



SkylineDx to Present New Data Demonstrating MMprofiler™ as Robust Prognostic Tool in Multiple Myeloma at the European Hematology Association 21st Annual Congress (EHA)

Studies Support Validity of SKY92 as a Superior Predictor of Risk Stratification in Newly Diagnosed and Relapsed Patients

Rotterdam, the Netherlands and Laguna Hills, CA, May 31, 2016- SkylineDx today announced the presentation of four posters that reconfirm the prognostic value of MMprofiler™ with SKY92, the only gene-based signature proven superior to the biomarkers currently used for risk-stratifying newly-diagnosed and relapsed multiple myeloma patients.¹ Of the four posters, three will be presented Friday, June 10, 2016, at the European Hematology Association (EHA) 21st Annual Congress in Copenhagen, Denmark. The fourth will be presented as an E-poster. Additionally, SkylineDx will host a “Meet the Experts” event in booth #C4.328 on June 10, from 2:30 – 3:30 p.m. (CEST).

Each of the four new abstracts utilized MMprofiler and its novel gene signature, SKY92, to determine the prognostic validity in both the clinical and analytical setting in identifying high risk or standard risk stratification in patients with multiple myeloma. Results show that the SKY92 signature, a key component of MMprofiler, is a powerful and robust prognostic marker, not only for overall survival, but also for progression free survival in younger, elderly, newly diagnosed, and relapsed patients with multiple myeloma across various treatments. Moreover, it can be used reliably as a predictor for survival to optimize follow-up and treatment strategies in an early stage.

“We are pleased to showcase MMprofiler and its reliability in determining risk stratification to optimize treatment in patients with multiple myeloma through these four posters,” said Dharminder S. Chahal, Chief Executive Officer of SkylineDx. “We are confident that these additional studies will help inform patients and physicians with clinically actionable information that will guide and speed up the therapeutic decision-making process, no matter what stage of the disease the patient is experiencing.”

MMprofiler with SKY92 is a gene-based risk identification signature that determines the level of risk for patients with multiple myeloma 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 that include FISH, and earlier gene expression signatures utilized in myeloma.



“With the information that MMprofiler provides, physicians are now able to make better informed decisions,” said Antonio Palumbo, M.D., Chief of Myeloma Unit, Department of Oncology, University of Torino, Italy. “The power to classify a patient’s risk level using MMprofiler enables the physician to potentially tailor a more precise and beneficial treatment for their multiple myeloma patient, thus potentially avoiding ineffective, costly, or potentially harmful treatments.”

The following three posters will be presented on Friday, June 10, from 5:15-6:45 p.m. (CEST) in Hall H of the Bella Center, Copenhagen, Denmark:

- Abstract #P283: Martin van Vliet Ph.D., SkylineDx, Rotterdam, Netherlands
 - Risk Stratification by SKY92+ISS Outperforms iFISH Markers t(4;14) and Del(17P) in Multiple Myeloma

- Abstract #P282: Martin van Vliet Ph.D., SkylineDx, Rotterdam, Netherlands
 - Precision as Part of the Analytical Validation of the SKY92 High Risk Signature and the MMprofiler Assay

- Abstract #P276: Martin van Vliet Ph.D., SkylineDx, Rotterdam, Netherlands
 - The SKY92 Prognostic Marker is Validated in Eight Multiple Myeloma Clinical Datasets

Additionally, the E-poster will be on display on E-poster screens from 9:30 a.m. (CEST) Friday, June 10 to 7:00 p.m. (CEST) Saturday, June 11, 2016:

- Abstract #E1262: Martin van Vliet Ph.D., SkylineDx, Rotterdam, Netherlands
 - Robustness of the Prognostic Value of the SKY92 Marker Versus FISH Markers Across Nine Multiple Myeloma Cohorts

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 (information available in Dutch only), www.themmf.org, www.myeloma.org.uk, or www.myeloma.org



About MMprofiler™

MMprofiler with SKY92 is the only CE-IVD marked, gene-based risk identification signature that has been proven superior to the biomarkers currently used for risk- stratifying newly diagnosed and relapsed multiple myeloma patients¹. A recently published peer reviewed study showed that MMprofiler is more accurate at identifying high-risk patients, and is the strongest predictor of overall survival – where median survival was 24 months for the highest-risk group². MMprofiler is available in Europe to be run quickly and confidently in laboratories or as a service from the SkylineDx laboratory in Rotterdam, The Netherlands. In the U.S., MMprofiler is available only as an investigational use and/or research use tool, as the performance characteristics of this product have not been established. For more information, please visit 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. MMprofiler is the company’s lead product. To learn more, please visit www.skylinedx.com.

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1. 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.

2. Kuiper R, et al. Prediction of high- and low-risk multiple myeloma based on gene expression and the International Staging System. *Blood*. 22 October 2015, Volume 126, Number 17, Pages 1996-2004