# Press Release



Bundesministerium für Bildung und Forschung

### PEPperPRINT and PROGEN develop novel test for early diagnosis of rheumatoid arthritis

#### Launch of SeroRA<sup>®</sup> antigen library enables superior RA biomarker screening

**Heidelberg, June 7, 2017** – German biotech company PEPperPRINT GmbH announced today that it will develop a novel biomarker test for the early and differentiated diagnosis of rheumatoid arthritis (RA) together with PROGEN Biotechnik GmbH. The German Federal Ministry of Education and Research (BMBF) approved funds of 600.000 € in the next three years for this joint development.

RA is the most common inflammatory rheumatoid disease that affects approximately 20 million people worldwide. An early diagnosis and targeted therapy within the first two years is pivotal to avoid joint damage and deformation that may lead to physical impairments and even invalidity.

The sensitivity of existing serological tests is in the range of 70%, which means that about 30% of RA patients are declared seronegative and are not correctly diagnosed according to their individual antibody profile. Therefore, one major goal of this project is the identification of a highly sensitive and RA-specific biomarker set that enables a clear serological diagnosis in the early phases of the disease with regard to complex and heterogeneous antibody profiles. Furthermore, the identification of individual RA-specific biomarkers plays a central role in patient stratification as a basis for timely and personalized therapy decisions.

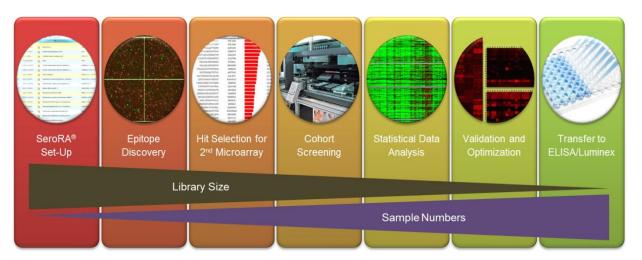
For test design, PEPperPRINT will utilize its new microarray-based SeroRA<sup>®</sup> library with more than 120,000 linear and cyclic constrained peptide antigens of human and pathogen origin to screen for IgG and IgA antibody profiles in serum samples of RA patient collectives. Dr. Volker Stadler, CEO of PEPperPRINT: "The size of our SeroRA<sup>®</sup> peptide microarray library exceeds that of other RA antigen libraries by several orders of magnitude. Moreover, the library covers not only several tens of thousands of native peptides but also the corresponding citrullinated and – for the very first time – homocitrullined variants. This powerful system enables the identification of completely new serum biomarkers and biomarker combinations for meaningful RA in vitro (IVD) and companion diagnostics (CDx)."

As part of the collaboration, PROGEN will carefully validate the biomarker candidates and will then use the final peptide selection to establish and optimize a sandwich-assay standard format for IVD purposes according to regulatory requirements. Dr. Sven Kuhlendahl, general manager of PROGEN: "We look forward to utilizing our longstanding expertise in immunochemistry for the development of a novel assay that enables the early diagnosis of RA with superior sensitivity and specificity."

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SeroRA<sup>®</sup> Workflow: The SeroRA<sup>®</sup> with more than 120,000 native, citrullinated and homocitrullinated peptide antigens is used for RA biomarker hit identification. Second generation SeroRA<sup>®</sup> microarrays with a narrowed peptide collection enable high-thoughput screening of IgG and IgA autoantibody profiles in RA patient collectives. The identification of RA biomarker sets by statistical data analysis is followed by further microarray-based peptide validation and optimization. The SeroRA<sup>®</sup> workflow is completed by transfer of the RA biomarker set to a diagnostic test platform.

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### About PEPperPRINT

PEPperPRINT is the leading provider of high-density peptide microarrays and high resolution linear and conformational epitope mapping services for antibody validation. Based on its proprietary peptide laser printing technology, the company's high-density PEPperCHIP<sup>®</sup> Peptide Microarrays set a new standard in terms of peptide diversity, signal quality and content flexibility. In addition to in-depth characterization of proteins, enzymes and antibodies, PEPperPRINT also offers high-throughput antibody screeening of patient sera e.g. in cancer, autoimmune or infectious diseases for serum biomarker discovery. The young and innovative biotech company is ISO 9001 certified and based in Heidelberg, Germany.

#### About PROGEN

Since 1983, PROGEN has been an established manufacturer and supplier of premium antibodies, in vitro diagnostics, and reagents for the global life science research community. While PROGEN's antibodies are among the most published antibodies in biomedical and cell biology literature, its ELISA kits aim at niche markets. Building on its core-competency in immunochemistry, the company has expanded its collaborations and business in recent years to access new research markets with innovative immunological products. The activities of the DIN EN ISO 13485 certified company focus on the development of ELISA tests for the determination of adeno-associated virus titers in gene therapy research and development. Since 2012, PROGEN has been a 100% subsidiary of the R-Biopharm AG.

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