

March 1, 2016

# Lilly to Present Phase 3 Data at the American Academy of Dermatology (AAD) Annual Meeting for Ixekizumab in Psoriasis and Psoriatic Arthritis

- 29 abstracts will highlight new data for ixekizumab, including 60-week safety and efficacy results in moderate-to-severe plaque psoriasis -

INDIANAPOLIS, March 1, 2016 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) will showcase results from pivotal Phase 3 data investigating ixekizumab for the treatment of moderate-to-severe plaque psoriasis and active psoriatic arthritis at the 74<sup>th</sup> annual meeting of the American Academy of Dermatology (AAD), which will take place March 4-8, 2016, in Washington, D.C.

A total of 29 abstracts, including three oral presentations, will feature Lilly's ixekizumab data for the treatment of moderate-to-severe plaque psoriasis across a number of areas, including efficacy and safety data at 12 weeks and 60 weeks, patient-reported outcomes and data evaluating the efficacy and safety of ixekizumab compared to etanercept. Two abstracts evaluating the efficacy and safety of ixekizumab for the treatment of active psoriatic arthritis will also be presented.

"Moderate-to-severe plaque psoriasis can significantly impact all aspects of a person's life, including both physical and emotional burdens," said Aarti Shah, Ph.D., Vice President and Global Brand Development Leader, Ixekizumab, Eli Lilly and Company. "We are pleased to bring a comprehensive review of data for ixekizumab to this year's American Academy of Dermatology annual meeting, which we believe highlights the potential for ixekizumab, if approved, to address the challenges faced by people living with this disease and physicians looking to provide a new treatment option for their patients."

Studies, as well as the times and locations of the data sessions, are highlighted below.

## **Oral Presentations**

## Saturday, March 5

- Late-Breaker Abstract #3855: 11:12 a.m. 11:22 a.m. ET
  - Efficacy and Safety of Continuous Ixekizumab Treatment for 60 Weeks in Moderate-to-Severe Plaque Psoriasis: Results from the UNCOVER-3 Trial
  - Presenter: Andrew Blauvelt, Oregon Medical Research Center, Portland, OR
  - Location: Room 146C

#### Monday, March 7

- "Pearls from the Posters" Abstract #3271: 10:00 a.m. 10:10 a.m. ET
  - i Impact of Ixekizumab on Palmoplantar Plaque Psoriasis Compared to Placebo and Etanercept: Results from UNCOVER-2
  - Presenter: Kristian Reich, Georg-August-University Göttingen and Dermatologikum Hamburg, Hamburg, Germany
  - Location: Room 208
- "Pearls from the Posters" Abstract #3017: 10:10 a.m. 10:20 a.m. ET
  - i Ixekizumab Shows Efficacy and Safety in Patients Who Failed Bi-weekly Etanercept Therapy: Analysis from UNCOVER-2, a Phase 3 Randomized Clinical Trial in Psoriasis
  - Presenter: Kim Papp, Probity Medical Research Inc., Ontario, Canada
  - Location: Room 208

