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Patients Show Significant Improvement in Signs and Symptoms of Psoriatic Arthritis, Less Progression of Structural Joint Damage When Treated with Ixekizumab for 24 Weeks

INDIANAPOLIS, Nov. 8, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that psoriatic arthritis (PsA) patients treated with ixekizumab for 24 weeks achieved significant improvements in signs and symptoms of their disease when compared to placebo, while also experiencing significantly less progression of radiographic structural joint damage, reduced disability when performing certain physical functions and improved skin clearance of plaque psoriasis.

Detailed results of the SPIRIT-P1 study were presented during the American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting in San Francisco. Ixekizumab is the company's investigational medicine for the treatment of active PsA and moderate-to-severe plaque psoriasis.

"The SPIRIT-P1 data show that ixekizumab may be able to address unmet or underserved needs that many patients living with psoriatic arthritis have, including the reduction of painful and debilitating skin and joint inflammation, which are the hallmarks of this chronic disease," said Philip Mease, M.D., chief of rheumatology research, Swedish Medical Center, and clinical professor, University of Washington, Seattle. Dr. Mease is a SPIRIT-P1 study investigator.

During the 24-week, double-blind period of this Phase 3 study, patients who had never received a biologic disease-modifying antirheumatic drug (bDMARD) were treated with either 80 mg of ixekizumab once every two weeks or every four weeks (following a 160 mg starting dose); adalimumab at the approved dose of 40 mg every other week; or placebo. Adalimumab was employed as an active control in the SPIRIT-P1 study and was not powered for comparison with ixekizumab treatment groups.

Significant Improvements in Disease Signs and Symptoms, Structural Joint Damage
In both dosing regimens, ixekizumab-treated patients demonstrated significant improvements compared with placebo in disease activity of PsA as demonstrated by the proportion of patients achieving an ACR20 response at 24 weeks, the study's primary objective. Improvements were experienced by ixekizumab-treated patients as early as one week after treatment initiation. ACR20 represents at least a 20 percent reduction in a composite measure of disease activity as defined by the ACR. Other measures included ACR50 and ACR70, which represent 50 percent and 70 percent reductions in disease activity.

At 24 weeks, 62 percent of patients treated every two weeks and 58 percent of patients treated every four weeks with ixekizumab achieved ACR20 compared with 30 percent of placebo-treated patients. The proportions of ixekizumab-treated patients who achieved ACR50 when treated every two weeks or every four weeks were 47 percent and 40 percent, respectively, compared with 15 percent of patients treated with placebo. Furthermore, 34 percent of patients treated with ixekizumab every two weeks and 23 percent of those treated every four weeks experienced a 70 percent reduction in disease activity. Six percent of patients treated with placebo achieved this level of improvement.

Patients treated with ixekizumab at both dosing regimens also experienced significantly less radiographic progression of structural joint damage than those treated with placebo, as measured by the change from baseline in the van der Heijde modified total Sharp score (mTSS) for PsA at 24 weeks. Structural joint damage caused by PsA may lead to permanent joint deformity and reduced physical function.

Reduced Disability in Physical Function, Improved Skin Clearance
Ixekizumab treatment groups also experienced significant improvements compared with placebo in other key secondary measures, including physical function as assessed using the Health Assessment Questionnaire Disability Index (HAQ-DI), and improved skin clearance of plaque psoriasis as measured by the Psoriasis Area and Severity Index (PASI), including PASI75, 90 and 100. A PASI75 score indicates at least a 75 percent reduction in a patient's plaque psoriasis from the patient's baseline assessment, while PASI90 reflects a 90 percent reduction and PASI100 represents a 100 percent reduction, reflecting complete skin clearance.

Efficacy results with adalimumab compared with placebo during the SPIRIT-P1 study were significant on most measures. At 24 weeks, 57 percent of patients treated with adalimumab, the study's active control, achieved ACR20, while 39 percent and 26 percent achieved ACR50 and ACR70, respectively.

The incidence of treatment-emergent adverse events (TEAE) was greater with ixekizumab treatment compared with placebo. The most common (≥4 percent) adverse events observed with ixekizumab treatment were injection site reaction, injection site

erythema and nasopharyngitis. These events are consistent with those reported in the Phase 3 studies of ixekizumab for the treatment of moderate-to-severe plaque psoriasis (UNCOVER 1, 2, 3). Serious adverse events and discontinuation rates due to adverse events were not significantly different between treatment groups.

"Many people living with this debilitating disease are still searching for an effective treatment," said J. Anthony Ware, M.D., senior vice president, product development, Lilly Bio-Medicines. "These results further support our continuing investigation of ixekizumab for the treatment of psoriatic arthritis, and our belief that this investigational medicine may offer a viable choice in the future for people seeking a better way to manage their disease."

About the SPIRIT-P1 Study
SPIRIT-P1 is a Phase 3 randomized, active- and placebo-controlled study examining the effect of ixekizumab compared with placebo in patients with active PsA who are bDMARD-naïve. Patients were required to have an established diagnosis of PsA and active disease for at least six months. The trial included 417 patients (stratified 1:1:1:1 ratio for all treatment groups) with active psoriatic arthritis who had at least three tender and three swollen joints and the presence of at least one disease-related joint erosion of the hand or foot as seen on X-ray or a C-reactive protein (CRP) greater than 6 mg/L at screening. During the study, ixekizumab-treated patients received a starting dose of 160 mg administered subcutaneously (SC), as two 80 mg injections, followed by one of two dosing regimens: either 80 mg administered SC once every two weeks or 80 mg administered SC once every four weeks. Adalimumab at the approved dose of 40 mg SC and regimen of every other week was selected as the active control for comparison with placebo. The SPIRIT-P1 study will also evaluate the long-term efficacy and safety of ixekizumab in PsA for up to three years.

About ixekizumab
Ixekizumab is a monoclonal antibody with high affinity and specificity that binds to and neutralizes the pro-inflammatory cytokine interleukin-17A (IL-17A), which research has shown can contribute to autoimmune diseases, including PsA and psoriasis. Ixekizumab does not bind to cytokines IL-17B, IL-17C, IL-17D, IL-17E or IL-17F and is administered via subcutaneous injection (under the skin). Ixekizumab is also in clinical development for the treatment of moderate-to-severe plaque psoriasis.

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 www.lilly.com and newsroom.lilly.com/social-channels.

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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 psoriatic arthritis 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 future study results will be similar to the results to date or that ixekizumab will receive regulatory approvals. 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:
J. Scott MacGregor; jsmacgregor@lilly.com; 317-440-4699 (media)
Phil Johnson; johnson_philip_l@lilly.com; 317-655-6874 (investors)

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