



## **SkylineDx Announces Multiple Studies Being Presented at the 58<sup>th</sup> Annual ASH Meeting Reinforcing Utility of MMprofiler™ Gene-Based Prognostic Signature to Impact Treatment of Patients with Multiple Myeloma**

*New Studies Demonstrate Value of Gene Expression Risk Profiling to Identify Ultra-High-Risk Multiple Myeloma Patients*

**Rotterdam, the Netherlands and Laguna Hills, CA, November 29, 2016** –SkylineDx today announced the presentation of new data that demonstrate the prognostic value of MMprofiler™ SKY92 gene signature, a gene expression profiling test for multiple myeloma (MM), as part of an integrated approach to identifying patients at ultra-high risk of MM. The data will be presented in a poster session on Monday, December 5, at the 58<sup>th</sup> annual meeting of the American Society of Hematology (ASH) in San Diego, CA.

“The data being presented at the ASH meeting suggest that gene expression testing with MMprofiler, when used in combination with molecular genetic risk profiling, can enable risk stratification in multiple myeloma by elucidating patterns of survival and disease progression in high-risk and ultra-high-risk patients,” said Dharminder S. Chahal, Chief Executive Officer of SkylineDx. “An integrated profiling testing strategy, with MMprofiler as a key component, may thus facilitate evaluation of risk-stratified treatment approaches in patients with multiple myeloma, and may even help identify potentially beneficial therapies for patients at ultra-high risk.”

In the ASH poster presentation, researchers will describe how they used MMprofiler, along with a molecular genetic risk profiling tool, to assess 221 newly diagnosed patients with MM who participated in the UK NCRI Myeloma XI trial. SKY92 is a prognostic gene signature that determines the level of risk for patients with MM by classifying them into a “high” or “standard” risk group. Included in a growing number of international treatment guidelines, MMprofiler assesses risk by measuring the activity of 92 MM-related genes that comprise SKY92, the novel, proprietary gene signature that is the lead product of SkylineDx. 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 that include fluorescent *in situ* hybridization (FISH) and earlier gene expression signatures utilized in myeloma.

The following posters related to SKY92 will be presented Monday, December 5, from 6:00-8:00pm PST in Hall GH of the San Diego Convention Center:

- Abstract #4407: Sherborne AL, et al.
  - Identifying Ultra-High Risk Myeloma by Integrated Molecular Genetic and Gene Expression Profiling
- Abstract #4424: Simone Weber et al.
  - Comprehensive Biologic Characterization of 99 Multiple Myeloma Patients Using Cytomorphology, FISH, Gene Expression Profiling and Mutation Screening Leads to Important Clinical and Therapeutic Insights
- Abstract #1141 Ruth Wester et al.
  - Phase 2 Study of Carfilzomib, Thalidomide, and Low-Dose Dexamethasone As Induction/Consolidation in Newly Diagnosed, Transplant Eligible Patients with Multiple Myeloma, the Carthadex Trial



### **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 M-protein – which has no useful function. It is often through the measurement of M-protein 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 M-protein 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), [www.mpeurope.org](http://www.mpeurope.org), [www.myeloma.org](http://www.myeloma.org), and [www.jsm.gr.jp](http://www.jsm.gr.jp).

### **About MMprofiler™**

MMprofiler SKY92 prognostic gene signature assesses risk by measuring the activity of 92 MM-related genes that comprise SKY92, the novel, proprietary gene signature. The lead product of SkylineDx, MMprofiler is proven superior to the biomarkers currently used to risk stratify newly diagnosed and relapsed multiple myeloma patients into a “high” or “standard” risk category.<sup>1</sup> Included in a growing number of international treatment guidelines, MMprofiler is CE-IVD registered in Europe and will be coming soon as a laboratory-developed test (LDT) in the United States. 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 prognostic 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. MMprofiler is the company’s lead product. To learn more, please visit [www.skylinedx.com](http://www.skylinedx.com).

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<sup>1</sup> Van Beers EH, et al. SKY92 GEP, iFISH, and ISS comparisons for risk stratification in multiple myeloma. Poster p661 presented at 2015 European Hematology Association Congress.