Economic Evaluation of Aclasta® (zoledronic acid 5 mg) versus Actonel® (risedronate) in Treatment of Paget’s Disease of Bone

*  A Canadian perspective

**Mittmann N, Isogai PK, Adachi JD, Kindlund CM and Barbeau M*

†Ryerson Research Centre, Division of Clinical Pharmacology, Department of Medicine, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada Department of Pharmacology, University of Toronto, Toronto, Ontario, Canada; *Joseph’s Healthcare, McMaster University, Hamilton, Ontario, Canada; **RheumRx Pharmaceuticals Canada Inc., Don Mills, Quebec, Canada

**ABSTRACT**

Aclasta® (zoledronic acid 5 mg) is a new agent available for the treatment of Paget’s disease of the bone (PD). The objective of this evaluation is to conduct an economic evaluation of Aclasta® and Actonel® (risedronate) in a PD patient population in Canada.

**BACKGROUND**

- Paget’s Disease of Bone (PD): typically affects 2-5% of the population over the age of 50 years in Canada.
- PD is characterized by an increase in the number, size and activity of osteoclasts, causing excessive bone resorption leading to increased bone formation.
- PD is generally asymptomatic; only about 5% of PD patients show clinical symptoms.
- The most common symptoms and complications are macroscopically, including bone deformity and hyperactivity. In some cases, long-term and deleterious, and difficulty in performing daily activities may cause significant pain due to microfractures.
- PDB can cause osteonecrosis, neurovascular, cardiac, or skeletal complications, and in rare cases, osteosarcoma (skull lesions below 1%).
- PD can greatly reduce the quality of life of those suffering from it, compromising physical activity, causing significant pain, and altering psychological functioning. Nearly half of all patients report depressed mood.
- PD cannot be cured; management aims to reduce bone turnover using antiresorptive therapy (bisphosphonate) in symptomatic patients.
- In clinical practice severe pathological (SAP) and the key surrogate marker used for measuring disease activity and response to treatment is PD.
- Actonel (risedronate) is the standard current of care in PD in Canada, holding 73.2% of the publicly reimbursed market for PD.
- Aclasta (zoledronic acid 5 mg) is a new agent for IV infusion which is a third generation antiresorptive containing bisphosphonate recently approved for the treatment of PD in men and women. Aclasta is administered as a single 5 mg injection and infusion from a 100 mL ready-to-use bottle.
- Clinical trials have shown that a significantly higher proportion of patients treated with Aclasta achieved a therapeutic response in significantly less time and for a significantly longer time of 12 months and overall compared to Actonel.

**OBJECTIVE**

- The objective of this evaluation is to conduct a cost analysis of Aclasta (zoledronic acid 5 mg) versus Aclasta (raloxifene 30 mg) daily for 2 months in a population of patients with PD over a 2 year time horizon

**METHODS**

<table>
<thead>
<tr>
<th>Resource</th>
<th>Units</th>
<th>Cost/Unit</th>
<th>Cost/Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aclasta</td>
<td>5 mg</td>
<td>$2.59</td>
<td>$17.58</td>
</tr>
<tr>
<td>Actonel</td>
<td>30 mg</td>
<td>$2.53</td>
<td>$15.18</td>
</tr>
<tr>
<td></td>
<td>5 mg</td>
<td>$2.36</td>
<td>$14.19</td>
</tr>
<tr>
<td></td>
<td>10 mg</td>
<td>$2.78</td>
<td>$17.63</td>
</tr>
<tr>
<td></td>
<td>30 mg</td>
<td>$2.53</td>
<td>$15.18</td>
</tr>
<tr>
<td>Radiographs</td>
<td></td>
<td></td>
<td>$23.98</td>
</tr>
<tr>
<td>Lab test</td>
<td></td>
<td></td>
<td>$28.96</td>
</tr>
<tr>
<td>Total treatment costs</td>
<td></td>
<td></td>
<td>$76.13</td>
</tr>
</tbody>
</table>

**RESULTS**

- Aclasta is an effective drug for the treatment of PD and provides good economic value.
- Over a 2 year time horizon, Aclasta is dominant both from a clinical and cost perspective when compared to Actonel for the treatment of PD.
- Cost savings with Aclasta ranged from $484.50 (base case) to $582.87 (of Actonel remission rates by 15% and improving the quality of life of patients treated with Aclasta.
- Low compliance with therapy potentially reduces treatment efficacy; analyses were performed with a reduction of 5%, 10% and 15% in Actonel remission rates.

**Sensitivity analyses**

- Analyses were performed to assess Aclasta’s treatment cost for Actonel, which increased by 2.7% in July 2005 to $110.54 per mg,41 and assessing a mark-up of 10% and dispensed for $84.54.

**DISCUSSION**

- Overall PDB treatment costs were $2,057.66 for Aclasta and $582.87 for Actonel.
- Drugs costs for Aclasta were $4,92 ($2.46*2).
- Clinical trials have shown a significantly higher proportion of patients treated with Aclasta achieved a therapeutic response in significantly less time and for a significantly longer time (12 months) and overall compared to Actonel.
- Actonel (risedronate) is the standard current of care in PD in Canada, holding 73.2% of the publicly reimbursed market for PD.