Author's response to reviews

Title: A study of docetaxel and irinotecan in children and young adults with recurrent or refractory Ewing sarcoma family of tumors

Authors:

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Version: 3
Date: 31 July 2014

Author's response to reviews: see over
Jul 31st, 2014

Dafne Solera
Editor-in-Chief, BMC Cancer

Dear Dr. Solera,

Please find the attached files for the manuscript (MS 2084626027120518) entitled “A study of docetaxel and irinotecan in children and young adults with recurrent or refractory Ewing sarcoma family of tumors” by Jong Hyung Yoon, Mi Mi Kwon, Hyeon Jin Park, Seog Yun Park, Kun Young Lim, Jungnam Joo, and Byung-Kiu Park* for consideration of publication in BMC Cancer. All authors have read and approved submission of this manuscript. This paper constitutes original material that has not been published previously in any language or format and has not been submitted elsewhere for print or electronic publication. This manuscript had been previously submitted to BMC Cancer for consideration as a full paper, and according to Decision on Jul 7th 2014, the editors advised us a revised manuscript, pursuant to editorial team’s comments. Accordingly, we tried to respond to the comments point-by-point. Specifically, we included the trial registry and the unique identifying number; conclusion section; email addresses and institutional details for every author. We further edited text language, and had our manuscript conformed to the journal style.

We hope that the incorporated changes and additions allow the manuscript to be suitable for publication in the Journal. We thank you for your time and efforts on this matter.

Sincerely,

Byung-Kiu Park, M.D., Ph.D.

(Comment)

Please submit a revised version of your manuscript with the number included in the abstract. The last section of the abstract should be Trial Registration: listing the trial registry and the unique identifying number and the date of registration.
We obtained approval from the IRB of the National Cancer Center, Korea (protocol number: NCCCTS-08-322) on Apr 21, 2008, and registered our study protocol in the ClinicalTrials.gov Protocol Registration System (ID: NCT01380275) on June 21, 2011. Relevant information was included in the last section of the abstract (shown in red characters). We enrolled the first patient in July, 2008, and included an approval letter from the IRB of the National Cancer Center at the end of the cover letter.

As we described in the methods section (page 7), we obtained informed consents from all parents/guardians and/or patients. Although we did not specifically mention in the consent form that their clinical details and images will be included if the study results are published, we think that their wills to participate in the study imply the acceptance of inclusion of their clinical details and images in the publication.

If you do not agree to above answer, we may obtain consents to publish from only two parents/guardians and/or patients because remaining seven patients died.

Please clearly label your conclusion section.

We added a conclusion section, and removed the final paragraph in the discussion section (shown in red in page 17).

Please include email address and institutional details for every author on your title page.

We included the relevant information on the title page.

We recommend that you ask a native English speaking colleague to help you copyedit the paper.
We have already submitted our revision which had been edited according to the recommendation by “Edanz” with the exception of several things we did not like to edit. This time, however, we further edited these things (shown in red characters) pursuant to the Edanz’s recommendation. I may forward the email from ‘Edanz’ on May 23, 2014, if you want to see it.

Please could you clarify whether Boryung Pharmaceutical Co., Ltd funded your study.

Boryung Pharmaceutical Co., Ltd did not give any other support except for a free supply of irinotecan. Actually, we don’t have any competing interests which are exemplified in the financial competing interests. To our understanding, in the situation like this, we think we can claim that the authors have no competing interests.

Please also ensure that your revised manuscript conforms to the journal style.

We had our manuscript conformed to the journal style.
# Approval Letter

<table>
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<tr>
<th>1. Name and address of Institutional Review Board :</th>
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<tr>
<td>Institutional Review Board of National Cancer Center, 323 Ilsan-ro, Ilsandong-gu, Goyang-si, Gyeonggi-do, 410-769, Republic of Korea</td>
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<th>2. Sponsor :</th>
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| 3. Principal Investigator : Park, Byung Kiu |

| 4. IRB No. : NCCCTS-08-322 |

| 5. Protocol Title : Phase II trial of docetaxel and irinotecan (DI) for recurrent or refractory bone and soft tissue sarcomas |

| 6. Submission date : 18 Apr 2008 |

| 7. Approval date : 21 Apr 2008 |

| 8. Review Type : ■ Full board review   □ Expedite review |

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<tr>
<td>1. Clinical Study Review Request Form</td>
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<td>2. Protocol, English</td>
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<td>3. Main Informed Consent Form : Korean ICF</td>
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This Institutional Review Board is organized and operates according to the ICH-GCP, KGCP, and other applicable laws and regulations. The investigator or any member of investigational staff who is a member of this IRB cannot participate in deliberations of the IRB or in the vote/opinion of the IRB.

Park, Byung Kiu / M.D., Ph.D.  
Name of Chairman

[Signature & Date]  
Feb 11, 2014