Submitted by:
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Date of Request: August 22, 2011
NCCN Guidelines Panel: Antagonist for locally advanced Prostate Cancer

On behalf of Ferring Pharmaceuticals, I respectfully request the NCCN Prostate cancer Guidelines Panel to review the enclosed data for inclusion of Firmagon® (degarelix for injection) for the treatment of patients with advanced prostate cancer.

Specific Changes: Recommend that degarelix for injection be added as a GnRH receptor antagonist for advanced prostate cancer and a first-line ADT regimen.

FDA Clearance: FDA has approved Firmagon® (degarelix for injection) for the treatment of patients with advanced prostate cancer.

Rational: Approval was based on a Phase 3 study looking at the safety and efficacy of Firmagon® (degarelix for injection) in an open-label, multi-center, randomized, parallel-group study in patients with prostate cancer. A total of 620 patients were randomized to receive one of two Firmagon® (degarelix for injection) regimens or leuprolide for one year:

a. Firmagon® (degarelix for injection) at a starting dose of 240 mg (40 mg/ml) followed by monthly doses of 160 mg (40mg/ml) subcutaneously,

b. Firmagon® (degarelix for injection) at a starting dose of 240 mg/ml (40 mg/ml) followed by monthly dose of 80 mg (20mg/ml) subcutaneously,

c. leuprolide 7.5 mg intramuscularly monthly.

The primary objective was to demonstrate that Firmagon® (degarelix for injection) is effective with respect to achieving and maintaining testosterone suppression to castration levels (T ≤ 50 ng/dL), at all monthly visits during 12 months treatment.
The results are the following:

Table 1:

<table>
<thead>
<tr>
<th></th>
<th>Firmagon® (degarelix for injection) 240/160 mg N=202</th>
<th>Firmagon® (degarelix for injection) 240/80 mg N=207</th>
<th>Leuprolide 7.5 mg N=201</th>
</tr>
</thead>
<tbody>
<tr>
<td># of Responders</td>
<td>199</td>
<td>202</td>
<td>194</td>
</tr>
<tr>
<td>Castration Rate</td>
<td>98.3% (94.8; 99.4)</td>
<td>97.2% (93.5; 98.8)</td>
<td>96.4% (92.5; 98.2)</td>
</tr>
</tbody>
</table>

*Kaplan Meier estimates within group

Percentage changes in testosterone from baseline to Day 28 (median with interquartile ranges) are shown below in Figure 1 and the percentages of patients who attained the medical castration of testosterone ≤ 50 ng/dL are summarized in Table 2.

Figure 1:
Table 2: Percentage of Patients Attaining testosterone ≤ 50 ng/dL within the First 28 Days

<table>
<thead>
<tr>
<th></th>
<th>Firmagon® (degarelix for injection) 240/160 mg N=202</th>
<th>Firmagon® (degarelix for injection) 240/80 mg N=207</th>
<th>leuprolide 7.5 mg N=201</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>44%</td>
<td>52%</td>
<td>0%</td>
</tr>
<tr>
<td>Day 3</td>
<td>96%</td>
<td>96%</td>
<td>0%</td>
</tr>
<tr>
<td>Day 7</td>
<td>99%</td>
<td>99%</td>
<td>1%</td>
</tr>
<tr>
<td>Day 14</td>
<td>99%</td>
<td>99%</td>
<td>18%</td>
</tr>
<tr>
<td>Day 28</td>
<td>99%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

In the clinical trial, PSA levels were monitored as a secondary endpoint. PSA levels were lowered by 64% two weeks after administration of Firmagon® (degarelix for injection), 85% after one month, 95% after three months, and remained suppressed throughout the one year of treatment. These PSA results should be interpreted with caution because of the heterogeneity of the patient population studies.

The following articles are submitted in support of this proposed change. We would like to acknowledge the contributions of the many experts in prostate cancer who have assisted Ferring Pharmaceuticals in the research and development of Firmagon® (degarelix for injection).

1. Firmagon® (degarelix for injection) prescribing information. Ferring Pharmaceuticals.

Sincerely,

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Ferring Pharmaceuticals Inc.