

SkylineDx Announces Prognostic Tool to be Used as Part of Major New Myeloma Clinical Trial

ICR to Use SkylineDx's MMprofiler™ Gene-Based Prognostic Signature in Phase IIb MUK nine High-risk Trial in Multiple Myeloma

Rotterdam, the Netherlands and Laguna Hills, CA, October 12, 2017 – SkylineDx today announced that The Institute of Cancer Research, London (ICR) and University of Leeds will use MMprofiler™ with SKY92, SkylineDx's prognostic tool to risk-stratify patients with multiple myeloma (MM), in a multi-centric Phase IIb high-risk trial known as MUK *nine*. The University of Leeds is the sponsor of this trial, which is partly funded by Myeloma UK, and ICR will perform the testing services to include high-risk patients with MM to evaluate an experimental treatment arm alongside standard treatment for these patients.

“Around 20% of myeloma patients are characterized as having high-risk myeloma, yet there is relatively little research looking at high-risk disease and treatment,” said Dr. Simon Ridley, Myeloma UK Director of Research. “This trial is looking to the future – we are trying to gain more insight into which treatment combinations might work best in different groups of high risk patients. We are pleased to work with SkylineDx in our efforts to characterize the potential clinical utility of new therapeutic approaches in high-risk myeloma.”

MMprofiler assesses risk by measuring the activity of 92 genes (the SKY92 gene signature) that are directly or indirectly related to the disease and that determines the level of risk for patients with multiple myeloma by classifying them into a “high” or “standard” risk group. Patients with a “high” risk classification have a poor prognosis as compared to patients with a standard risk profile, regardless of treatment.

“Investigation of new therapeutic approaches in individuals with high-risk multiple myeloma requires accurate and reliable patient identification and risk stratification,” said Dharminder S. Chahal, Chief Executive Officer of SkylineDx. “The use of MMprofiler in the MUK *nine* trial will facilitate patient selection, and may enhance our understanding of the potential utility of these new treatment modalities in this underserved patient population.”

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, 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.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.

About Myeloma UK

Myeloma UK is the only organisation in the UK dealing exclusively with myeloma – our ultimate goal is to find a cure. We are dedicated to ensuring that patients get access to the right treatment at the right time, and to improving standards of treatment and care through research, education and awareness raising. Our organisation also provides a range of information and support services to patients, family and friends to help deal with a diagnosis of myeloma.

Myeloma UK receives no government funding and relies almost entirely on voluntary donations and fundraising. For more information, please visit www.myeloma.org.uk.

The Institute of Cancer Research, London, is one of the world's most influential cancer research organisations.

Scientists and clinicians at The Institute of Cancer Research (ICR) are working every day to make a real impact on cancer patients' lives. Through its unique partnership with The Royal Marsden NHS Foundation Trust and 'bench-to-bedside' approach, the ICR is able to create and deliver results in a way that other institutions cannot. Together the two organisations are rated in the top four centres for cancer research and treatment globally.

The ICR has an outstanding record of achievement dating back more than 100 years. It provided the first convincing evidence that DNA damage is the basic cause of cancer, laying the foundation for the now universally accepted idea that cancer is a genetic disease. Today it is a world leader at identifying cancer-related genes and discovering new targeted drugs for personalised cancer treatment.

A college of the University of London, the ICR is the UK's top-ranked academic institution for research quality, and provides postgraduate higher education of international distinction. It has charitable status and relies on support from partner organisations, charities and the general public.

The ICR's mission is to make the discoveries that defeat cancer. For more information visit <http://www.icr.ac.uk>.

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¹ 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.