med 2015;163:461-4.

7. Your submission indicates that one or more of the authors is employed by a pharmaceutical company, device company, or other commercial entity. This must be included as a statement in the Financial Disclosure section on the title page.

8. All studies should follow the principles set forth in the Helsinki Declaration of 1975, as revised in 2013, and manuscripts

should be approved by the necessary authority before submission. Applicable original research studies should be reviewed by an institutional review board (IRB) or ethics committee. This review should be documented in your cover letter as well in the Methods section of the body text, with an explanation if the study was considered exempt. If your research is based on a publicly available data set approved by your IRB for exemption, please provide documentation of this in your cover letter by submitting the URL of the IRB website outlining the exempt data sets or a letter from a representative of the IRB. In addition, insert a sentence in the Methods section stating that the study was approved or exempt from approval. In all cases, the complete name of the IRB should be provided in the manuscript.

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10. Titles in Obstetrics & Gynecology are limited to 100 characters (including spaces). Do not structure the title as a declarative statement or a question. Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles. Abbreviations, jargon, trade names, formulas, and obsolete terminology also should not be used in the title. Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," or "A Systematic Review," as appropriate, in a subtitle. Otherwise, do not specify the type of manuscript in the title.

11. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

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* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).
* If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."

12. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words. Please provide a word count.

13. Abstracts for all randomized, controlled trials should be structured according to the journal's standard format. The Methods section should include the primary outcome and sample size justification. The Results section should begin with the dates of enrollment to the study, a description of demographics, and the primary outcome analysis. Please review the sample abstract that is located online here: http://edmgr.ovid.com/ong/accounts/sampleabstract_RCT.pdf. Please edit your abstract as needed.

14. Only standard abbreviations and acronyms are allowed. A selected list is available online at http://edmgr.ovid.com /ong/accounts/abbreviations.pdf. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

15. The commercial name (with the generic name in parentheses) may be used once in the body of the manuscript. Use the generic name at each mention thereafter. Commercial names should not be used in the title, précis, or abstract.

16. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

17. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%").

18. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

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In addition, the American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the references you are citing are still current and available. Check the Clinical Guidance page at https://www.acog.org/clinical (click on "Clinical Guidance" at the top). If the reference is still available on the site and isn't listed as "Withdrawn," it's still a current document.

If the reference you are citing has been updated and replaced by a newer version, please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript.

20. Figure 1: Please consider writing out the exclusion criteria. Please upload as a figure file on Editorial Manager.

21. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.

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If you choose to revise your manuscript, please submit your revision through Editorial Manager at http://ong.editorialmanager.com. Your manuscript should be uploaded as a Microsoft Word document. Your revision's cover letter should include the following:

* A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf), and
* A point-by-point response to each of the received comments in this letter. Do not omit your responses to the Editorial Office or Editors' comments.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors and that each author has given approval to the final form of the revision.

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Feb 18, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Jason D. Wright, MD
Editor-in-Chief

2020 IMPACT FACTOR: 7.661
2020 IMPACT FACTOR RANKING: 3rd out of 83 ob/gyn journals

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time. (Use the following URL: https://www.editorialmanager.com/ong/login.asp?a=r). Please contact the publication office if you have any questions.

3655 Nobel Drive, Suite 260
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February 17, 2022

Dear Editor,

Thank you for your review of our manuscript entitled *Phase 3 Randomized Study of a Single-Dose Bioadhesive Clindamycin 2% Gel for Bacterial Vaginosis*. We have revised it as suggested by the reviewers and editor and are resubmitting it for consideration.

As requested, I am copying the reviewers' comments and editor's comments below, followed by our responses, in red, followed by the rest of the original cover letter.

REVIEWER COMMENTS:

Reviewer #1:

Comments/Clarifications

- page 5, Line 61 What is the design and mechanism of action of the bioadhesive gel? how does it facilitate administration and proper distribution in the vaginal mucosa ? How does it regulate the retention time and extended release? Please see text added to the fifth paragraph of the Introduction.

- page 10 line 181 Was this a checklist of symptoms they will check or they would list their symptoms? The eDiary included daily questions about whether the subject had experienced vaginal discharge, odor, and/or itching, and if so, whether it was bothersome and, if bothersome, how bothersome (mild, moderate, or severe), as well as any treatments used.

