BACKGROUND
In moderate-to-severe psoriasis, maintaining adequate control of disease activity generally requires long-term treatment.1-3
Ixekizumab is a high-affinity monoclonal antibody that selectively targets interleukin-17A (IL-17A).
- It has demonstrated significant efficacy in the treatment of moderate-to-severe psoriasis.4
- It is approved for treating moderate-to-severe plaque psoriasis.
Safety profile is aligned with IL-17A inhibition and similar to that of ustekinumab (UST=45 mg ustekinumab), a fully human monoclonal antibody that binds to IL-12 and IL-23 subunits of the IL-23 receptor.

OBJECTIVE
The Integrated Psoriasis Safety Dataset (IPSD) is an update and extension of an existing database containing safety and efficacy data from 12 ixekizumab clinical trials. The dataset consists of safety data from 37 clinical trials (34 clinical trials plus 3 controlled or uncontrolled trials) and includes 11 psoriasis clinical trials and 95 additional non-psoriasis clinical trials. The dataset will be updated through the end of 2017 to include all ixekizumab clinical trials conducted through August 2017. The Integrated Psoriasis Safety Dataset (IPSD) is relevant to psoriasis patients and healthcare providers.3

METHODS
Integrated Psoriasis Safety Database
Treatment-emergent adverse event (TEAE) data were included from 12 controlled and uncontrolled ixekizumab clinical trials in psoriasis, as well as 3 previously published, randomized, double-blind clinical trials (UNCVER-1, -2, and -3). Data were provided for all patients who received at least 1 dose of ixekizumab.3

Study Design
The study was conducted in 2 phases: a placebo-controlled phase (Phase 1) that ended in January 2016 and a long-term extension phase (Phase 2) that ended in December 2017. Patients who completed Phase 1 were rolled over to Phase 2 and continued receiving ixekizumab through the end of Phase 2. Patients who completed Phase 2 were roll-over to Phase 3 and continued receiving ixekizumab through the end of Phase 3. Table 1A shows the maintenance and step-up regimen used during each phase.4

MECIs were adjudicated by an external adjudication committee.

KEY RESULTS
Duration of Ixekizumab Exposure
Incidence Rates of Overall TEAEs Decreased or Remained Similar Group
Incidence Rates of Select TEAEs Decreased or Remained Similar Group

Incidence Rates of Safety Topics of Special Interest

CONCLUSIONS
The updated IPSD provides a rich clinical safety database in a large number of psoriasis patients, including patients who have been on ixekizumab for more than 3 years. The safety profile of ixekizumab is similar to that observed with ustekinumab.

References

An Update on the Long-Term Safety Experience of Ixekizumab: Results from the Psoriasis Clinical Development Program with More than 3 Years of Follow-up from 12 Clinical Trials and More than 15,000 Patient-Years of Exposure to Ixekizumab

April Armstrong,1 Noah Agada,2 Wen Xu,2 Gailo Gallo2
1Department of Clinical Research, Keck School of Medicine of the University of Southern California, Los Angeles, USA; 2Eli Lilly and Company, Indianapolis, USA

Table 1A: Maintenance and Step-up Regimen

<table>
<thead>
<tr>
<th>Phase</th>
<th>Maintenance Regimen</th>
<th>Step-up Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1</td>
<td>IXE Q4W=80 mg ixekizumab every 4 weeks; IXE Q12W=80 mg ixekizumab every 12 weeks; PBO</td>
<td>IXE Q4W=80 mg ixekizumab every 4 weeks; IXE Q12W=80 mg ixekizumab every 12 weeks; PBO</td>
</tr>
<tr>
<td>Phase 2</td>
<td>IXE Q4W=80 mg ixekizumab every 4 weeks; IXE Q2W=80 mg ixekizumab every 2 weeks; PBO</td>
<td>IXE Q4W=80 mg ixekizumab every 4 weeks; IXE Q2W=80 mg ixekizumab every 2 weeks; PBO</td>
</tr>
<tr>
<td>Phase 3</td>
<td>IXE Q4W=80 mg ixekizumab every 4 weeks; IXE Q12W=80 mg ixekizumab every 12 weeks; PBO</td>
<td>IXE Q4W=80 mg ixekizumab every 4 weeks; IXE Q12W=80 mg ixekizumab every 12 weeks; PBO</td>
</tr>
</tbody>
</table>

Abbreviations
- TEAE: Treatment-emergent adverse event
- IR: Incidence rate
- IXE: Ixekizumab
- Q4W: Every 4 weeks
- Q12W: Every 12 weeks
- Q2W: Every 2 weeks
- PBO: Placebo
- PY: Person-years
- N: Number of patients
- n: Number of events
- 95% CI: 95% confidence interval
- NR: Not reported
- MACE: Major adverse cerebro-cardiovascular events
- NMSC: Non-melanoma skin cancer
- CVD: Cardiovascular disease

Privacy Notice Regarding the Collection of Personal Information
By scanning this QR code, you are consenting to have your IP address and, if you choose, email address temporarily retained in a secured computer system and used only for counting purposes, performing file download, and sending you tailored website content. Please review and accept the Privacy Notice Regarding the Collection of Personal Information before scanning this QR code. You can also visit www.lilly.com/privacy to learn more about our privacy practices.