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ASIA EDITION

Lilly and Incyte's drug gets FDA approval

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As part of the approval, the companies have agreed to conduct a randomized controlled clinical trial to evaluate the long-term safety of baricitinib in patients with rheumatoid arthritis.

Singapore- Eli Lilly and Company and Incyte Corporation announced that the U.S. Food and Drug Administration (FDA) has approved the 2-mg dose of OLUMIANT (baricitinib), a once-daily oral medication for the treatment of adults with moderately-to-severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF) inhibitor therapies. Use of OLUMIANT in combination with other Janus kinase (JAK) inhibitors or biologic disease-modifying anti-rheumatic drugs (bDMARDs), or with potent immune-suppressants such as azathioprine and cyclosporine is not recommended. OLUMIANT may be used as monotherapy or in combination with methotrexate (MTX) or other non-biologic DMARDs.

"We are pleased to provide RA patients in the U.S. an effective treatment option with OLUMIANT, as people with RA who have had an inadequate response to TNF inhibitors are generally considered to be some of the most difficult to treat RA patients," said Christi Shaw, president, Lilly Bio-Medicines.

As part of the approval, the companies have agreed to conduct a randomized controlled clinical trial to evaluate the long-term safety of baricitinib in patients with rheumatoid arthritis.