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"The speed & resolution of new mass spectrometers allow higher throughput for proteomic studies"

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US-based Discovery Life Sciences, the Biospecimen and Biomarker Specialists, has recently entered into an agreement with Olink to install the largest commercial platform of the Olink technology in the Americas (outside of Olink itself) to become a leading global certified service provider for the Olink Proximity Extension Assay (PEA) technology, a unique antibody based proteomic technology. Protein biomarker discovery can help bridge the gap between genomes and phenotypes, enabling improved understanding of real-time human biology and a stronger grasp of the transition from health to disease.

To find out more about the protein biomarker space, BioSpectrum Asia got in touch with Michael Pisano, Ph.D., EVP, Proteomics, Discovery Life Sciences™

How is the protein biomarker discovery space evolving globally, particularly in Asia? Could you quote some recent examples?

With the support of emerging technologies and techniques, biomarker research has made substantial progress, making biomarker detection and application more globally accessible. Discovery's recent collaboration with Olink positions us to provide the market, in Asia and beyond, with a global "one-stop shop" to support the discovery and validation of plasma

proteomics at scale and with high specificity across all major biological pathways and sample matrices. These types of milestones across the healthcare industry are propelling the market worldwide. In Asia specifically, Shanghai Pharma has a prominent presence in the market. Partnerships between companies like Quanterix and WuXi AppTec Laboratory Testing Division offer drug development companies access to state-of-the-art biomarker technology assay development, application, and deployment.

We can understand better how biomarker discovery has evolved when we look at examples like the prognostic, diagnostic, and predictive value of the HER2 biomarker, which has been established for breast, gastric, and gastro-esophageal junction cancers. Over the past two decades, therapies such as Trastuzumab, Lapatinib, and Trastuzumab-duocarmazine have been developed to treat these cancers, but their use and efficacy depend on the accurate classification of the HER2 status of the tumor.

Differences in HER2 expression among these cancers and tissue types require expert analysis to score and interpret and have led the field in establishing methodological guidelines to meet this need. Discovery's Global Tissue Biomarker Services Europe (formerly Targos Molecular Pathology GmbH), has been instrumental in helping to determine HER2 assay design, evaluation, scoring, and clinical utility for use in breast, esophageal and gastric cancers.

What are the unique opportunities & challenges associated with protein biomarker discovery?

One of the most significant challenges associated with protein biomarker discovery is coverage due to the complexity of the proteome. The number/type of proteins in a biological sample is in the hundreds of millions when you consider all of the proteoforms and variants that may be present at any time and how these continuously change in space and time. To achieve deep coverage, one has to sacrifice throughput. However, once putative biomarkers are uncovered, one can move to a targeted approach which can be highly multiplexed and brings higher throughput. At the same time, one can use a targeted approach as the discovery tool allowing for higher throughput.

Can we develop better solutions to address the growing burden of non-communicable diseases, such as diabetes, cancer, through protein biomarkers?

Absolutely. The discovery of novel protein biomarkers can enable earlier detection (and even prediction) of these non-communicable diseases, leading to better patient outcomes during treatment. Early intervention, regardless of the therapeutic area, is one of the strongest contributors to mortality and quality of life. In addition, protein biomarkers are being used to develop targeted therapies–especially in oncology.

Which are the major technologies used for protein biomarker discovery? Would this offer new opportunities to the equipment-based life sciences companies?

Significant progress has been made in protein biomarker discovery due to technological innovations that remove many barriers. For example, the speed and resolution of new mass spectrometers, better, more automated separation technologies, and various new platforms that allow higher throughput for proteomic studies.

Combining these advanced technologies, as with the Proteogenomic Consortium (Seer, Sciex, and DLS) formed earlier this year, that combines Seer's Proteograph™ Product Suite and the SCIEX ZenoTOF 7600 system with Zeno SWATH DIA, we can now provide unbiased, deep, and rapid assessment of the human plasma proteome at scale facilitating discoveries of novel variant proteins and putative biomarkers.

It certainly does provide opportunities to the equipment-based life sciences companies as we still are only scratching the surface as far as coverage of the proteome is concerned. So advances that will enable detection of the entire proteome gets proteomics to the ultimate goal of the field.

Can industry-academia partnership help in strengthening this space?

Partnerships with academics and research organizations across the world can help strengthen the biomarker discovery

space through the identification of new therapies and to find cures for the world’s most challenging diseases.

For example, the Biomarkers Consortium was established by the Foundation for the National Institutes of Health, the National Institutes of Health, the U.S. Food and Drug Administration and Pharmaceutical Research and Manufacturers of America. In addition, the Centers for Medicare & Medicaid Services and Biotechnology Industry Organization have been instrumental in implementing and organizing The Biomarkers Consortium. The Consortium brings together various partners from industry, government, and research institutions to identify, develop and qualify potential biomarkers to improve drug development and regulatory decision-making. The Consortium's vision is to create and lead cross-sector efforts that validate and qualify biomarkers and other drug development tools to accelerate better decision-making for the development of new therapeutics and health technologies.