SkylineDx Poster Presentations at ASH Meeting Further Validate Use of MMprofiler™ with SKY92 in Multiple Myeloma

First Validation of SKY92 Prognostic Signature in Bortezomib-Thalidomide-Dexamethasone (VTD) Setting

Additional Data Yield Key Insights into Biology of Multiple Myeloma and Inform Design of Myeloma UK (MUK) Nine OPTIMUM Trial

Rotterdam, the Netherlands and Laguna Hills, CA, December 5, 2017 – SkylineDx today announced the presentation of new data at the 59th Annual Meeting and Exposition of the American Society of Hematology (ASH) in Atlanta, Georgia, that further validate the use of MMprofiler™ with SKY92, the company’s prognostic tool to risk-stratify patients with multiple myeloma (MM).

The following MMprofiler™ with SKY92 datasets will be presented in ASH poster session 651:

Myeloma – Biology and Pathophysiology, excluding Therapy: Poster III, at the Georgia World Congress Center, Building A, Level 1, Hall A2, on Monday, December 11, from 6-8pm ET:

• Abstract 4358: Erik H. Van Beers, SkylineDx
  MMprofiler with SKY92 Combined with ISS Identifies High and Low Risk Multiple Myeloma in the VTD Arm of GIMEMA-MMY-3006
  SkylineDx researchers will present the first report of the SKY92-based risk score in newly diagnosed multiple myeloma (NDMM) patients receiving the first-line combination regimen of bortezomib (Velcade®), thalidomide, and dexamethasone (VTD). The findings reportedly strengthen the prognostic power of SKY92 gene signature in yet another dataset, and support the rationale for using MMprofiler in combination with molecular genetic risk profiling to facilitate evaluation of risk-stratified treatment approaches in MM.

• Abstract 4368: Davine Hofste op Bruinink, Erasmus Medical Center Cancer Institute
  The Level of Circulating Myeloma Cells at Diagnosis Correlates with a Plasma Cell Leukemia-like Phenotype of the Corresponding Myeloma Cells in Bone Marrow
  Independent researchers will present data from a study in which SKY92 high-risk (HR-SKY92) score yielded key insights into the importance of circulating tumor cells (CTCs) in the biology of MM. The researchers surmise that they are the first to describe a differential gene expression profile between MM samples with a high CTC load versus a normal CTC load, adding that their findings point the way toward further analysis of the biological changes that occur during disease progression from MM to plasma cell leukemia (PCL).

In addition, the following dataset will be presented on Saturday, December 9, from 5:30-7:30pm ET, as part of ASH poster session 651: Myeloma – Biology and Pathophysiology, excluding Therapy: Poster I (also at the Georgia World Congress Center, Building A, Level 1, Hall A2):

• Abstract 1767: Amy L. Sherborne, The Institute of Cancer Research
  Improving outcomes for patients with high-risk multiple myeloma via prospective trial evidence: The Myeloma UK Nine Optimum Trial
  Investigators will provide a preview of the Myeloma UK (MUK) nine OPTIMUM trial, which will compare outcomes with the combination of daratumumab, cyclophosphamide, Velcade, lenalidomide, and dexamethasone (DCVRd) against control data from the UK NCRI Myeloma XI trial, in which MMprofiler™ with SKY92 was used to risk-stratify patients’ tumors. The OPTIMUM trial, one of the first trials designed to provide comparative evidence for stratified treatment of patients with high-risk MM (HRMM), has regulatory approval and is scheduled to start in late 2017 in 22 hospitals of the Myeloma UK Clinical Trial Network.

"With proof of principle firmly established in numerous treatment settings, it is gratifying to have further validation of MMprofiler with SKY92 in the VTD setting, and to gain such important insights into signalling pathways in multiple myeloma," said Dharminder S. Chahal, Chief Executive Officer of SkylineDx. "With two datasets enhancing our understanding of the biology behind multiple myeloma, and with a third dataset informing the design of what promises to be a landmark trial, the ASH data
presentations showcase how MMprofiler with SKY92 may ultimately inform therapeutic decision-making for patients living with this devastating disease.”

For more information on MMprofiler™ with SKY92, including the three datasets presented at ASH, visit the SkylineDx booth (#2047) in the ASH Exhibit Hall at the Georgia World Congress Center Building B, Level 1, Halls B2-B4.

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.


About MMprofiler™ with SKY92
MMprofiler™ assesses risk by measuring the activity of 92 MM-related genes that comprise SKY92, SkylineDx’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.1 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.mmpfiiorler.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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