



XTL BIOPHARMACEUTICALS' PRECLINICAL STUDIES OF HCDR1 DEMONSTRATE THERAPEUTIC POTENTIAL IN THE TREATMENT OF SJÖGREN'S SYNDROME

- *New patent application filed for hCDR1 in the treatment of Sjögren's syndrome*
- *Substantial unmet medical need in estimated 4 million U.S. patients*
- *Second indication significantly expands market opportunity for XTL's lead drug candidate*

RAANANA, ISRAEL - (January 5, 2017) – [XTL Biopharmaceuticals Ltd.](#) (NASDAQ: XTLB, TASE: XTLB.TA) (“XTL” or the “Company”), a clinical-stage biopharmaceutical company developing treatments for autoimmune diseases, today announced the Company intends to pursue Sjögren's syndrome as the second indication for its lead drug candidate hCDR1. Currently in development for the treatment of systemic lupus erythematosus (SLE), hCDR1 has been tested in over 400 patients, and is set to enter a global Phase 2 trial for SLE.

New *in-vitro* data from studies evaluating cells obtained from serum samples of patients with Sjögren's syndrome demonstrate that incubation with hCDR1 resulted in a significant reduction of gene expression of three cytokines considered to be pathogenic in Sjögren's syndrome. These data correspond to some of the *in vitro* data obtained in studies testing serum samples from patients with SLE.

Josh Levine, CEO of XTL, stated, “Sjögren's syndrome impacts more than twice the number of people as SLE does in the U.S. and represents a significant unmet therapeutic need. While there are currently only a handful of drugs in clinical trials to treat Sjögren's syndrome, there is no specific FDA approved therapy to treat the systemic manifestations of the disease. Given the similarities of the disease manifestations between Sjögren's syndrome and SLE, these new *in-vitro* data further support the clinical results achieved in the prior Phase 2 trial of hCDR1 in SLE. Based on hCDR1's well established mechanism of action and its favorable safety profile in over 400 patients, we plan to pursue an accelerated clinical development path with hCDR1 for this new indication.”

A patent application has been filed with the U.S. Patent and Trademark Office for hCDR1 in the treatment of Sjögren's syndrome.

About Sjögren's syndrome

Sjögren's syndrome is a systemic autoimmune disease with some autoantibodies and clinical manifestations similar to those detected in SLE. Although many patients experience dry eyes, dry mouth, fatigue and joint pain, Sjögren's syndrome also causes dysfunction of organs such as the kidneys, gastrointestinal system, blood vessels, lungs, liver, pancreas, and the central nervous system. Patients also have a substantially higher risk of developing lymphoma. Today, as many as four million Americans are living with this disease, according to the Sjögren's Syndrome Foundation.



Current standard of care in the U.S. includes treating specific symptoms such as dry eyes, dry mouth, and arthritis. Systemic manifestations are often treated with drugs used to treat other autoimmune diseases, such as hydroxychloroquine, methotrexate, or azathioprine. However, these treatments are not sufficient in many patients and may have significant side effects. There is no approved specific drug for the treatment of systemic manifestations in Sjögren's syndrome.

About hCDR1

hCDR1 is a novel compound with a unique mechanism of action and clinical data on over 400 patients in three clinical studies. The drug has a favorable safety profile, is well tolerated by patients and has demonstrated efficacy in at least one clinically meaningful endpoint. For more information please see a peer reviewed article in Lupus Science and Medicine journal ([full article](#)).

About XTL Biopharmaceuticals Ltd. (XTL)

XTL Biopharmaceuticals Ltd., is a clinical-stage biotech company focused on the development of pharmaceutical products for the treatment of autoimmune diseases. The Company's lead drug candidate, hCDR1, is a world-class clinical asset for the treatment of autoimmune diseases including systemic lupus erythematosus (SLE) and Sjögren's Syndrome (SS). The few treatments currently on the market for these diseases are not effective enough for most patients and some have significant side effects. hCDR1 has robust clinical data in three clinical trials with 400 patients and over 200 preclinical studies with data published in more than 40 peer reviewed scientific journals.

XTL is traded on the Nasdaq Capital Market (NASDAQ: XTLB) and the Tel Aviv Stock Exchange (TASE: XTLB.TA). XTL shares are included in the following indices: Tel-Aviv Biomed, Tel-Aviv MidCap, and Tel-Aviv Tech Index.

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