



Femta Pharmaceuticals Announces IND Filing Of FM101, A Novel Monoclonal Antibody Targeting IL-6 with Potent Anti-Inflammatory Activity

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Femta Pharmaceuticals announced today that it has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) to initiate a clinical development program for FM101, a high-affinity, humanized monoclonal antibody against Interleukin-6 (IL-6), in patients with rheumatoid arthritis (RA).

FM101 is part of a novel class of immune modulators that inhibit the action of the pro-inflammatory cytokine IL-6. IL-6 has been shown to be a major player in the etiology of a number of inflammatory diseases. Pre-clinical studies have shown that FM101 is effective in inhibiting IL-6 both *in vivo* and *in vitro*. GLP toxicology studies have shown FM101 to be safe and well tolerated at doses at least as high as 100mg/kg.

The proposed Phase I study entitled “A Multicenter, Randomized, Double-Blind, Placebo Controlled, Phase 1 Safety and Preliminary Efficacy Study of FM101 in Patients with Active Rheumatoid Arthritis despite Methotrexate Therapy” is designed to evaluate the safety and tolerability of increasing and multiple doses of the FM101 in patients with moderate to severe RA.

RA is a progressive and debilitating disease of unknown etiology that results in destruction of the synovial joints and has a worldwide distribution with an estimated prevalence of 1 to 2%. Prevalence increases with age, approaching 5% in women over 55 years. The average annual incidence in the United States (US) is about 70 per 100,000 annually for a total of 1.3 million Americans ≥ 18 years of age. Both incidence and prevalence of RA are two to three times greater in women than in men and about 80% of patients develop RA between ages 30 and 60. The cost of RA in the US is approximately \$128 billion per year in medical care and lost wages and productivity. In addition to the high economic cost, RA also accounts for 22% of all deaths from arthritis, and people with RA are more likely to die than persons of the same age in the general population.

About FM101

FM101 is a recombinant humanized monoclonal antibody directed against a neutralizing epitope on human IL-6. IL-6 is a pro-inflammatory molecule that is found in the joints of RA patients and contributes to the pain, joint destruction and chronic inflammation commonly seen in this population. Pre-clinical studies have shown that FM101 is effective in inhibiting IL-6 in a number of *in vitro* and *in vivo* models.



About Femta

Femta Pharmaceuticals is focused on the rapid and cost effective development of highly effective and competitive therapeutic monoclonal antibodies for the treatment of various disease states. Our monoclonal antibodies have applications in the areas of inflammation, autoimmune disease and oncology. Femta develops high affinity, high specificity monoclonal antibodies with improved effector functions as well as favorable safety and pharmacokinetic profiles. The high affinity of our antibodies will contribute to making our products more efficacious with better safety profiles, as well as potentially reducing drug dosage. Femta's product candidates and programs are protected by the company's extensive global intellectual property portfolio. More information about Femta can be found at www.femtapharma.com.

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