

## Miraculins Outlines Details of PreVu 510(k) FDA Clearance

### *U.S. Market Holds Significant Potential for Non-Invasive Skin Cholesterol Test*

**WINNIPEG, Manitoba – March 6, 2012** - Miraculins Inc. (TSX-V:MOM), a medical diagnostic company focused on acquiring, developing and commercializing diagnostic tests and risk assessment technologies for unmet clinical needs, today outlined the details of the FDA clearance for its PreVu<sup>®</sup> Non-Invasive Skin Cholesterol Point of Care (POC) Test. The FDA clearance was issued prior to Miraculins' acquisition of the PreVu technology and remains in effect in the U.S. marketplace.

"With the recent, significant announcements that the PreVu POC Test has been cleared for sale by Health Canada and has been CE-Marked for sale in the European Union, Management believes it is important to remind the market that an FDA clearance for the PreVu POC Test was in place at the time of our acquisition and was one of the key considerations in our decision to purchase PreVu," said Christopher J. Moreau, President and CEO of Miraculins. "PreVu's regulatory clearance in the U.S. is a valuable asset that we will soon be capitalizing on as we finalize our U.S. expansion strategy and begin to execute on our plans."

The FDA has directed that "Skin cholesterol as measured by the PreVu POC can be used as part of risk assessment for coronary heart disease in persons with a history of myocardial infarction and/or in persons suspected of having significant multi-vessel coronary artery disease (>50% stenosis in >1 vessel as diagnosed by coronary angiography) where further diagnostic evaluation is being considered. Test results, when considered in conjunction with clinical evaluation, blood cholesterol tests and other risk factors identified for coronary artery disease, will aid the physician in focusing diagnostic and patient management options."

"I am very energized and impressed by the clearance that PreVu has in the U.S.," said Dr. Henry Solomon, MD, FACP, FACC, past Chief Medical Officer of the American College of Cardiology and a U.S. member of the PreVu Medical Advisory Board (PMAB). "While it is not currently purposed for general risk screening, we do not believe this is necessary in order for us to make the test available to those individuals suspected of having serious coronary artery disease (CAD), by virtue of easily attainable information from their personal and medical history. The PMAB and Miraculins Management are working together on a strategy to identify such individuals and we believe they comprise a significant component of the American population."

Miraculins' recent appointment of Mr. Thomas Tsakeris, former Director, Division of Clinical Laboratory Devices (DCLD), Office of Device Evaluation, Center for Devices and Radiological Health (CDRH), FDA, as a key regulatory consultant, is also part of the Company's efforts to develop a fully integrated sales and marketing launch plan in the U.S., in full compliance with PreVu's FDA clearance.

Currently, the Company is considering multiple distribution strategies and partners, including both user pay and reimbursement models. With regards to the latter, Miraculins has also launched a key, in-depth study designed to generate a comprehensive, reimbursement environmental assessment for its skin cholesterol technology, including a review of coding and valuation, as well as coverage assessments of applicable comparative technologies and clinical procedures.

Miraculins can begin to market the PreVu test in the U.S. after registering with the FDA as a device establishment, and after PreVu is listed as a device under Miraculins. This step is strictly administrative and is being timed to coincide with the finalization of the Company's U.S. sales and marketing launch strategy and the preparation of all related support materials and product labeling, including a web site being built exclusively for the U.S. marketplace. By registering and listing, Miraculins will be informing the FDA that commercial distribution has commenced. Miraculins has indicated it plans to register shortly and will update the market accordingly on its specific U.S. launch plans at that time.

Skin cholesterol is the cholesterol that has been deposited and diffused into tissue, as opposed to free circulating in the bloodstream, and has been shown in clinical trials to be strongly associated with significant CAD as measured by treadmill stress testing, coronary angiography, coronary calcium and carotid artery thickening. The PreVu test is completely painless, non-invasive, involves no blood draw or needles, requires no overnight fasting and involves no handling of potentially hazardous biomaterials. It has been developed to provide new and additive information about CAD risk that is independent of traditional risk factors, such as blood cholesterol, to help physicians more effectively assess their patients' risk.

The PreVu POC test has been cleared in Europe and Canada as a general screening test to help uncover individuals with hidden, high levels of risk of CAD across all demographics.

#### **About Miraculins Inc.**

Miraculins is a medical diagnostic development company focused on acquiring, developing and commercializing non-invasive tests for unmet clinical needs. The Company's PreVu test is a revolutionary new coronary artery disease risk assessment technology that measures cholesterol levels in a patient's skin non-invasively, painlessly and without the need for fasting. The PreVu Non-Invasive Skin Cholesterol Point of Care (POC) Test technology has been cleared for sale by Health Canada and CE-Marked in the European Union. PreVu has previously been successfully test marketed in North America on a limited basis. Miraculins additional programs include a research use only ELISA kit for the detection of PSP94; and a suite of biomarkers to aid in the early detection of the devastating disease of pregnancy known as preeclampsia. The Company's preeclampsia program is being advanced in partnership with Alere, Inc. (NYSE:ALR) (formerly known as Inverness Medical Innovations), one of the world's largest diagnostic companies.

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