

Phone 204.453.1408 Fax 204.453.1546 info@miraculins.com

Miraculins Receives Guidance from U.S. FDA Related to its Scout[®] Device as an Aid in the Identification of Pre-Diabetes

Company to Continue on Pathway to Support a De Novo Submission in the United States

WINNIPEG, Manitoba – April 28, 2015 - Miraculins Inc. (TSX-V: MOM) ("Miraculins" or the "Company"), a medical diagnostic company focused on acquiring, developing and commercializing diagnostic tests and risk assessment technologies for unmet clinical needs, announces that it has recently received important feedback from the United States Food and Drug Administration (FDA) as part of the *de novo* pre-submission process. Based on this communication from the FDA, Miraculins plans to continue advancing on the *de novo* clearance pathway for the Scout[®] device.

The *de novo* process is generally considered to be appropriate for "novel" medical devices for which there are no legally marketed predicate devices, and whose risk profiles do not warrant the regulatory pathway known as a premarket approval (PMA), which is required of products considered to have the highest risk to public safety (Class III). The Company is of the view that there is no predicate for the Scout[®] device, and based on the feedback received from FDA the *de novo* process could provide the appropriate regulatory pathway for marketing clearance in the U.S.

"Miraculins believes that the communication from the FDA related to a potential *de novo* classification is a positive and significant development in the regulatory history of the Scout[®]," said Christopher Moreau, President and CEO of Miraculins. "Miraculins has been evolving a new regulatory strategy for the Scout[®] in the U.S. over the last year to focus on the important market of undiagnosed individuals with pre-diabetes where prevention can have the greatest healthcare and economic impact, and as a result of this encouraging FDA guidance the Company will continue to take steps to advance a *de novo* submission." In the U.S. it is estimated by the Centers for Disease Control and Prevention in Atlanta that 1 in 3 adults or 86 million people have pre-diabetes (the precursor to type 2 diabetes), yet 9 out 10 are unaware they have the condition.

The *de novo* process is expected to be less burdensome than would be the case if the Company sought a PMA for the Scout[®] device. The *de novo* pre-submission process does not provide a formal determination of regulatory classification nor does it constitute a final determination of the device's risks and benefits, but rather allows the FDA to review and provide preliminary feedback on the suitability of the *de novo* classification process for a device, as well as for the planned data to be gathered and submitted by the Company to obtain marketing clearance. A final determination of the device's safety and effectiveness will be made by FDA once the formal *de novo* marketing application is submitted.

About Miraculins Inc.

Miraculins is a medical diagnostic company focused on acquiring, developing and commercializing non-invasive technologies for unmet clinical needs. A significant number of promising diagnostic opportunities remain un-commercialized because of the sizable gap between the discovery stage, when research institutions are typically involved, and the commercialization stage, when the larger commercial enterprises become interested. Miraculins has direct experience in bridging this gap. The Company's Scout[®] device has been regulatory cleared in certain markets both as a clinical tool to assist in the identification of prediabetes and type 2 diabetes, and is the first non-invasive testing system designed to provide a highly sensitive

and convenient method for measuring prediabetes/type 2 diabetes related biomarkers in the skin, the accumulation of which are accelerated by abnormal blood sugar levels and oxidative stress. Unlike current testing methods, a Scout[®] test requires no blood draw, no fasting, and no waiting for a lab result. The product has been used and validated in thousands of patients around the world. For more information visit <u>www.miraculins.com.</u>

For more information, please contact:

Christopher J. Moreau President & CEO Miraculins Inc. Ph: 204-477-7599 Fax: 204-453-1546

info@miraculins.com www.miraculins.com

Neither the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.

Caution Regarding Forward-Looking Information

Certain statements contained in this press release constitute forward-looking information within the meaning of applicable Canadian provincial securities legislation (collectively, "forward-looking statements"). These forward-looking statements relate to, among other things, our objectives, goals, targets, strategies, intentions, plans, beliefs, estimates and outlook, including, without limitation, our anticipated future operating results, the pre-submission process as regards the de novo classification of the Scout[®] medical device and can, in some cases, be identified by the use of words such as "believe," "anticipate," "expect," "intend," "plan," "will," "may" and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements.

These statements reflect management's current beliefs and are based on information currently available to management. Certain material factors or assumptions are applied in making forwardlooking statements, and actual results may differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from these expectations include, among other things: Miraculins' early stage of development, lack of product revenues and history of operating losses, uncertainties related to clinical trials and product development, rapid technological change, uncertainties related to forecasts, competition, potential product liability, additional financing requirements and access to capital, unproven markets, supply of raw materials, income tax matters, management of growth, partnerships for development and commercialization of technology, effects of insurers' willingness to pay for products, system failures, dependence on key personnel, foreign currency risk, risks related to regulatory matters and risks related to intellectual property and other risks detailed from time to time in Miraculins' filings with Canadian securities regulatory authorities, as well as Miraculins' ability to anticipate and manage the risks associated with the foregoing. Additional information about these factors and about the material factors or assumptions underlying such forwardlooking statements may be found in the body of this news release. Miraculins cautions that the foregoing list of important factors that may affect future results is not exhaustive. When relying on Miraculins' forward-looking statements to make decisions with respect to Miraculins investors and others should carefully consider the foregoing factors and other uncertainties and potential events.

These risks and uncertainties should be considered carefully and prospective investors should not place undue reliance on the forward-looking statements. Although the forward-looking statements contained in this press release are based upon what management believes to be reasonable assumptions, Miraculins cannot provide assurance that actual results will be consistent with these forward-looking statements. Miraculins undertakes no obligation to update or revise any forward-looking statements except as may be required by law.

Scout[®] is a registered trademark of Miraculins Inc. All Rights Reserved. 2015.