- page 12 line 223 The cervical mass was not noted on screening? As outlined below, the patient's SAE was considered resolved and not related to the study drug. The details are as follows. She was screened and randomized into the study on 04-Aug-2020. She applied study drug later that same day. On 06-Aug-2020, 2 days after randomization, the site called the patient to inquire into alerts arising from the patient's ediary indicating the onset of new vaginal symptoms. The patient declined to return to the clinic early, but was seen for her scheduled Interim Assessment visit on 13-Aug-2020, at which time she reported severe vulvovaginal pain and mild pruritus. Upon examination her vaginal odor was noted to be worse, and microscopic examination revealed diffuse polymorphonuclear leukocytes and trichomonas. The pelvic and bimanual examination at V2 also noted "pus coming from the cervix," a "nodule noted post endocervix," and "uterus enlarged and tender." The location of the nodule made it difficult to palpate on bimanual exam. The patient was diagnosed with severe pelvic inflammatory disease and trichomoniasis, for which the investigator administered ceftriaxone (250 mg x one dose) and prescribed doxycycline (100 mg bid) and metronidazole (500 mg, bid) for 14 days. The patient was also scheduled for an ultrasound to further evaluate the cervical mass. The patient's screening Chlamydia trachomatis NAAT, Neisseria gonorrhea NAAT, Candida culture and in-clinic rapid trichomonas test were all negative; none of these diagnostic assessments were repeated after screening. On 13-Aug-2020,

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the transvaginal ultrasound showed an abnormal mass involving the posterior cervix and a hyperechoic mass in the lower uterine segment and ectocervix. On 02-Sep-2020, at the final (TOC) study visit, a Pap smear was performed -- reportedly the first Pap smear the patient had received in many years. (Exclusion criteria for the study included: "Patients who would undergo evaluation or treatment during the study for abnormal cytology and/or findings from high-risk HPV testing and/or Pap test finding.") On 09-Sep-2020, results of the Pap smear were reported as "high grade squamous intraepithelial lesion with features suspicious for invasion," and the patient was determined to be HPV 16 positive. The site submitted follow-up information indicating that the patient had undergone surgical removal of the cervix on 13-Oct-2020, at which time her post-operative diagnosis was Stage 1B1 squamous cell carcinoma of the cervix. The patient's SAE was considered resolved with sequelae on 13-Oct-2020, with sequelae related to the need for additional radiation therapy and follow-up. The investigator assessed the event as Grade 4 in severity and not related to Blinded Study Drug. Upon unblinding at the end of the study, it was determined that the patient had received placebo.

- page 12 line 228 What treatment was given to these women and what was the interval from the clindamycin treatment? In the clindamycin group, all patients with vulvovaginal candidiasis were treated with oral fluconazole except for one patient who was treated with vaginal miconazole and two who were not treated. The one placebo patient was treated with oral fluconazole. On average, treatment was begun 16 days after application of study drug, with a range of 7 to 39 days.

- page 13 line 238 What about percentage of those who had burning/stinging Clinda vs placebo and vulvovaginal pain clinda vs placebo ? these are symptoms that are clnically significant. This information has been added to this section.

- page 13 line 242 Whats the location of the edema? At each visit, the investigator performed a vulvovaginal examination to assess the treatment area and rate erythema, petechiae, erosion/ulceration, and edema on the following scale: 0 = absent, 1 = mild (slight, barely perceptible), 2 = moderate (distinct presence), and 3 = severe (marked, intense). The location was vulvovaginal, but more specific detail was not collected.

- page 15 line 279 What about oral metronidazole? does this statement include that? What are the advantages over oral metronidazole. Clarifying text has been added to this section.

Reviewer #2: This is a randomized controlled trial comparing 1 day clindamycin therapy with novel adhesive properties to placebo for treatment of bacterial vaginosis. The study followed FDA guidelines for approval studies.

1. Methods: It is not clear to me why subjects with + yeast (which could have been a rapid Affirm test) and gonorrhea and chlamydia were not excluded from the trial. Similarly, why not exclude those with Nugent Scores less than 7 from the beginning? Please see edited wording starting with the third paragraph under "Methods." Results from Nugent scores became available several days

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after screening and study drug administration. Rather than discontinue subjects with Nugent scores of <7 at screening, they were kept in the study as part of the Safety Population.

2. Methods: Did the FDA require a placebo arm? I am just wondering why this novel treatment wasn't compared to an existing treatment given that the patients had a diagnosis that was left untreated in the placebo arm. Although the 2019 FDA guidance (https://www.fda.gov/media/129530/download) specifies that "The sponsor should conduct randomized, double-blind, and either placebo-controlled or active controlled trials, with the hypothesis that the investigational drug is superior to the control treatment," all but one trial of the other approved single-dose bacterial vaginosis products have compared the investigational product with placebo (One trial of Clindesse was placebo-controlled and the other involved a 7-day clindamycin treatment as comparator.)

