Dose Escalation Among Psoriasis Patients Treated With Adalimumab, Etanercept, or Ustekinumab

Chureen Carter, PharmD, MS¹, Mingliang Zhang, PhD¹
Kathleen Wilson, MPH², Zhun Cao, PhD³, David Smith, PhD²

¹Janssen Scientific Affairs, LLC, Horsham, PA
²Truven Health Analytics, Cambridge, MA
³Premier Inc., Boston, MA (formerly Truven Health Analytics at the time of the study)

Poster #112
Background

- Dosing for ustekinumab (UST), a newer biologic for the treatment of plaque psoriasis (PsO), is weight-dependent (either 45mg or 90mg) with induction doses administered at weeks 0 and 4, and maintenance doses administered every 12 weeks thereafter.

- Dose escalation is well-characterized among psoriasis patients treated with adalimumab (ADA) or etanercept (ETA), but no real-world studies have included a comparison of dose escalation among PsO patients treated with UST.
Objective

• To characterize dose escalation among PsO patients treated with the biologic medications ADA, ETA, or UST
Methods

• This retrospective, observational study used administrative claims from the Truven Health MarketScan® Research databases.

• Adult patients 18 years or older with the following were included: first administration of ADA, ETA, or UST between 2/8/2010-1/31/2011 (index date), ≥12 months continuous enrollment prior to and following the index date, and a diagnosis of PsO (ICD-9-CM diagnosis code 696.1) prior to or on the index date.

• Patients with ≥1 diagnosis code for rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, Crohn’s disease, or ankylosing spondylitis during the 12-month pre-index period were excluded.
Methods (cont'd)

• For ADA and ETA patients, dose escalation during the maintenance period was defined as an average weekly dose 15% greater than recommended dosing\(^1\)
  - Dose: strength times the metric quantity on the prescription claim of the index medication

• UST dose escalation was defined as the presence of any dose higher than the initial dose
  - Dose of ustekinumab was also calculated differently depending on whether the claim had an NDC code for ustekinumab prescription or J code for ustekinumab administration
  - Dose for claims with NDC codes were calculated by multiplying the strength times the metric quantity. Dose for claims with J codes for ustekinumab administrations were imputed based on payment field on the medical claim.

• The time between UST doses was also reported for the first 6 doses

---

Results
Results

• A total of 573 UST, 2933 ADA, and 4011 ETA patients met selection criteria and had complete dose information (mean age was 48.9-49.9 years and 55.1-58.2% male)

• Induction period dose escalation was observed in 1.0% of ETA patients and 0.3% of ADA patients. Maintenance period dose escalation was observed in 27% of ETA patients and 7.0% of ADA patients.

Dose Escalation of ADA and ETA During First-Year of Treatment

- Average weekly dose > induction period label dose
- Average weekly dose > maintenance period label dose

Results (cont'd)

UST Dose Change by Index Dose

<table>
<thead>
<tr>
<th>Dose Number</th>
<th>Percent of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOSE 1 (Index) (n = 573)</td>
<td>30.7% 68.8% 0.0%</td>
</tr>
<tr>
<td>DOSE 2 (n = 556)</td>
<td>29.7% 66.5% 1.6%</td>
</tr>
<tr>
<td>DOSE 3 (n = 531)</td>
<td>29.9% 55.4% 12.2%</td>
</tr>
<tr>
<td>DOSE 4 (n = 490)</td>
<td>29.2% 52.4% 15.5%</td>
</tr>
<tr>
<td>DOSE 5 (n = 444)</td>
<td>29.3% 50.9% 16.9%</td>
</tr>
<tr>
<td>DOSE 6 (n = 401)</td>
<td>30.2% 48.4% 18.5%</td>
</tr>
</tbody>
</table>

- 90 mg, initial 90mg
- 45 mg, initial 90mg
- 90 mg, initial 45mg
- 45 mg, initial 45mg

Results (cont'd)

- For UST patients, the time interval between doses followed the administration guidelines\(^1\), and the median number of days between the first 6 doses was 28, 85, 91, 90, and 92 days, respectively

\(^1\) STELARA (ustekinumab) Prescribing Information. Janssen Biotech, Inc. 03/2014
Conclusions

• Dose escalation during the maintenance period was observed for all PsO biologics, but was found to be more common among PsO patients receiving ETA compared with ADA or UST
  – Proportion of ADA or ETA patients with calculated dose escalation was dependent on 15% threshold
  – There was no clinical information to explain the reasons for dose escalation
  – Dose escalation results are limited to the PsO population

• Furthermore, these data suggest PsO patients received UST administrations in accordance with prescribing recommendations