Long-Term Cancer Surveillance: Five-Year Update for the Forteo Patient Registry Surveillance Study

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ABSTRACT

Background: Postmarketing safety surveillance studies can be challenging to implement, especially when the outcome of interest is a rare cancer. The Forteo Patient Registry was designed to estimate the incidence of osteosarcoma in patients who have received treatment with teriparatide (Forteo).

Objective: To provide a study update of the voluntary Forteo Patient Registry, designed to estimate the incidence of osteosarcoma in patients who have received treatment with teriparatide (Forteo).

Methods: This surveillance study is a multyear, prospective registry in the US designed to link information from adult patients with a history of teriparatide use (enrolled in the 10-year teriparatide study) to determine any correlation of teriparatide use with adult osteosarcoma occurring at a rate of 2 cases per million population in adults residing in the US using data linkage with population-based state cancer registries are presented.

Results: Overall, 2014, the 5th annual linkage was completed with 42,544 patients enrolled in the Forteo Patient Registry (mean = 200,000 patients enrolled in the 10-year teriparatide study) to determine any correlation of teriparatide use with adult osteosarcoma occurring at a rate of 2 cases per million population in adults residing in the US using data linkage with population-based state cancer registries are presented.

Conclusions: Although no incident cases of osteosarcoma among patients in the Forteo Patient Registry have been identified through this linkage process, our ability to draw conclusions after 5 years about the incidence of osteosarcoma among teriparatide users is limited due to follow-up time currently available.

BACKGROUND

Osteosarcoma is a rare cancer. Interim results from an ongoing study to examine the relationship between bone mass in men with primary or hypogonadal osteoporosis who are at high risk for osteoporosis and the Forteo patient support program.

METHODS

Study Design

• The study is a voluntary, prospective, cohort study of adult residing in the US who receive treatment with a Forteo delivery device during the enrollment period (2009-2016) and who provide voluntary consent to have their personal data linked to cancer registry data.

• On an annual basis from 2009 to 2024, data from registered patients are linked with participating state cancer registries to identify any new confirmed cases of osteosarcoma diagnosed after the initiation of Forteo.

• State cancer registries include all osteosarcoma cases diagnosed 2009 or later at the time of diagnosis (cases included are confirmed retroactively).

Table 1. Characteristics of the First Five Annual Linkages

<table>
<thead>
<tr>
<th>Year of Linkage</th>
<th>Number of Linkages</th>
<th>Number of Participants</th>
<th>Number of Osteosarcoma Cases Identified</th>
<th>Percentage of Patients Linked</th>
<th>Percentage of Osteosarcoma Cases Linked</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>27</td>
<td>6,338</td>
<td>96</td>
<td>92%</td>
<td>1%</td>
</tr>
<tr>
<td>2011</td>
<td>37</td>
<td>16,365</td>
<td>961</td>
<td>85%</td>
<td>6%</td>
</tr>
<tr>
<td>2012</td>
<td>41</td>
<td>34,909</td>
<td>2,490</td>
<td>92%</td>
<td>7%</td>
</tr>
<tr>
<td>2013</td>
<td>44</td>
<td>42,544</td>
<td>4,364</td>
<td>92%</td>
<td>10%</td>
</tr>
<tr>
<td>2014</td>
<td>44</td>
<td>42,544</td>
<td>15,392</td>
<td>92%</td>
<td>10%</td>
</tr>
</tbody>
</table>

CONCLUSIONS

• No cases of osteosarcoma were identified by linking the full Forteo Patient Registry population to cancer registries in the first five linkages.

• Based on the estimated person-years of follow-up, adjusted for estimated mortality, no cases would have been expected if patients receiving teriparatide had the same incidence of osteosarcoma in the general population.

• The study is currently planned to enroll patients through 2019 and link with cancer registries through 2024.

REFERENCES

1. Vahle JL, Sato M, Long GG, Youn JK, Francis PC, Engelhardt JA, et al. Skeletal changes in rats given parathyroid hormone: an in vivo autoradiographic study and a review of osteoblast bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fracture. The Forteo Patient Registry was established in 2005, when a report for the first time was able to link cancer registries, our ability to draw conclusions after 5 years about the incidence of osteosarcoma among teriparatide users is limited due to follow-up time currently available.

Conflict of Interest

This study was funded by Eli Lilly and Company, Nicole Kellier, and Daniel Masica and was performed by RTI Health Solutions (RTI), which contracted with Eli Lilly and Company, David Harris, Alicia Gilsenan, Abenah Harding, Elizabeth Andrews, and Nicole Kellier. RTI Health Solutions is an independent research organization that conducts research with multiple pharmaceutical companies and has an independent right to publish the results of this study.

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