Background

Teriparatide is a recombinant human parathyroid hormone (teriparatide) that is commercially available for the treatment of postmenopausal osteoporosis with osteoporosis at high risk for fracture. It is also approved for increasing bone mass in men with primary or hyperparathyroidism osteoporosis at high risk for fracture. In 2008, the FDA released findings that include treatment of men and women with glucocorticoid-induced osteoporosis who are at high risk for fracture.

In prospective studies, teriparatide caused a dose-dependent increase in the incidence of osteosarcoma. Cases of osteosarcoma have been reported rarely in the postmarketing period. The association with teriparatide is an ongoing surveillance study.

Osteosarcoma is a bone cancer in humans, with an estimated incidence of 0.6 cases per million per year.

As a condition of approval, the US Food and Drug Administration (FDA) requires long-term surveillance studies be conducted for osteosarcoma.

The expected number of patients with osteosarcoma exposed to teriparatide is estimated to be 2,426,000 person-years.

The expected number of osteosarcoma cases among patients exposed to teriparatide was 0.23 cases per million person-years.

Two reports of teriparatide use prior to diagnosis were identified. Given the two observed cases, the SIR for the category (28 ± 15.9; 50-95 confidence interval (CI) 0.1-1.6).

Patient and osteosarcoma characteristics that may be potentially risk factors are included in Table 1.

Osteosarcoma typically occurs in young adults, non-Hispanic whites, with a mean age at diagnosis of 32.3 years versus 29.9 years for the general population.

The incidence of osteosarcoma was measured to be 1.95/100,000 person-years.

As of March 31, 2017, interviews were completed for 1,046 patients (9187 Intraosseous well-differentiated osteosarcoma, representing 90% of the cumulative distribution of cases (Table 2).

The age-sex distribution of patients receiving teriparatide, captured by the study, is ascertained with medications, and exposure to possible risk factors) is ascertained with the patient or proxy via a 25- to 30-minute telephone interview.

The interview procedure included a standardized patient intake form and standard questions on patient demographics, health history, medical history, treatment history, exposure to risk factors, and patient experience.

The expected number of patients with osteosarcoma exposed to teriparatide is estimated to be 15.4 cases per million person-years.

Osteosarcoma is defined as osteosarcoma (ICD-O-3 codes 9182-9197, with exclusion of osteosarcoma, NOS).

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