2. Methods: What was the definition of a clinical cure? Why the large difference between clinical cure and bacteriological cure? The definition of clinical cure can be found in the abstract and, in more detail, in the Methods section: "Clinical cure was defined as resolution of 3 of 4 Amsel's criteria, namely: absence of the abnormal vaginal discharge consistent with BV as determined by the investigator, negative whiff test, and the presence of < 20% clue cells. The fourth Amsel criterion, vaginal pH, was not part of the primary endpoint, per the 2019 FDA Guidance (FDA 2021). Bacteriological cure was defined as a Nugent's score < 4, and therapeutic cure as both a clinical cure and bacteriological cure."

Bacteriological cure was defined as a Nugent's score of < 4. The Nugent score is considered the gold standard for diagnosing bacterial vaginosis. Because the sensitivity of the Amsel criteria is not 100%, there will always be some false negatives (cases in which bacterial vaginosis is still present by Nugent score but the Amsel's criteria indicate a clinical cure). As a result, the clinical cure rate may be expected to be greater than the bacteriological cure.

4. Results: I may have missed it but I don't see reported how many women required additional BV therapy in each arm. Three patients in each group developed an AE of bacterial vaginosis.

5. Discussion: How is the product any better than other products on the market to treat BV? Without a comparator arm, we don't really know. Lines 277-281 are inadequate and need more citations and data on the other treatments. What about cost? Clinical cure rates for other products have been added to this section. With respect to cost, the product will be introduced later this year at a price point that is commensurate with other branded products in this category.

Reviewer #3: This is a double blind randomized trial of a single dose bioadhesive clindamycin 2% gel, assessing the efficacy and safety for bacterial vaginosis treatment.

- Line 61 Is this product different from the currently available single dose clindamycin products. If so, how is it different? Please see text added to the fifth paragraph of the Introduction.

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- Line 134 Were there any restrictions on vaginal intercourse or douching for participants in the study? Patients were to abstain from sexual intercourse and/or sexual activity throughout the first 7 days following treatment. Patients had to be willing to refrain from the use of all intravaginal products (e.g., douches, feminine deodorant sprays, condoms, spermicides, vaginal moisturizers or lubricants, tampons, vaginal birth control rings [e.g., NuvaRing®], and diaphragms) through the first 7 days at a minimum, and ideally through Visit 3 (Day 21 to 30) or study exit/early discontinuation. See text added to "Methods."

- Lines 142 -143 Consider providing more details explaining your sequential approach. This has been added.

- Line 210-217 Also report the CMH test statistics in addition to the p-values. This has been added.

- Lines 230 - 232 In your modified ITT population, you had excluded those with other vaginal or cervical infections at baseline (also described in Lines 97-102), which population do you describe here that had positive yeast cultures prior to dosing? This was in the Safety Population, added to the title of Appendix 4, Supplemental Digital Content.

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

- Abstract: Needs to conform to our RCT template. Done

- Table 2: Should round all wgts (means, SD etc) to nearest 0.1 kg, all heights to nearest 0.1cm and all BMI to nearest 0.1 kg/m^2. Corrected

- Fig. 1: Need to provide primary outcome etc for the ITT population of n = 306 patients, in addition to Tables 3, 4 (the mITT). This has been added to the Supplemental Digital Content as Appendix 5.

- Iines 226-233 and Appendix 4: Should include in main text in Table format, either separately or in Table 5, the most frequent TEAEs (vulvovaginal candidiasis or pruritus) among the treatment and placebo groups. Table 6 has been added, which shows the most frequent product-related TEAEs.

EDITOR COMMENTS:

1. The Editors of Obstetrics & Gynecology have increased transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:

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A. OPT-IN: Yes, please publish my point-by-point response letter. OPT-IN
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* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable). Done
* Name the IRB or Ethics Committee institution in the Methods section (if applicable). Done
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Bacterial vaginosis is the most common vaginal condition among women of reproductive age, with a prevalence estimated by the CDC of 29.2% among U.S. women ages 14–49. Women with BV are at increased risk for acquisition of STIs, including HIV, complications after gynecologic surgery, and complications of pregnancy. Recurrence is frequent, leading to distress and frustration on the part of both patient and clinician. This new treatment, which is as effective in newly diagnosed patients as it is in previously treated patients, is likely to be of interest to your readers, and of therapeutic benefit to their patients.

I am submitting this manuscript solely to *Obstetrics and Gynecology*. It has not been submitted elsewhere and will not be unless a negative decision is made by the editors of *Obstetrics and Gynecology.* A poster entitled “Phase 3 Study of a Single-Dose Bioadhesive Clindamycin 2% Gel for Bacterial Vaginosis” was presented by Steven Chavoustie, MD, at the 2021 ACOG meeting, held virtually on April 30-May 2, 2021.

The study was approved by the following Institutional Review Board:

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The study's ClinicalTrials.gov Identifier is NCT04370548.

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