Abatacept as effective as adalimumab in rheumatoid arthritis

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Data from AMPLE presented at EULAR 2013, the Annual Congress of the European League Against Rheumatism, demonstrate comparable efficacy and similar safety profiles between subcutaneous abatacept (ABA) and adalimumab (ADA).

AMPLE, the first two-year head-to-head biologics trial, was comprised of 646 biologic-naïve patients with active rheumatoid arthritis (RA) equally randomised to either ABA or ADA, with a stable dose of methotrexate (MTX). 79.2% (252 of 318) ABA patients and 74.7% (245 of 328) ADA patients completed the trial.

RA is a chronic autoimmune disease that principally attacks flexible joints. Affecting approximately 1 in 100 people worldwide, RA can cause pain, stiffness, progressive joint destruction and deformity, and reduce physical function, quality of life and life expectancy. At least 50% of RA patients in developed countries are unable to hold down a full-time job within 10 years of onset.2

"To date, there have been no randomised, controlled studies directly comparing the efficacy and safety of different biological DMARDs using the combination of a biologic medication and methotrexate, the most commonly prescribed treatment approach in moderate to severe RA", said lead author of the study Dr. Michael Schiff, University of Colorado, USA.

"This robust data set demonstrates that subcutaneous abatacept and

adalimumab are equally efficacious in clinical, functional and radiographic outcomes. This study is a great leap forward for patients as it shows another treatment is as effective as adalimumab" Dr. Schiff concluded.

AMPLE is a Phase IIIb randomised, investigator-blinded study with a primary efficacy endpoint at day 365. Biologic-naïve patients with active RA and an inadequate response to MTX were randomized to 125 mg ABA weekly (without an IV load) or 40 mg ADA bi-weekly, with a stable dose of MTX. All clinical efficacy endpoints were captured and read through day 729, including radiographs assessed using the van der Heijde modified Total Sharp score (mTSS), by readers blinded to treatment allocation and sequence.

At Year one, 64.8% ABA and 63.4% ADA patients were ACR20* responders. Consistent with Year one, clinical efficacy measures and inhibition of radiographical progression were comparable between groups at Year two. There were similar rates of adverse events (AE) and serious adverse events (SAE) in the ABA and ADA groups (13.8% vs. 16.5%) and malignancies (2.2% vs. 2.1%). More autoimmune AEs occurred in the ABA arm (3.8% vs. 1.8%); none were SAEs. Injection site reactions occurred less frequently in the ABA arm (4.1% vs. 10.4%). There were fewer discontinuations due to adverse events (3.8% vs. 9.5%), serious adverse events (1.6% vs. 4.9%), and due to serious infections (0/12 vs. 9/19 patients) in the ABA vs. ADA groups, respectively.

Abatacept (Orencia), produced by Bristol-Myers Squibb, is a first-in-class biologic which reduces co-stimulation of T-cells, in turn reducing activation of other cells in the inflammatory process, blocking the pain, inflammation and joint progression pathways in RA.

Adalimumab (Humira), produced by Abbott, is a biologic TNF-blocker

(anti-TNF). Adalimumab binds to TNF-alpha receptors, blocking the pain, inflammation and joint progression pathways in RA.

More information: * ACR (American College of Rheumatology) criteria measures improvement in tender or swollen joint counts and improvement in three of the following five parameters: acute phase reactant (such as sedimentation rate), patient assessment, physician assessment, pain scale and disability/functional questionnaire. ACR20 refers to a 20% improvement in tender/swollen joint counts, as well as in three of the five criteria.

1.Schiff M et al., Head-to-head comparison of subcutaneous abatacept versus adalimumab on background methotrexate in RA: two year results from the AMPLE study [abstract]. EULAR Annual European Congress of Rheumatology; 12-15 June 2013; Madrid, Spain. Abstract nr. OP0044

2.Chronic Diseases and Health Promotion: Chronic Rheumatic Conditions, World Health Organization. Available from: www.who.int/chp/topics/rheumatic/en/ Last accessed: May 2013

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