

# Pfizer Announces 12 Presentations Including New Research Data on Tofacitinib for Chronic Plaque Psoriasis and Atopic Dermatitis at World Congress of Dermatology

Monday, June 08, 2015 - 07:00am

## Reinforces Pfizer's Leadership in JAK Inhibition Research

Pfizer Inc. (NYSE:PFE) announced today that it has twelve presentations, including new research data on tofacitinib for chronic plaque psoriasis and atopic dermatitis, at the upcoming 23rd World Congress of Dermatology (WCD) meeting to be held on June 8-13 in Vancouver, Canada. Among the highlights are three late-breaking research presentations, including 52-week pooled results from the **O**ral treatment **P**soriasis **T**rials (OPT) Pivotal studies, an integrated safety summary across the OPT development program for oral tofacitinib, and the first presentation of two year results from OPT Extend, the ongoing long-term extension study of tofacitinib in moderate to severe chronic plaque psoriasis. In addition, new Phase 2a data for topical tofacitinib in the treatment of atopic dermatitis will be presented for the first time.

“We are proud of the data from the tofacitinib psoriasis clinical development program being presented at WCD as it adds to the body of evidence regarding the potential of tofacitinib as an additional oral treatment option for moderate to severe chronic plaque psoriasis,” said Rory O'Connor, senior vice president, Global Medical Affairs, Global Innovative Pharmaceuticals Business, Pfizer Inc. “The breadth and depth of the presentations at WCD underscores Pfizer's leadership in oral Janus kinase (JAK) inhibition research.”

Pfizer continues to invest in the study of JAK inhibition across chronic inflammatory and immune-mediated diseases.

A supplemental new drug application (sNDA) for tofacitinib 5 mg and 10 mg tablets is currently under review with the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. The FDA has provided an anticipated Prescription Drug User Fee Act (PDUFA) action date of October 2015 for the sNDA. This sNDA is the first in a number of regulatory applications that Pfizer intends to submit around the world for a potential tofacitinib psoriasis indication in 2015 and beyond.

The following Pfizer research data will be presented at WCD:

Three late-breaking presentations evaluating the safety and efficacy of tofacitinib:

- “Efficacy, safety, and patient-reported outcomes up to 52 weeks with tofacitinib, an oral Janus kinase inhibitor for the treatment of chronic plaque psoriasis: results from two randomized, Phase 3 trials.” Papp K, Krueger J, Feldman, et al. [Oral Presentation FC04-08; June 9, 2015 2:45 – 3:00 p.m.]

- “Efficacy and safety of topical Janus kinase inhibitor tofacitinib in the treatment of atopic dermatitis: results of a Phase 2a randomized clinical trial.” Bissonnette R, Papp K, Poulin Y, et al. [Poster Presentation 72192P]
- “Safety of tofacitinib, an oral Janus kinase inhibitor, for the treatment of chronic plaque psoriasis: integrated data analysis from the global clinical trials.” Langley R, Cohen A, Foley P, et al. [Oral Presentation FC11-08; June 10, 2015 9:15 – 9:30 a.m.]

Important safety and efficacy data from the OPT clinical development program, including interim results from an ongoing long-term study:

- “Two Phase 3 studies of oral tofacitinib in patients with moderate to severe plaque psoriasis: 16-week efficacy and safety results.” Papp K, Menter A, Abe M, et al. [Poster Presentation 72192b]
- “Efficacy of tofacitinib in moderate-to-severe psoriasis: subgroup analysis of patients by baseline characteristics.” Menter A, Papp K, Cather J, et al. [Feature Poster Display 72192f]
- “Tofacitinib in patients with moderate to severe chronic plaque psoriasis: 2-year efficacy and safety in an open-label long-term extension study.” Augustin M, Paul C, Valenzuela F, et al. [Poster Presentation 72192l]
- “Improvement in patient-reported outcomes up to 52 weeks: results from two Phase 3 studies of tofacitinib for moderate to severe chronic plaque psoriasis.” Mamolo C, Steven Feldman S, Matthias Augustin M, et al. [Oral Presentation 72192b; June 12, 2015 08:15 - 08:25 a.m.]
- “Clinically meaningful improvement in pruritus with tofacitinib: results from a Phase 3 program.” Mamolo C, Luger T, Cappelleri J, et al. [Poster Presentation 72192d]

Key findings providing greater insight into validity of clinical measures, treatment patterns and healthcare resource utilization:

- “Validation of the Physician Global Assessment: confirmation with Phase 3 clinical trials.” Cappelleri J, Callis-Duffin K, Bushmakina A, et al. [Oral Presentation 72192c; Saturday, June 13, 2015 12:55 - 1:05 p.m.]
- “Treatment patterns and healthcare resource utilization (HCRU) among psoriasis patients in a large United States national claims database.” Wiederkehr D, Mamolo C, Gruben D, et al. [Oral Presentation 72192j; Thursday, June 11, 2015 1:55 – 2:05 p.m.]
- “Initiation, switching and cessation of psoriasis treatments among patients with moderate to severe psoriasis in the United States: results from a retrospective cohort study.” Mamolo C, Armstrong A, Koning J, et al. [Oral Presentation 72192m; Wednesday, June 10, 2015 8:00 – 9:30 a.m.]

Clinical pharmacology research characterizing tofacitinib pharmacokinetics:

- “Population pharmacokinetics of tofacitinib in adult patients with moderate to severe chronic plaque psoriasis.” Ma G, Xie R, Ito K, et al. [Poster Presentation 72192e]

## About the OPT Clinical Trial Program

The Phase 3 OPT clinical trial program is a global, comprehensive clinical development program that includes over 3,600 patients in 36 countries, and is one of the largest global clinical trial programs in moderate to severe chronic plaque psoriasis to date. The OPT Program consists of five Phase 3 studies of tofacitinib in adults with moderate to severe chronic plaque psoriasis including:

- **OPT Pivotal #1/OPT Pivotal #2:** Phase 3 registration trials to evaluate the safety and efficacy of tofacitinib in patients with plaque psoriasis who had a Psoriasis Area and Severity Index (PASI) score of

12 or greater and were candidates for systemic or phototherapy.

