Reviewer's report

Title: Gemcitabine and docetaxel combination chemotherapy for advanced bone and soft tissue sarcomas: protocol for an open-label, non-randomised, Phase 2 study

Version: 0 Date: 15 Mar 2019

Reviewer: Scott Okuno

Reviewer's report:

1. Phase II study of bone and STS with gemcitabine and Docetaxel with only 20 pts planned study.

2. This manuscript is a proposed study, not a completed study.

3. Primary endpoint is PFS and for combined bone and STS. The endpoints for STS and bone are different. So would not combine in one study.

4. Sample size of 20 is too small for any meaningful conclusions.

5. There are published completed phase II and phase III studies for subsets of sarcomas already with gemcitabine and docetaxel.

6. Target sample size is based on response rate, but the primary endpoint is PFS.

7. Not clear what PFS you are looking at, but it looks like PFS at 1 year. Typically the PFS is not at 1 year, but at 16 weeks for STS and different for bone.

8. Because of the great variations of PFS for the various bone sarcomas, would need to be clear on which bone sarcoma you include and exclude.

9. Need to be clear what STS are included and excluded as the PFS and response to chemo is different.

10. Why the dose of 70 mg of docetaxel. Most use different dosing of 75 or 100 mg/m2?

11. For sarcomas, the dosing of gemcitabine is typically a fix rate infusion, so need to be specific of rate in the protocol.

12. For patients with prior pelvic radiation, the dose of gemcitabine is typically decreased from 900 mg/m2 to 675 mg/m2.

13. Some would use neulasta on day 9 or on-body on day 8. Please specify if can be used growth factors.
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

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None

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