

Mycobacterial Cell Wall–DNA Complex (MCC) (Urocidin)

Source: <http://sci.tech–archive.net/Archive/sci.med.diseases.cancer/2006–04/msg00021.html>

- *From:* J <analyse@invalid>
 - *Date:* Tue, 04 Apr 2006 04:10:02 –0400
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<http://www.theglobeandmail.com/servlet/story/LAC.20060404.RBIONICHE04/TPStory/Business>

Bioniche wins FDA approval for cancer trial

Reuters News Agency

TORONTO — Bioniche Life Sciences Inc. said yesterday the U.S. Food and Drug Administration had given it approval to begin the second Phase 3 trial of its treatment for bladder cancer.

The small biotech company said the trial on Mycobacterial Cell Wall–DNA Complex (MCC) will involve approximately 630 patients in a randomized, double–blind multicentre trial.

Bioniche said the study, to be conducted in North America and Europe, will compare Urocidin to Bacillus Calmette–Guerin (BCG) as first–line therapy in non–muscle invasive superficial bladder cancer at high risk of recurrence or progression.

The company said both the first and second Phase 3 trials will be carried out simultaneously.

Last week, company president and chief executive officer Graeme McRae said that completion of the trials and subsequent approval to market the product in the huge U.S. market will boost Bioniche's earnings by 270 per cent, or \$100–million (U.S.) in its first year, compared with 2005 revenue of about \$27–million.

Application to the FDA is not seen until at least 2010, Mr. McRae said, with a more conservative date for approval set for 2012.

Bioniche closed on the Toronto Stock Exchange yesterday at 95 cents (Canadian), up 15 cents.

Details of phase III trial with Urocidin revealed for treatment of bladder cancer

December 14th, 2004

Mycobacterial Cell Wall–DNA Complex (MCC) (Urocidin)

Bioniche Life Sciences, Inc., (BNC), a research–based, technology–driven Canadian biopharmaceutical company, announced details of its upcoming phase III clinical trial using its proprietary Mycobacterial Cell Wall–DNA Complex (MCC) – trademarked Urocidin – for the treatment of bladder cancer.

This will be an international trial involving approximately 60 sites in North America and Europe.

Alvaro Morales, professor of urology and oncology at Queen's University in Kingston, Ontario is the International Principal Investigator for the trial. At yesterday's Annual Meeting of Shareholders, Morales introduced the two other lead investigators:

http://www.bioniche.com/news_item.cfm?id=1566

Dr. Alvaro Morales, Principal Investigator for Bioniche's Phase I/II clinical trial in refractory Carcinoma in situ (CIS) of the bladder, showed results indicating that of the 25 enrolled patients, 24% were alive and disease free (complete response) after 18 months, and 8% showed a partial response for a total positive response rate of 32%. MCC (Urocidin?) was extremely well tolerated by the patients and there were no apparent safety concerns

The Company's Senior Vice–President, Scientific Affairs and Chief Scientific Officer, Dr. Nigel Phillips, presented data that demonstrated MCC is effective in causing cell cycle arrest and inducing apoptosis in a range of bladder cancer cell lines derived from high grade bladder cancers and where the cells possess mutations in cell cycle/apoptosis regulators. Dr. Phillips also presented data showing that MCC (Urocidin?) stimulates urinary apoptosis markers and cytokines following intravesical administration to patients with Carcinoma in situ of the bladder.

Building on the positive clinical results obtained to date for the treatment of Carcinoma in situ of the bladder, these findings indicate MCC may be effective in treating other types of aggressive bladder cancer, such as high–grade transitional cell carcinoma, said Dr. Phillips.

Dr. Mario Filion, Bioniche's Head of Biomedical Research, presented data demonstrating that the combination of MCC with hyaluronic acid (HA) enhances both the apoptosis–inducing activity of MCC against prostate cancer cell lines, and the immune stimulatory activity of MCC (stimulation of anticancer cytokine synthesis by human immune effector cells).

These data are confirming the therapeutic potential of MCC in different urology–oncology indications. We will be reporting on Phase I safety results using an MCC/HA suspension in prostate cancer patients before the end of the year,