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Biocancell to begin Phase IIb trial for bladder cancer drug

The FDA approved the trial at 5 Israeli hospitals and one in Arizona.

Tidhar Nir — 13 Jan 08 14:13

[Biocancell Therapeutics Ltd.](#) (TASE:[BICL](#)) has obtained US Food and Drug Administration (FDA) approval to continue a Phase IIb clinical trial on the company's BC-819 treatment for bladder cancer. The trial will begin at five medical centers in Israel and one in Arizona in a few weeks and will be completed during the fourth quarter of 2008.

The purpose of the trial is to measure BC-819's efficiency and safety following the successful Phase I/IIa clinical trials. The new trial will include 33 patients, divided into groups of 18 and 15. Each participant will receive six weekly treatments of BC-819. Patients responding to the treatment will be offered an additional nine monthly maintenance treatments.

Biocancell noted that BC-819 is its leading product. It is a plasmid in which H19 regulatory sequences drive the expression of Diphtheria Toxin A gene. The drug is also being evaluated as treatment for liver, pancreatic and ovarian cancer and has shown efficacy in pre-clinical studies as well as in compassionate use.

The company added that urinary bladder cancer affects 350,000 people a year, including 200,000 in the US and Europe. Annual US spending on bladder cancer treatment is \$1.9 billion.

Biocancell rose 1% by midday.

Published by Globes [online], Israel business news - www.globes-online.com - on January 13, 2008

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