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Gilead Sciences submits NDA to treat RA in Japan

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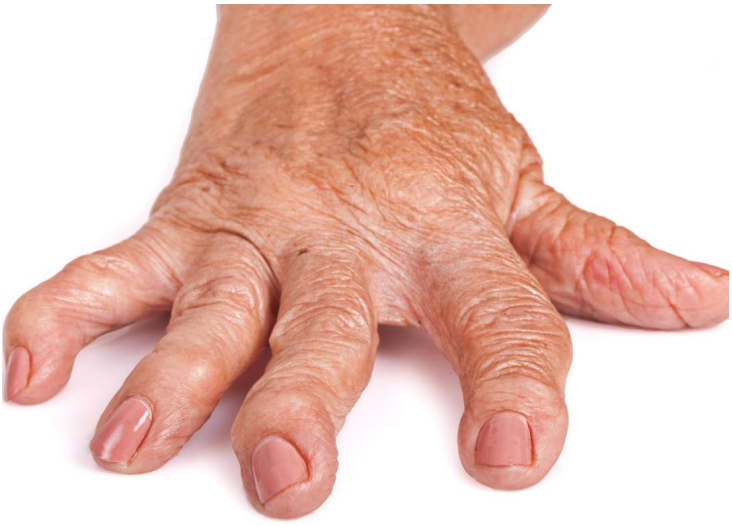

Gilead Sciences, Inc. has announced the New Drug Application (NDA) for filgotinib, an investigational, oral, selective JAK1 inhibitor for the treatment of adults with rheumatoid arthritis (RA) has been submitted to the Japanese Ministry of Health, Labor and Welfare (MHLW).

The NDA for filgotinib is supported by data from the Phase 3 FINCH clinical trial program in which once-daily treatment with filgotinib demonstrated the potential to improve clinical signs and symptoms, to achieve low disease activity and remission, and to inhibit structural damage for patients living with RA. Safety data across the FINCH clinical trial program was consistent with previously reported results.

“Despite multiple medications currently available to treat rheumatoid arthritis, there are still far too many people who do not experience adequate relief from their symptoms,” said John Sundy, MD, PhD, Senior Vice President, Inflammation and Respiratory Diseases, Gilead Sciences. “The FINCH clinical trial program demonstrated that filgotinib may offer a wide range of people living with RA, including those in the early treatment and those who have tried standard therapies without success, an important new treatment option.”

“This new drug application is an important milestone as we continue to expand Gilead’s presence in Japan to now also include inflammation,” said Luc Hermans, MD, President and Representative Director, Gilead Sciences, K.K. “We are committed to bringing innovative products to patients and healthcare providers in Japan, expanding beyond antivirals into new areas where our medicines can make a meaningful difference to patients.”

There are estimated to be up to one million people living with RA in Japan.

Filgotinib is an investigational agent and is not approved anywhere globally. Its efficacy and safety have not been established by any regulatory authorities.