#### **Poster Presentations**

- Abstract #3031: 11:35 a.m. 11:40 a.m. ET
  - i Efficacy of Ixekizumab Therapy: Integrated Analysis of 3 Double-blind, Controlled Trials (UNCOVER-1, UNCOVER-2, UNCOVER-3)
  - Presenter: Neil Korman, Case Western Reserve University School of Medicine, Cleveland, OH
  - Location: E-Poster Presentation Center 3
- Abstract #2911: 12:40 p.m. 12:45 p.m. ET
  - Impact of Ixekizumab on Skin Pain in Patients with Moderate-to-Severe Psoriasis Compared to Placebo and Etanercept in UNCOVER-2
  - Presenter: Alice Gottlieb, Tufts Medical Center, Boston, MA
  - Location: E-Poster Presentation Center 3
- Abstract #3101: 1:00 p.m. 1:05 p.m. ET
  - integrated Safety of Ixekizumab in Patients with Moderate-to-Severe Psoriasis: Results from a Pooled Analysis of 7 Clinical Trials
  - i Presenter: Nayan Acharya, Eli Lilly & Company, Indianapolis, IN
  - Location: E-Poster Presentation Center 3
- Abstract #3413: 1:10 p.m. 1:15 p.m. ET
  - i Ixekizumab Shows No Association with Major Adverse Cardiac Events (MACE) in Patients with Moderate-to-Severe Psoriasis: An Integrated Safety Analysis of Clinical Trials
  - Presenter: Dan Braun, Eli Lilly and Company, Indianapolis, IN
  - Location: E-Poster Presentation Center 3
- Abstract #3100: 4:05 p.m. 4:10 p.m. ET
  - Rapid Onset of Efficacy in Patients with Psoriasis Treated with Ixekizumab: A Pooled Analysis of Data from Two Phase 3 Randomized Clinical Trials (UNCOVER-2 and UNCOVER-3)
  - i Presenter: Craig Leonardi, Saint Louis University School of Medicine, St. Louis, MO
  - Location: E-Poster Presentation 3

## Sunday, March 6

- Abstract #3450: 8:15 a.m. 8:20 a.m. ET
  - A Statistical Tool to Convert Published PASI 75, PASI 90 and PASI 100 Response Rates into Absolute PASI Values
  - Presenter: Alexander Schacht, Eli Lilly & Company, Indianapolis, IN
  - Location: E-Poster Presentation Center 3
- Abstract #3813: 8:40 a.m. 8:45 a.m. ET
  - An Exposure Response Model to Describe the Relationship Between Ixekizumab Concentrations and the Static Physicians' Global Assessment (sPGA) Score and the Psoriasis Area and Severity Index (PASI) in Patients with Moderate-to-Severe Plaque Psoriasis
  - Presenter: Olawale Osuntokun, Eli Lilly & Company, Indianapolis, IN
  - Location: E-Poster Presentation Center 3
- Abstract #2446: 9:00 a.m. 9:05 a.m. ET
  - Association Between Complete or Near Complete Resolution of Psoriasis and Improvements in Health-Related Quality of Life, Itching and Skin Pain: An Integrated Subanalysis of UNCOVER-2 and UNCOVER-3
  - Presenter: Luis Puig, Hospital de Sant Pau, Department of Dermatology, Barcelona, Spain
  - Location: E-Poster Presentation Center 3
- Abstract #3765: 10:00 a.m. 10:05 a.m. ET
  - Comparison of Efficacy of Ixekizumab and Ustekinumab in the Treatment of Plaque Psoriasis: An Indirect Comparison via Etanercept
  - Presenter: Alexander Schacht, Eli Lilly & Company, Indianapolis, IN
  - Location: E-Poster Presentation Center 3
- Abstract #2857: 10:15 a.m. 10:20 a.m. ET
  - Comparison of the Pharmacokinetics of Ixekizumab Following Subcutaneous Administration Using a Prefilled Syringe Versus an Autoinjector in Patients with Moderate-to-Severe Psoriasis
  - Presenter: Kristina Callis Duffin, University of Utah, Salt Lake City, UT
  - Location: E-Poster Presentation Center 3
- Abstract #3421: 11:05 a.m. 11:10 a.m. ET
  - Ease of Use and Confidence with Prefilled Syringe to Administer Ixekizumab in a Phase 3 Trial Evaluated with Subcutaneous Administration Assessment Questionnaire (SQAAQ)
  - Presenter: Kristina Callis Duffin, University of Utah, Salt Lake City, UT
  - Location: E-Poster Presentation Center 3
- Abstract #3400: 11:10 a.m. 11:15 a.m. ET
  - Ease of Use and Confidence with an Auto-injector to Administer Ixekizumab in a Phase 3 Trial Evaluated with Subcutaneous Administration Assessment Questionnaire (SQAAQ)
  - Presenter: Jerry Bagel, Windsor Dermatology, Windsor, NJ
  - Location: E-Poster Presentation Center 3
- Abstract #3428: 11:45 a.m. 11:50 a.m. ET

