



Press Release

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## SkylineDx Receives CE-IVD Mark for MMprofiler™ -- Its Innovative Gene Signature-Based Test for Multiple Myeloma

*CE-IVD Approval Marks SkylineDx's European Commercialization of its MMprofiler technology*

**Rotterdam, the Netherlands and Laguna Hills, CA, November 25, 2015** – [SkylineDx](http://www.skylinedx.com), today announced they have received CE-IVD registration from the European Competent Authority (Ministry of Health) for the [MMprofiler™](#), the company's prognostic test to determine the level of risk of a patient with multiple myeloma (MM). [SkylineDx](#) is an emerging commercial-stage company focused on the development and commercialization of innovative gene signature-based tests. This market authorization is an important step in raising the standards for gene expression profiling and bringing the MMprofiler to a wider market.

"Receiving this CE-IVD mark is our first, and most significant, commercialization milestone for MMprofiler," said Dharminder S. Chahal, Chief Executive Officer of SkylineDx. "We are one step closer to fulfilling our commitment to advancing the use of innovative gene signature-based tests to help physicians make better informed personalized treatment decisions for patients with multiple myeloma worldwide."

The CE-IVD certification will enable European physicians to access this important advancement and now offer it to their multiple myeloma patients. MMprofiler provides physicians with the ability to utilize the well-validated SKY92 "high-risk signature" to more accurately measure the prognosis of a patient with multiple myeloma by classifying them into a "high" or "standard" risk group. Patients with a "high" risk classification have a poor prognosis as compared to patients with a standard risk profile, regardless of treatment. The performance of the SKY92 gene signature to risk stratify these patients exceeds that of current standard clinical parameters such as serum albumen levels, as well as FISH, utilized in myeloma.

### **About CE-IVD**

The CE-mark (CE-IVD) indicates that an IVD device complies with the European In Vitro Diagnostics Directive (98/79/EC), and that the device may be legally commercialized and distributed in the EU.

### **About Multiple Myeloma**

Multiple myeloma is a type of blood cancer that arises from plasma cells, a type of white blood cell, which is made in the bone marrow. Most medical problems related to multiple myeloma are caused by the build-up of abnormal plasma cells in the bone marrow and the presence of paraprotein in the blood or in the urine. While multiple myeloma does not exist as a tumor, the malignant plasma cells



may cause the formation of tumors throughout the body, damage to the kidneys and will impair immune system function. <sup>1,2</sup>

Multiple myeloma, the second most common blood cancer, is a relapsing-remitting cancer. This means there are periods when the disease is causing symptoms and complications that require treatment, followed by periods of remission.<sup>1</sup> For more information, visit: [www.themmr.org](http://www.themmr.org), [www.myeloma.org.uk](http://www.myeloma.org.uk), and [www.myeloma.org](http://www.myeloma.org)

#### **About the MMprofiler™**

The MMprofiler is a prognostic test to determine the level of risk of a multiple myeloma patient by classifying such patient into a “high” or “standard” risk group with the use of the well-validated SKY92 gene signature. These high-risk multiple myeloma patients have a high unmet medical need for improved therapies. In the USA the MMprofiler is available for research use only and currently not permitted to be used for clinical diagnostic use. For more information, please visit [www.mmprofiler.com](http://www.mmprofiler.com).

#### **About SkylineDx**

SkylineDx is biotech company located in Rotterdam, the Netherlands and Laguna Hills, CA. Originally a spin-off of the Erasmus Medical Center in Rotterdam, the company specializes in the development and marketing of innovative gene signature-based tests to assist healthcare professionals in making personalized treatment decisions for individual patients. These tests are designed to accurately determine the type or status of the disease or to predict a patient’s response to a specific treatment. Based on the test results, healthcare professionals can tailor the treatment to the individual patient. The MMprofiler™ is the company’s product. To learn more, please visit [www.skylinedx.com](http://www.skylinedx.com).

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<sup>1</sup> Myeloma UK. 2015. Available at: <http://www.myeloma.org.uk/information/what-is-myeloma/>. Accessed November 5, 2015.

<sup>2</sup> Multiple Myeloma Research Foundation. Multiple Myeloma - Myeloma - Myeloma Cancer - Plasma Cell Myeloma. 2015. Available at: <http://www.themmr.org/multiple-myeloma/>. Accessed November 5, 2015.