



XTL BIOPHARMACEUTICALS ADVANCES FORMULATION OF ITS hCDR1 DRUG FOR CLINICAL TRIALS IN THE TREATMENT OF LUPUS THROUGH USE OF CYDEX PHARMACEUTICALS' CAPTISOL®

XTL to formulate hCDR1 using Captisol® in its advanced clinical studies

RAANANA, ISRAEL - (January 13, 2016) – XTL Biopharmaceuticals Ltd. (NASDAQ: XTLB, TASE: XTLB) (“XTL” or the “Company”), a clinical-stage biopharmaceutical company developing its lead product for the treatment of lupus, today announced that it has reached agreement with CyDex Pharmaceuticals Inc. (La Jolla, CA) (CyDex) for the use and supply of Captisol® in the formulation of its lead drug, hCDR1, for the treatment of systemic lupus erythematosus (SLE).

The agreement grants XTL a non-exclusive, royalty-free license to use Captisol® in the formulation of its drug for the purpose of conducting its advanced clinical study on hCDR1 for the treatment of SLE subject to the payment of certain milestone and other payments.

Josh Levine, Chief Executive Officer of XTL, commented, “We are pleased with the completion of this strategic agreement with CyDex for the use and supply of Captisol®. This partnership represents a key element of our preparations for the advanced clinical study of hCDR1 and together with our agreement with BioConnection NV for the production of our drug product, we believe this will advance much of the chemistry manufacturing and control activities required prior to IND approval.”

“With our progress on the production of the drug product and an FDA response to our proposed study design expected in early 2016, we are positioning ourselves to initiate the trial in the second half of 2016. We believe that hCDR1 has the potential to be a ‘first in class’ and ‘best in class’ drug in an area with a significant unmet medical need. There is currently no effective solution for SLE in the market and the competitive pipeline is remarkably weak,” Levine added.

About hCDR1

hCDR1 is a novel compound with a unique mechanism of action and with clinical data on over 400 patients in 3 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 further information please see a peer reviewed article in Lupus Science and Medicine journal ([full article](#)).

About Systemic Lupus Erythematosus (SLE)

Lupus is a chronic autoimmune disease involving many systems in the human body, including joints, kidneys, central nervous system, heart, hematological system and others. The biologic basis of the disease is a defect in the immune (defense) system, leading to production of self



(auto) antibodies, attacking the normal organs and causing irreversible damage. According to the Lupus Foundation of America, at least 1.5 million Americans have the disease (more than 5 million worldwide) with more than 16,000 new cases diagnosed each year. The majority of patients are women of childbearing years. There has been only one drug approved by the FDA in the last over 50 years and recently two of the few drugs in advanced development did not meet their primary endpoints in Phase 3 trials.

About Captisol®

Captisol® is a patent protected, uniquely modified cyclodextrin, whose chemical structure was rationally designed to enable the creation of new products by significantly improving solubility, stability, bioavailability and dosing of active pharmaceutical ingredients (APIs).

About XTL Biopharmaceuticals Ltd. (XTL)

XTL Biopharmaceuticals Ltd., a biopharmaceutical company, focuses on the acquisition, development, and commercialization of pharmaceutical products for the treatment of unmet clinical needs with a focus on treatments for autoimmune diseases.

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

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Cautionary Statement

This press release may contain forward-looking statements, about XTL's expectations, beliefs or intentions regarding, among other things, its product development efforts, business, financial condition, results of operations, strategies or prospects. In addition, from time to time, XTL or its representatives have made or may make forward-looking statements, orally or in writing. Forward-looking statements can be identified by the use of forward-looking words such as "believe," "expect," "intend," "plan," "may," "should" or "anticipate" or their negatives or other variations of these words or other comparable words or by the fact that these statements do not



relate strictly to historical or current matters. These forward-looking statements may be included in, but are not limited to, various filings made by XTL with the U.S. Securities and Exchange Commission, press releases or oral statements made by or with the approval of one of XTL's authorized executive officers. Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause XTL's actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause XTL's actual activities or results to differ materially from the activities and results anticipated in such forward-looking statements, including, but not limited to, the factors summarized in XTL's filings with the SEC and in its periodic filings with the TASE. In addition, XTL operates in an industry sector where securities values are highly volatile and may be influenced by economic and other factors beyond its control. XTL does not undertake any obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise. Please see the risk factors associated with an investment in our ADSs or ordinary shares which are included in our Annual Report on Form 20-F as filed with the U.S. Securities and Exchange Commission on April 28 2015.