Reviewer's report

Title: A 6-month depot formulation of leuprolide acetate is safe and effective in daily clinical practice: a non-interventional prospective study in 1273 patients

Version: 1 Date: 6 May 2011

Reviewer: Yasuhisa Fujii

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Minor Essential Revisions
This is an interesting study showing a novel 6-monthly formulation of leuprolide can achieve reliable reduction of PSA and testosterone in routine clinical practice.

There are a few minor points to be considered.

Minor points

1. Effective reduction of PSA and testosterone levels
In 99 patients who switched from leuprolide, Takeda (Trenantone) to the 6-monthly formulation of leuprolide (Eligard 45mg), the median serum testosterone levels decreased from 150 ng/dL to 17.3 ng/dL during the first six months. Similarly, in 57 patients who switched from goserelin, AstraZeneca (Zoladex) to Eligard 45mg, the median testosterone levels decreased from 72.3 ng/dL to 18.0 ng/dL during the same period. These results mean that more than half of the patients had their testosterone level above castrate level even though they were being treated with GnRH analogues.

Many previous studies have reported that any GnRH analogue available can decrease testosterone level within castrate range in almost all patients. It is better for the author to explain why so many patients had such high testosterone levels.

One possible explanation is that these patients had interrupted the GnRH analogue treatment when they started the 6-monthly formulation of leuprolide (Eligard 45mg). If so, the subpopulation analysis is misleading and should be omitted.

2. Pre-treatment, Table 1
Please add “Astellas” after “3 monthly leuprolide acetate” and “1 monthly leuprolide acetate”.

The reviewer would like to know the difference between “leuprolide acetate, Takeda” and “leuproerelin acetate, Takeda”. I am wondering these two drugs are the same.

Level of interest: An article of outstanding merit and interest in its field
Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.