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ASIA EDITION

FDA Grants Breakthrough Therapy Designation for Genentech's Gazyva (Obinutuzumab)

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There are currently no FDA-approved medicines for lupus nephritis



Genentech, a member of the Roche Group has announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation (BTD) to Gazyva® (obinutuzumab) for adults with lupus nephritis. This designation was granted based on data from the Phase II NOBILITY study in adult patients with proliferative lupus nephritis which showed Gazyva, in combination with standard of care (mycophenolate mofetil or mycophenolic acid and corticosteroids), demonstrated enhanced efficacy compared to placebo plus standard of care alone in achieving complete renal response at one year.

New treatment options are needed for lupus nephritis, a potentially life-threatening inflammation of the kidneys that most commonly affects women," said Sandra Horning, M.D., chief medical officer and head of Global Product Development. "We are committed to developing Gazyva as a potential new therapy for lupus nephritis and plan to begin enrolling patients in a Phase III trial next year."

Lupus nephritis is a potentially life-threatening manifestation of systemic lupus erythematosus resulting from inflammation of the kidneys and is associated with a high risk of end-stage renal disease or death. Breakthrough Therapy Designation is designed to accelerate the development and review of medicines intended to treat serious or life-threatening conditions with preliminary evidence that indicates they may demonstrate a substantial improvement over existing therapies. This is the 27th Breakthrough Therapy Designation for Genentech's portfolio of medicines.

Lupus nephritis overwhelmingly impacts women, particularly young women of color. About 90% of those diagnosed with lupus are women, and African American, Hispanic, Native American and Asian American women are two to three times more likely than Caucasian women to get lupus. Genentech is committed to addressing barriers to clinical trial participation and advancing inclusive research to create new standards for clinical studies. Genentech is taking action to recruit a broader, more diverse population of participants into clinical trials, including diseases such as lupus nephritis, to ensure clinical trial participants more closely reflect those impacted by the disease for which a medicine is being studied.