XTL ANNOUNCES PUBLICATION OF RESULTS OF PHASE 2 STUDY ON hCDR1 (Edratide) IN PATIENTS WITH ACTIVE SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) IN LUPUS SCIENCE & MEDICINE

RAANANA, ISRAEL - (August 26, 2015) – XTL Biopharmaceuticals Ltd. (NASDAQ: XTLB, TASE: XTL) (“XTL” or the “Company”), announced today that previously reported results of a Phase 2b study on the safety and efficacy of its lead drug candidate, hCDR1 (Edratide) for the treatment of SLE (lupus) were published in the Lupus Science & Medicine Journal. See link for full article (full article).

The article, authored by leading rheumatologists, Dr. Murray Urowitz, Dr. David Isenberg and Dr. Dan Wallace, reported the results of a study conducted by Teva Pharmaceuticals in which Edratide demonstrated efficacy in one and possibly more clinically meaningful endpoints. According to the article, dose ranging studies demonstrated that the 0.5mg dose administered weekly as a subcutaneous injection was the most effective dose and that the drug showed no safety signals in the 26 week study.

Further the article stated that the study (PRELUDE) showed that Edratide was safe and well tolerated and while the primary endpoints based solely on SLEDAI-2K and AMS were not met, the secondary predefined endpoint, BILAG, was met for the 0.5 mg Edratide arm in the intention to treat (ITT) cohort (N=316) (OR=2.09, p=0.03) with trends in the 1.0 and 2.5 mg doses. The article also stated that there was a positive trend in the Composite SLE Responder Index of the ITT cohort and post hoc analysis showed that the BILAG secondary endpoint was also met for the 0.5 mg Edratide for a number of subgroup dose levels, including low or no steroids, seropositivity and patients with 2 grade BILAG improvement.

The article concluded that the favorable safety profile and encouraging clinically significant effects noted in some of the endpoints support the need for additional longer term Edratide studies that incorporate recent advances in the understanding and treatment of SLE, including steroid treatment algorithms, and using a composite primary endpoint which is likely to include BILAG.

Josh Levine, Chief Executive Officer of XTL, commented, “The encouraging data published in a peer-reviewed article in Lupus Science & Medicine regarding Edratide, our lead drug candidate for the treatment of SLE, further strengthens XTL’s resolve to bring this drug candidate to market as soon as possible. With the recent announcements of drugs being developed for the treatment of lupus by UCB and Eli Lilly failing to reach their primary endpoints in Phase 3 trials, there remains a significant unmet medical need in SLE.”

“We believe that there is a substantial opportunity for our lead drug candidate, hCDR1 (Edratide). We look forward to continuing the development of Edratide in advanced clinical trials and providing a measure of hope to patients suffering from this disease and the clinicians who treat them. We will continue to share our progress with you in the coming months.”
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.

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

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