SKY92 risk stratification at relapse provides additional prognostic information for standard-risk Multiple Myeloma patients

RNA-Seq based risk stratification in Multiple Myeloma patients validates SKY92 as a high-risk marker in the COMMPASS trial

Rotterdam, the Netherlands and Laguna Hills, CA, June 6, 2018 – SkylineDx today announced the presentation of new data at the European Hematology Association 23th Annual Congress (EHA) in Stockholm, Sweden, that further validates the use of MMprofiler™ with SKY92, the company's prognostic tool to risk-stratify patients with Multiple Myeloma (MM).

Globally, several clinical trials are investigating risk-stratified treatment strategies to address the unmet medical need of high-risk Multiple Myeloma as it remains a tremendous clinical challenge today.

Two publicly available MM patient data sets – the Multiple Myeloma Research Foundation (MMRF) CoMMpass trial (NCT145429) and the University of Arkansas for Medical Sciences (UAMS) total therapy cohort (TTx) – were used to assess the risk at both diagnosis and relapse of the same patients. This is the first longitudinal analysis of SKY92. In the CoMMpass cohort, the 17% high-risk that was seen at diagnosis increased to 40% at relapse ($p = 0.046$). The patients that were classified as high-risk at relapse passed away within one year from that time point (poster PS1295 in the Poster Area between 5.30-7PM on Saturday, June 16th at EHA).

For 632 patients from the CoMMpass trial, overall survival - and corresponding RNA-Seq data was available. Poster PF528 (Poster Area between 5.30-7PM on Friday, June 15th at EHA) concludes that this analysis is the first demonstration that the SKY92 classifier can effectively be converted from microarray to a RNA-Seq platform. Furthermore, besides the identification of the SKY92 high-risk group (18%), the CoMMpass analysis independently validates the identification of another subgroup. Approximately 28% of patients can be identified by SKY92 combined with ISS as a low-risk group with 94% overall survival at 36 months.

“With the confirmation that SKY92 can be applied to RNA-Seq data we made tremendous progress in the availability of this superior biomarker on independent platforms, making it available to even more patients in the future,” said Dharminder S. Chahal, Chief Executive Officer of SkylineDx. “This is much needed as the percentage of SKY92 high-risk patients significantly increases following disease progression making continuous informed treatment decisions and clinical research necessary to improve outcomes for these patients.”

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.themmrf.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, 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 MM patients into a "high" or "standard" risk category. Included in a growing number of international treatment guidelines, MMprofiler™ is CE-IVD registered in Europe and as laboratory-developed test (LDT) in the United States. For more information, please visit

www.mmprofiler.com

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About SkylineDx

SkylineDx is a commercial-stage biotech company headquartered in Rotterdam, the Netherlands, with a commercial office in Laguna Hills, California, USA. Originally a spin-off of the Erasmus Medical Center in Rotterdam, the company uses its expertise to bridge the gap between academically discovered gene expression signatures and commercially available diagnostic products with high clinical utility. With the focus on the discovery, development and early commercialization of novel gene signature-based diagnostics, SkylineDx assists healthcare professionals in accurately determining 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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