

Eli Lilly : FDA Grants Fast Track Designation To Baricitinib Development Program

(RTTNews.com) – Eli Lilly and Co. (LLY) and Incyte Corp. (INCY) announced that the U.S. Food and Drug Administration has granted Fast Track designation to baricitinib, which is being studied for the treatment of systemic lupus erythematosus or SLE.

The Fast Track designation process aims to facilitate the development and expedite the review of new medicines that treat serious conditions and fill unmet medical needs, with the goal of delivering potentially important therapies to patients sooner.

Earlier this year, positive results of a Phase 2 study of baricitinib for the treatment of SLE, which informed the FDA's Fast Track designation, were published by The Lancet and presented at the European Congress of Rheumatology.

Lilly said it is currently studying two doses of baricitinib in Phase 3 SLE trials. Additionally, Lilly is investigating baricitinib as a potential treatment for moderate to severe atopic dermatitis, a serious form of eczema, with Phase 3 results projected to be shared during the first half of 2019.

Baricitinib is approved in over 50 countries globally as OLUMIANT for the treatment of adults with rheumatoid arthritis.

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