



SkylineDx Researchers Publish Data Demonstrating Utility of SKY92 as Prognostic Tool in Multiple Myeloma (MM)

Clinical Lymphoma, Myeloma and Leukemia *Paper Validates Use of SKY92 and its Combination with International Staging System (ISS)*

Rotterdam, the Netherlands and Laguna Hills, CA, July 25, 2017 – SkylineDx today announced the publication of new data that validate the Company’s SKY92 gene expression signature as a prognostic tool to evaluate patients with multiple myeloma (MM). In a paper published in the current issue of *Clinical Lymphoma, Myeloma and Leukemia*, SkylineDx researchers substantiate SKY92 as a tool for identifying high-risk patients, as well as SKY92 combined with the International Staging System (ISS) for identifying low-risk patients.¹ The ISS assesses two serum parameters to identify three patient groups with different prognoses.²

“High-risk disease is now recognized as one of the most challenging unmet needs in the treatment of multiple myeloma,” said lead author Erik H. van Beers, Ph.D., vice president of Genomics at SkylineDx. “To further optimize disease management, we need to be able to differentiate high-risk from low-risk patients, using tools that are highly accurate and yield reproducible results across different patient groups and treatments. We have demonstrated the prognostic value of SKY92 not only as a marker of high risk, but also as a marker of low risk when combined with ISS. Both validated markers may serve as the basis for the discovery of improved individualized therapies for patients with multiple myeloma.”

Dr. van Beers and colleagues compared eight risk assessment platforms to analyze gene expression data from 91 newly diagnosed, untreated patients included in an independent dataset amassed by the Multiple Myeloma Research Foundation and the Multiple Myeloma Genomics Initiative (MMRF/MMGI). The investigators used the gene expression profiling (GEP) classifiers SKY92, UAMS70, UAMS80, IFM15, HM19, Cancer Testis Antigen (CTA), Centrosome Index, and Proliferation Index to identify high-risk patients.¹

Of the eight GEP classifiers, SKY92 identified the largest proportion (21%) of high-risk cases and also attained the highest Cox proportional hazard ratio (8.2) for overall survival (OS). Additionally, SKY92 high-risk cases predicted nine of the 13 (60%) deaths that occurred at 2 years and 16 of the 31 (52%) deaths at 5 years, a predictive rate that was higher than any of the other classifiers.¹

Dr. van Beers and colleagues also combined the SKY92 standard-risk classifier with the ISS to identify low-risk patients in the MMRF/MMGI cohort. This combination was recently identified as an optimal and robust marker for detecting low-risk MM³ – a discovery reprinted in the current issue of the *Dutch Journal of Hematology*.⁴ The SKY92/ISS marker identified 42% of patients as low-risk with median OS not reached at 96 months. The low-risk classification was strongly supported by the achieved hazard ratio of 10.¹

“The MMRF/MMGI dataset was not part of our previous discovery, which demonstrated that the combination of SKY92 and ISS identifies the lowest-risk patients with high accuracy and leaves the smallest proportion of patients identified as intermediate risk,” commented Dr. van Beers. “Thus, the dataset remained available for independent validation – an important factor in the adoption of gene expression profiling tools.”



“We are pleased to have validated the SKY92/ISS low-risk marker by applying it to the well-characterized MMRf/MMGI cohort,” added co-investigator Rafael Fonseca, M.D., professor of Medicine, chair of the Department of Internal Medicine, and consultant in the Division of Hematology/Oncology at the Mayo Clinic in Scottsdale, Arizona. “Our findings further strengthen the prognostic utility of the combination marker.”

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. 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.themmr.org, www.myeloma.org.uk, www.mpeurope.org, or www.myeloma.org.

About MMprofiler with SKY92

MMprofiler assesses risk by measuring the activity of 92 MM-related genes that comprise SKY92, the company’s novel, prognostic gene classifier. The lead product of SkylineDx, MMprofiler is proven to be superior to the biomarkers currently used to risk-stratify newly diagnosed and relapsed multiple myeloma patients into a “high” or “standard” risk category.⁵ 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.

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 with SKY92 is the company’s lead product. To learn more, please visit www.skylinedx.com.

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¹ van Beers EH, van Vliet M, Kuiper R, et al. Prognostic validation of SKY92 and its combination with ISS in an independent cohort of Multiple Myeloma patients. *Clin Lymphoma Myeloma Leuk*. 2017. doi: 10.1016/j.clml.2017.06.020.

² International Staging System. Multiple Myeloma Research Foundation. 2017. <https://www.themmr.org/multiple-myeloma/prognosis/myeloma-stages/international-staging-system/>. Accessed July 10, 2017.

³ Kuiper R, van Duin M, van Vliet, MH, et al. Prediction of high- and low-risk multiple myeloma based on gene expression and the International Staging System. *Blood*. 2015;126(17):1996-2004.

⁴ Broijl A, Kuiper R, van Duin M, et al. Hoog- en laagrisico-multipel myeloom kunnen worden voorspeld met de combinatie van EMC92 en ISS. *Dutch J Hematol*. 2017;11:339-40.

⁵ van Beers EH, van Vliet M, de Best L, et al. SKY92 GEP, iFISH, and ISS comparisons for risk stratification in multiple myeloma. Poster p661 presented at 20th European Hematology Association Congress, Vienna, Austria, June 13, 2015.