- Efficacy of Ixekizumab in Moderate-to-Severe Psoriasis Patients Who Have or Have Not Received Prior Biologic Therapies: An Integrated Analysis of 3 Phase 3 Studies
- Presenter: Alice B. Gottlieb, Tufts Medical Center, Boston, MA
- Location: E-Poster Presentation Center 3
- Abstract #2515: 11:50 a.m. 11:55 a.m. ET
  - <sup>i</sup> Efficacy of Ixekizumab in Patients with Psoriatic Arthritis: Results of a Phase 3 Randomized, Double-blind, Active- and Placebo-controlled Study
  - Presenter: Phillip J. Mease, Swedish Medical Center and University of Washington, Seattle, WA
  - Location: E-Poster Presentation Center 3
- Abstract #3417: 12:15 p.m. 12:20 p.m. ET
  - Evaluation of Inflammatory Bowel Disease in Patients with Plaque Psoriasis Studied in Phase 3 Trials of Ixekizumab (UNCOVER Trials): Adjudicated Data from the Induction Period
  - Presenter: Richard Langley, Dalhousie University, Halifax, Nova Scotia
  - Location: E-Poster Presentation Center 3
- Abstract #2859: 1:00 p.m. 1:05 p.m. ET
  - Impact of Ixekizumab Treatment on Depressive Symptoms: an Integrated Analysis of Three Phase 3 Clinical Studies in Patients with Moderate-to-Severe Psoriasis
  - Presenter: Christopher Griffiths, University of Manchester, Manchester, UK
  - Location: E-Poster Presentation Center 3
- Abstract #2865: 1:05 p.m. 1:10 p.m. ET
  - i Impact of Ixekizumab Treatment on Scalp Psoriasis: Results from the UNCOVER-2 Trial
  - Presenter: Howard Sofen, UCLA School of Medicine, Los Angeles, CA
  - Location: E-Poster Presentation Center 3
- Abstract #2713: 1:10 p.m. 1:15 p.m. ET
  - Impact of Ixekizumab Treatment on Sexual Function in Moderate-to-Severe Psoriasis Patients: 12-Week Results from Two Phase 3 Trials UNCOVER-2 and UNCOVER-3
  - Presenter: Lyn Guenther, University of Western Ontario, London, ON, Canada
  - Location: E-Poster Presentation Center 3
- Abstract #2345: 1:25 p.m. 1:30 p.m. ET
  - Improvements in Fingernail Lesions in Patients with Moderate-to-Severe Psoriasis Treated with Ixekizumab Versus Placebo and Etanercept: Results from UNCOVER-2
  - Presenter: Lyn Guenther, University of Western Ontario, London, ON, Canada
  - Location: E-Poster Presentation Center 3
- Abstract #2666: 1:55 p.m. 2:00 p.m. ET
  - Ixekizumab Improves Physical Function, Quality of Life, and Work Productivity in Biologic Disease-Modifying Antirheumatic Drug-Naive Patients with Active Psoriatic Arthritis
  - Presenter: Alice Gottlieb, Tufts Medical Center, Boston, MA
  - Location: E-Poster Presentation Center 3
- Abstract #3232: 2:05 p.m. 2:10 p.m. ET
  - Ixekizumab, a Novel Anti-IL-17A Antibody, Exhibits Low Immunogenicity During Long-Term Treatment in Patients with Psoriasis
  - Presenter: Andrew Blauvelt, Oregon Medical Research Center, Portland, OR
  - Location: E-Poster Presentation Center 3

