

# Kitov Reports KIT-302 Study Successfully Meets U.S. Food & Drug Administration Bioequivalence Standards

***Kitov plans to file New Drug Application with FDA this year for combination drug that simultaneously treats osteoarthritis pain and hypertension***

**Tel-Aviv, Israel (PR Newswire) – May 10, 2016** – Kitov Pharmaceuticals

(NASDAQ/TASE: KTOV), an innovative biopharmaceutical company focused on late-stage drug development, today announced that KIT-302 has successfully completed its pharmacokinetic (PK) bioequivalence (BE) study and successfully met the U.S. Food and Drug Administration's (FDA) standards for establishing bioequivalence to the reference drugs.

The study compared the PK of Kitov's drug product of KIT-302 which is a fixed dose combination consisting of celecoxib (200 mg), indicated for osteoarthritis pain, and amlodipine (10 mg), indicated for high blood pressure, to off-the-shelf branded 200 mg celecoxib capsules and 10 mg amlodipine tablets. These evaluations were conducted under both fed and fasted conditions. The results demonstrated that for both the C<sub>max</sub> (the maximum blood level achieved) and Area Under the Curve (the area under the concentration time curve for drug levels), the 90% confidence intervals for both the amlodipine and celecoxib components of KIT-302 were documented to be between 80% and 125% of the values obtained with the off-the-shelf drugs. These results mean Kitov has fulfilled the FDA standard for demonstrating BE under both fed and fasted conditions.

"We are pleased to complete our pharmacokinetic BE study on schedule this quarter. These results bring us one step closer towards submitting our New Drug Application to the FDA for KIT-302 at the end of this year and the anticipated marketing approval in

2017,” stated Dr. J. Paul Waymack, Chairman of Kitov's Board and Chief Medical Officer.

According to FDA requirements, a similar PK bioequivalence study for the KIT-302 product, containing a lower dosage (2.5 mg) of amlodipine will be conducted by the end of this year. The FDA has indicated that KIT-302's final approval will not be dependent on this study's results.

### **About Kitov Pharmaceuticals**

Kitov Pharmaceuticals (NASDAQ/TASE: KTOV) is an innovative biopharmaceutical company focused on late-stage drug development. Leveraging deep regulatory and clinical-trial expertise, Kitov's veteran team of healthcare professionals maintains a proven track record in streamlined end-to-end drug development and approval. Kitov's pipeline currently features two combination drugs intended to treat osteoarthritis pain and hypertension simultaneously, including one that achieved the primary efficacy endpoint for its Phase III clinical trial. Lowering development risk and cost through fast-track regulatory approval of novel late-stage therapeutics, Kitov delivers rapid ROI and long-term potential to investors, while making a meaningful impact on people's lives. For more information, the content of which is not part of this press release, visit [www.kitovpharma.com](http://www.kitovpharma.com).

### **Forward-Looking Statements**

This press release contains forward-looking statements about the Company's expectations, beliefs and intentions. Forward-looking statements can be identified by the use of forward-looking words such as "believe", "expect", "intend", "plan", "may", "should", "could", "might", "seek", "target", "will", "project", "forecast", "continue" or "anticipate" or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. These forward-looking statements involve certain risks and uncertainties, including, among others, the risk that drug development involves a lengthy and expensive process with

uncertain outcome; the Company's ability to successfully develop and commercialize its pharmaceutical product; the length, progress and results of any clinical trials; the introduction of competing products; the impact of any changes in regulation and legislation that could affect the pharmaceutical industry; the difficulty in receiving the regulatory approvals to commercialize the Company's products; the lack of sufficient funding to finance the clinical trials; the difficulty of predicting actions of the USA FDA; the regulatory environment and changes in the health policies and regimes in the countries in which we operate; or changes in the global pharmaceutical industry. . Any forward-looking statement in this press release speaks only as of the date of this press release. The Company undertakes no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by any applicable securities laws. More detailed information about the risks and uncertainties affecting the Company is contained under the heading "Risk Factors" in Kitov Pharmaceuticals Holdings Ltd.'s Registration Statement on Form F-1 filed with the SEC, which is available on the SEC's website, [www.sec.gov](http://www.sec.gov).

**Contact:**

Simcha Rock  
Chief Financial Officer  
+972-2-6254124  
[Simcha@kitovpharma.com](mailto:Simcha@kitovpharma.com)

Bob Yedid  
Managing Director  
LifeSci Advisors, LLC  
646-597-6989  
[bob@LifeSciAdvisors.com](mailto:bob@LifeSciAdvisors.com)