- **OPT Compare:** A 12-week, Phase 3 study comparing the efficacy and safety of tofacitinib 5 mg and 10 mg twice daily to ENBREL® (etanercept) 50 mg twice weekly as well as to placebo.
- **OPT Retreatment:** A Phase 3 study evaluating the efficacy and safety of the withdrawal from, and then the retreatment with, tofacitinib 5 mg and 10 mg twice daily compared to placebo.
- **OPT Extend:** An ongoing long-term extension study evaluating the safety and tolerability of tofacitinib. Patients who participated in the Phase 2 or Phase 3 studies had the option, if eligible, to enroll in this study.

## About Plaque Psoriasis

Psoriasis is a chronic, immune-mediated inflammatory skin disease, affecting the skin and other parts of the body, such as nails. It affects approximately two-to-three percent of people worldwide.<sup>1,2,3,4,5,6,7</sup> The most common form is plaque psoriasis, which affects about 80 percent of people who have the condition.<sup>8</sup> Of those, as many as 20 percent have moderate to severe chronic plaque psoriasis.<sup>6</sup> A need for additional therapies remains. According to published surveys, approximately 50 percent of patients with psoriasis are dissatisfied with their treatment.<sup>9</sup> Under-treatment also represents a significant problem. Even though guidelines typically state that patients with moderate to severe psoriasis are candidates for systemic therapy, many treated adult plaque psoriasis patients appear to be undertreated, with approximately 30 percent of treated moderate patients and 22 percent of treated severe patients receiving only topical therapy in the United States.<sup>9</sup>

## Pfizer Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at [www.pfizer.com](http://www.pfizer.com).

*DISCLOSURE NOTICE: The information contained in this release is as of June 8, 2015. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.*

*This release contains forward-looking information about tofacitinib, including a potential new indication for tofacitinib for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis (the "Potential Indication"), plans to submit regulatory applications for the Potential Indication in various jurisdictions and its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including, without limitation, the ability to meet anticipated clinical trial commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; whether and when any applications may be filed with regulatory authorities in jurisdictions other than the United States for tofacitinib for the Potential Indication; whether and when the FDA may approve the supplemental new drug application for tofacitinib for the Potential Indication and whether and when regulatory authorities in other jurisdictions may approve any such other applications, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the*

*efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of tofacitinib for the Potential Indication; and competitive developments.*

*A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).*

1 Levy L, Solomon S, Emer J. Dove Medical Press Ltd. Psoriasis: Targets and Therapy 2012;2 29–43.

- Ref#1 Levy (Dove Press 2012)/p29/col1/par2/ln1-2

2 Rachakonda T, Schupp CW, Armstrong AW. Psoriasis prevalence among adults in the United States. J Am Acad Dermatol 2014; 70 (3):512-16.

- Ref#2a Rachakonda (J Am Acad Dermatol 2014)/pg1/Conclusions
- Ref#2b Rachakonda (J Am Acad Dermatol 2014)/pg1/col1/par1/ln1-3

3 Augustin M, Alvaro-Gracia JM, Bagot M., et al. A framework for improving the quality of care for people with psoriasis. J Eur Acad Dermatol. 2012;26 (Suppl. 4):1–16.

- Ref#3 Augustin (J Eur Acad Dermatol Venereol 2012)/pg2/col2/par4/ln1-3

4 Perera GK, Di Meglio P, Nestle FO. Psoriasis. Annu Rev Pathol Mech Dis. 2012;7:385-422.

- Ref#4a Perera (Annu Rev Pathol Med Dis 2012)/p386/col2/par1/ln3-7
- Ref#4b Perera (Annu Rev Pathol Med Dis 2012)/p409/col2/par1/ln3-11

5 Nestle FO, Kaplan DH, Barker J. Psoriasis. N Engl J Med. 2009;361(5):496-509.

- Ref#5 Nestle (N Engl J Med 2009)/p497/fig1/ln3-4

6 Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol. 2008;58(5):826-50.

- Ref#6a Menter (J Am Acad Dermatol 2008)/p826/col1/p1/ln1-2
- Ref#6b Menter (J Am Acad Dermatol 2008)/p828/col2/par1/ln6-11

7 Johnson MA, Armstrong AW. Clinical and histologic diagnostic guidelines for psoriasis: a critical review. Clin Rev Allerg Immunol. 2013;44(2):166-172.

- Ref#7 Johnson (Clinic Rev Allerg Immunol 2013)/p166/col1/p1/ln1-3

8 American Academy of Dermatology. Psoriasis. Available at: <https://www.aad.org/media-resources/stats-and-facts/conditions/psoriasis>. January 13, 2015.

- Ref#8 AAD (Psoriasis)/p1/par1/ln2-3

9 Armstrong, A. Undertreatment, Treatment Trends, and Treatment Dissatisfaction Among Patients With Psoriasis and Psoriatic Arthritis in the United States. Findings From the National Psoriasis Foundation Surveys, 2003-2011. JAMA Dermatology. 2013; 5264.

- Ref#9 Armstrong (JAMA Dermatol 2013)/pE1/Results

Media Contact: Steven Danehy M: 978-273-3946 E: Steven.Danehy@pfizer.com or Investor Contact: Chuck Triano O: 212-733-3901 E: Charles.E.Triano@pfizer.com