



**FOR IMMEDIATE RELEASE**

**MICROLOGIX MEETS WITH FDA ON MBI-226**

***Statistically Significant Secondary Endpoints from Previous Phase 3 Trial Provide NDA Path Forward  
Micrologix to Seek New Commercialization Partner Following Fujisawa Termination***

**Vancouver, BC, CANADA – January 21, 2004** – Micrologix Biotech Inc., a developer of anti-infective drugs (**TSX: MBI; OTC: MGIXF**), has met with the United States Food & Drug Administration (“FDA”) to address the regulatory requirements for a New Drug Application (NDA) for MBI-226, a topical cationic peptide currently in Phase III development for the prevention of catheter-related bloodstream infections. In summary, an NDA path forward for MBI-226 can be achieved without the requirement for a statistically significant reduction in catheter-related bloodstream infections as a primary endpoint. The NDA requirements for MBI-226, which may include a confirmatory second Phase III study, will be established in consultation with an FDA representative over the next several months, using the secondary endpoints from a first Phase III study completed in July 2003 as a basis for seeking approval.

In the completed Phase III study, MBI-226 achieved a clear, statistically significant reduction in the two secondary efficacy endpoints of the study – catheter colonization ( $p=0.002$ ) and catheter-related local infections ( $p=0.004$ ) – as compared to povidone-iodine. These two endpoints are documented extensively in the published literature to be related to the development of catheter-related bloodstream infections. The primary endpoint, a reduction in catheter-related bloodstream infections, resulted in a 15% improvement as compared to povidone-iodine, which was not statistically significant.

Fujisawa Healthcare, Inc., the development partner for MBI-226, had until January 22, 2004 to decide on terminating their participation in the program. Fujisawa has elected to terminate the agreement and will return all rights pertaining to MBI-226 to Micrologix, including all clinical data, manufacturing development, and the Investigational New Drug (IND) application filed with the FDA.

Jim DeMesa, M.D., President & CEO of Micrologix stated, “This is an important time for the future of MBI-226. While we are disappointed that our partnership with Fujisawa will not continue, the outcome of the FDA meeting shows a viable regulatory path forward exists for MBI-226 based on the secondary endpoints from the previous Phase III study, which was our main objective. Our intent is to advance the program with a commercialization partner, and to that end, we are actively pursuing opportunities with companies expressing an interest in MBI-226; a Phase III product opportunity with a path to NDA and a high degree of statistically proven efficacy in a pivotal Phase III study.”

David Friedland, M.D., Vice President of Clinical and Medical Affairs for Micrologix stated, “Since MBI-226 achieved a high degree of statistical significance in decreasing catheter colonization and local catheter site infections in a well-designed Phase III trial, we expect a second study, if required, to achieve similar efficacy. Such a study is estimated to involve approximately 1000 patients and take 12-18 months to complete.”

**About Catheter Colonization, Local Catheter Site Infections, and Catheter-Related Bloodstream Infections**

Catheter colonization is widely believed to be related to the development of catheter-related bloodstream infections. Current literature indicates the morbidity and mortality of catheter colonization to be similar to that associated with catheter-related bloodstream infections. Local catheter site infections, also related to catheter colonization and bloodstream infections, require a change of catheters, increasing the risk of complications and adding to hospital costs. The vast majority of catheter-related bloodstream infections occur when bacteria and/or fungi that colonize the patient's skin around the catheter insertion site migrate down the catheter tract to colonize the implanted portion of the device. These microorganisms then break away from the colonized catheter, seeding into the blood and causing subsequent bloodstream infections, also known as "blood poisoning". In many cases, the organisms that cause these infections have developed resistance to conventional antibiotics.

Central venous catheters ("CVC") are devices used by physicians to deliver therapeutic and nutritional agents, sample blood and monitor a patient's status. They are commonly inserted through the chest wall, groin, or neck, into a major vein, for example, the jugular vein. Each year in the US, more than five million CVCs are sold, and it is estimated by the US Center for Disease Control that catheter-related bloodstream infections develop in approximately 250,000 patients, resulting in approximately 50,000 deaths. On average, a patient with a CVC-related bloodstream infection spends an additional 6.5 days in intensive care at a cost of US\$25,000. As such, these infections increase the annual cost to the US health care system by more than US\$5 billion annually.

It is expected that the unique anti-microbial properties of MBI-226 could be applied to other percutaneous, devices (in addition to CVCs) where high device-related infection rates occur such as: dialysis catheters, pediatric catheters, and neonatal umbilical catheters.

**About Micrologix**

Micrologix Biotech Inc. is engaged in the research, development, and commercialization of drugs that advance therapy, improve health, and enrich lives. The Company's focus is toward anti-infective drug development with three product candidates in human clinical development, multiple product opportunities in preclinical development, and several early-stage technologies in various stages of research and evaluation.

"Jim DeMesa"

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James DeMesa, MD  
President & CEO

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The Toronto Stock Exchange has not reviewed and does not accept responsibility for the adequacy or accuracy of this release.