



Conquering hepatitis C in our time

## **XTLbio Receives Fast Track Designation for Hepatitis C Therapy from US Food and Drug Administration**

**Rehovot, Israel, 18 July 2005** – XTL Biopharmaceuticals Ltd (“XTLbio”) (LSE: XTL) today announced that it has received Fast Track designation from the United States Food and Drug Administration for XTL-6865 (formerly known as HepeX-C). Fast Track designation is granted to facilitate the development and expedite the regulatory review of new drugs that are intended to treat serious or life threatening conditions and that demonstrate the potential to address unmet medical needs. XTL-6865 is being developed to prevent hepatitis C (HCV) re-infection following a liver transplant and for the treatment of chronic HCV disease. The Fast Track designation was limited by the Agency to the post-transplant indication.

XTL-6865 is a combination of two fully human monoclonal antibodies (Ab68 and Ab65) against the hepatitis C virus E2 envelope protein. A single antibody version of this product was tested in a pilot clinical program that included both Phase I and Phase II clinical trials. In April 2005, XTLbio submitted a US investigational new drug application (IND) to the FDA in order to commence a Phase Ia/Ib clinical trial later this year for XTL-6865, the dual-MAb product.

A Biologics License Application (BLA) is submitted before a drug is approved for marketing by the FDA. Fast track designation gives XTLbio the opportunity to submit a BLA for XTL-6865 in sequential sections, and to have these sections reviewed as they are submitted. Fast track designation also opens the possibility for receiving a priority review or accelerated approval of the BLA where the review time at the Agency would be six months, further reducing the time to market.

Michael Weiss, Interim Non-Executive Chairman, commented:

*“The designation of XTL-6865 as a Fast Track programme recognises the need for new forms of treatment for patients with recurrent HCV following a liver transplant.”*

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### **Notes to Editors**

XTL Biopharmaceuticals Ltd. (XTLbio) is a biopharmaceutical company developing drugs against hepatitis. Established in 1993, XTLbio became a public company in 2000 and its ordinary shares are listed on the Official List of the UK Listing Authority and are traded on the London Stock Exchange under the symbol XTL and in the Tel Aviv Stock Exchange, Israel.