



Press Release

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## SkylineDx to Present New Data Demonstrating Prognostic Value of MMprofiler™ in Multiple Myeloma at American Society of Hematology Annual Meeting

*Studies Support Use of MMprofiler™ for Stratifying High and Low-Risk in Newly Diagnosed Elderly and Relapsed Patients*

*MassGen Poster Highlights Use of MMprofiler™ in Phase II Modified RVD (Revlimid/Velcade/Dexamethasone) Trial*

**Rotterdam, the Netherlands and Laguna Hills, CA, December 1, 2015** [SkylineDx](http://www.skylinedx.com) today announced the presentation of two posters that demonstrate the prognostic value of the [MMprofiler™](#), SkylineDx's gene expression profiling test for multiple myeloma (MM), as a risk assessment tool. The posters will be presented Sunday, December 6, 2015, at the 57<sup>th</sup> annual meeting of the American Society of Hematology (ASH) in Orlando, Fla.

"The ASH annual meeting is an important, highly visible forum for showcasing the clinical utility of the MMprofiler™ as a prognostic tool in patients with multiple myeloma, one that provides clinically actionable information to inform therapeutic decision-making," said Dharminder S. Chahal, Chief Executive Officer of SkylineDx. "We are pleased that the ASH program committee has accepted these two posters for presentation, one of which supports the use of the MMprofiler™ in elderly patients with newly diagnosed multiple myeloma and the other provides further validation for the MMprofiler™ in stratifying patients based on high versus low risk in relapsed patients"

The MMprofiler™ is a prognostic test that determines the level of risk for patients with MM by classifying them into a "high" or "standard" risk group. MMprofiler™ assesses risk by measuring the activity of 92 genes (the SKY92 gene signature) that are directly or indirectly related to the disease. 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 standard clinical parameters such as serum albumin levels, as well as FISH, and earlier gene expression signatures utilized in myeloma.

SkylineDx recently launched the MMprofiler™ as a CE-marked *in vitro* diagnostic (IVD) test kit in Europe this past November. Physicians can now send their multiple myeloma patient samples directly to SkylineDx to be run as a service in their central laboratory located in Rotterdam, The Netherlands. It also enables molecular diagnostic laboratories throughout Europe to use the MMprofiler™ for analysis at their own facilities.



Both posters will be presented Sunday, December 6, from 6:00-8:00pm EST in Hall A, Level 2 of the Orange County Convention Center:

- [Abstract #2967](#): Mark van Duin Ph.D., Department of Hematology, Erasmus MC Cancer Institute, Rotterdam, Netherlands
  - Validation of the EMC92/SKY92 Signature in HOVON (Dutch-Belgian Cooperative Trial Group)-87/Nmsg (Nordic Myeloma Study Group)-18: Gene Expression Based Prognostication Is Applicable in Elderly Patients with Newly Diagnosed Multiple Myeloma
- [Abstract #2970](#): Martin van Vliet Ph.D., SkylineDx, Rotterdam, Netherlands
  - The Combination of SKY92 and ISS Provides a Powerful Tool to Identify Both High Risk and Low Risk Multiple Myeloma Cases, Validation in Two Independent Cohorts

In addition, researchers from Massachusetts General Hospital Cancer Center in Boston, Mass. will present a poster highlighting the use of the MMprofiler™ in a Phase II trial of modified lenalidomide, bortezomib, and dexamethasone in transplant-ineligible patients with newly diagnosed MM.

This poster will be presented Monday, December 7, from 6:00-8:00pm EST in Hall A, Level 2 of the Orange County Convention Center:

- [Abstract #4217](#): Elizabeth K. O'Donnell M.D., Massachusetts General Hospital Cancer Center, Boston, MA
  - A Phase II Study of Modified Lenalidomide, Bortezomib, and Dexamethasone (RVD-lite) for Transplant-Ineligible Patients with Newly Diagnosed Multiple Myeloma

### **About Multiple Myeloma**

Multiple myeloma (MM) is a cancer that arises from plasma cells, a type of white blood cell made in the bone marrow. In patients with MM, the plasma cells become abnormal, multiply uncontrollably, and release only one type of antibody – known as paraprotein – which has no useful function. It is often through the measurement of paraprotein that MM is diagnosed and monitored. Most medical problems related to MM are caused by the build-up of abnormal plasma cells in the bone marrow and the presence of the paraprotein in the blood or urine. The most common symptoms of MM include bone pain, recurring infection, kidney damage, and fatigue. According to the World Cancer Research Fund International, an estimated 114,000 people around the world are diagnosed with MM annually, and the disease represents 0.8% of all cancers globally.

For more information about MM, visit [www.hematon.nl/myeloom](http://www.hematon.nl/myeloom) (*information available in Dutch only*), [www.themmr.org](http://www.themmr.org), [www.myeloma.org.uk](http://www.myeloma.org.uk), or [www.myeloma.org](http://www.myeloma.org)

### **About the MMprofiler™**

The MMprofiler™ is a CE-IVD marked 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 novel SKY92 gene signature. 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 a commercial-stage biotech company based in Rotterdam, the Netherlands. Originally a spin-off of the Erasmus Medical Center in Rotterdam, the company specializes in the development and marketing of innovative gene signature-based diagnostic 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 lead product. To learn more, please visit [www.skylinedx.com](http://www.skylinedx.com).

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