## Monday, March 7

- Abstract #2709: 8:15 a.m. 8:20 a.m. ET
  - Safety Profile of Patients Achieving Complete or Near Complete Resolution of Moderate-to-Severe Psoriasis After 12 Weeks of Etanercept or Ixekizumab: Integrated Analyses from UNCOVER-2 and UNCOVER-3
  - Presenter: Andrew Blauvelt, Oregon Medical Research Center, Portland, OR
  - Location: E-Poster Presentation Center 1
- Abstract #2710: 10:50 a.m. 10:55 a.m. ET
  - Treatment with Ixekizumab Over 60 weeks Provides Sustained Improvements in Health-Related Quality of Life: Results from UNCOVER-1, a Randomized Phase 3 Trial
  - i Presenter: Richard Langley, Dalhousie University, Halifax, NS
  - Location: E-Poster Presentation Center 1
- Abstract #2501: 10:55 a.m. 11:00 a.m. ET
  - Treatment with Ixekizumab Over 60 weeks Provides Sustained Improvements in Itch and Other Patient-Reported Outcomes: Results from UNCOVER-1, a Phase 3 Trial
  - Presenter: Gil Yosipovitch, Temple University, Philadelphia, PA
  - Location: E-Poster Presentation Center 1
- Abstract #2711: 11:00 a.m. 11:05 a.m. ET
  - Treatment with Ixekizumab Over 60 Weeks Provides Sustained Improvements in Work Productivity and Activity Levels: Results from UNCOVER-1, a Phase 3 Trial in Patients with Moderate-to-Severe Psoriasis

- Presenter: April Armstrong, University of Colorado Denver, Denver, CO
- Location: E-Poster Presentation Center 1
- Abstract #3257: 11:20 a.m. 11:25 a.m. ET
  - Evaluation of the Psoriasis Skin Appearance and Bothersomeness Measure in Patients with Moderate-to-Severe Psoriasis Treated with Ixekizumab Compared to Etanercept and Placebo: Results from UNCOVER-2
  - Presenter: Orin Golblum, Eli Lilly & Company, Indianapolis, IN
  - Location: E-Poster Presentation Center 1

#### **About Ixekizumab**

Ixekizumab is an IgG4 monoclonal antibody that selectively binds with interleukin 17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Ixekizumab inhibits the release of pro-inflammatory cytokines and chemokines.

## About Moderate-to-Severe Plaque Psoriasis

Psoriasis is a chronic, immune disease that affects the skin. It occurs when the immune system sends out faulty signals that speed up the growth cycle of skin cells. Psoriasis affects approximately 125 million people worldwide, approximately 20 percent of whom have moderate-to-severe plaque psoriasis. Psoriasis can occur on any part of the body and is associated with other serious health conditions, such as diabetes and heart disease. The most common form of psoriasis, plaque psoriasis, appears as raised, red patches covered with a silvery white buildup of dead skin cells.

# About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at <a href="www.lilly.com">www.lilly.com</a> and <a href="mailto:newsroom.lilly.com/social-channels">newsroom.lilly.com/social-channels</a>.

#### P-LLY

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about ixekizumab as a potential treatment for moderate-to-severe plaque psoriasis, and reflects Lilly's current belief. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that ixekizumab will receive additional regulatory approvals or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

Refer to: Jen Dial; dial jennifer kay@lilly.com; 317-220-1172 (Lilly BioMedicines)



<sup>&</sup>lt;sup>1</sup> Psoriasis media kit. National Psoriasis Foundation website. <a href="https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf">https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf</a>. Accessed February 29, 2016.

<sup>&</sup>lt;sup>2</sup> Psoriasis. American Academy of Dermatology website. <a href="https://www.aad.org/media-resources/stats-and-facts/conditions/psoriasis">https://www.aad.org/media-resources/stats-and-facts/conditions/psoriasis</a>. Accessed February 29, 2016.

To view the original version on PR Newswire, visit: <a href="http://www.prnewswire.com/news-releases/lilly-to-present-phase-3-data-at-the-american-academy-of-dermatology-aad-annual-meeting-for-ixekizumab-in-psoriasis-and-psoriatic-arthritis-300228548.html">http://www.prnewswire.com/news-releases/lilly-to-present-phase-3-data-at-the-american-academy-of-dermatology-aad-annual-meeting-for-ixekizumab-in-psoriasis-and-psoriatic-arthritis-300228548.html</a>

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