



**2008 European Autoimmune Disease Diagnostics
Frost & Sullivan Excellence in Research Award**



"We accelerate growth"

2008 European Autoimmune Disease Diagnostics Excellence in Research Award

Award Description

Frost & Sullivan's Excellence in Research Award is bestowed upon a company that has carried out new 'disruptive' research; and has, in general, a strong commitment to research and development. This award recognizes a company's research and development program that has or is expected to bring significant contributions to the industry in terms of adoption, change, and competitive posture. The fruits of this research may already have or will potentially impact certain market sectors. The award also recognizes the company's overall research excellence as well as its commitment toward differentiating itself based on science-backed services or solutions.

Research Methodology

To choose the award recipient, Frost & Sullivan's analyst team tracks research and innovation in key high-tech markets. The selection process includes primary participant interviews and extensive primary and secondary research via the bottom-up approach. The analyst team shortlists candidate on the basis of a set of qualitative and quantitative measurements. The analysts also consider the pace of research and technology innovation, and the significance or potential relevance of the research to the overall industry. The ultimate award recipient is chosen after a thorough evaluation of this research.

Measurement Criteria

In addition to the methodology described above, there are specific criteria used to determine the final rankings. The recipient of this award has excelled based on one or more of the following criteria:

- Number or type of research projects
- Significance of research in the industry, and across industries (if applicable)
- Absolute R&D expenditures (vis-à-vis industry norm), and % growth (if applicable)
- Caliber/reputation of research staff
- Potential of products of research to become industry standard(s)
- Breadth of intellectual property ownership (patents, scientific publications, papers in peer-reviewed journals, and so on)



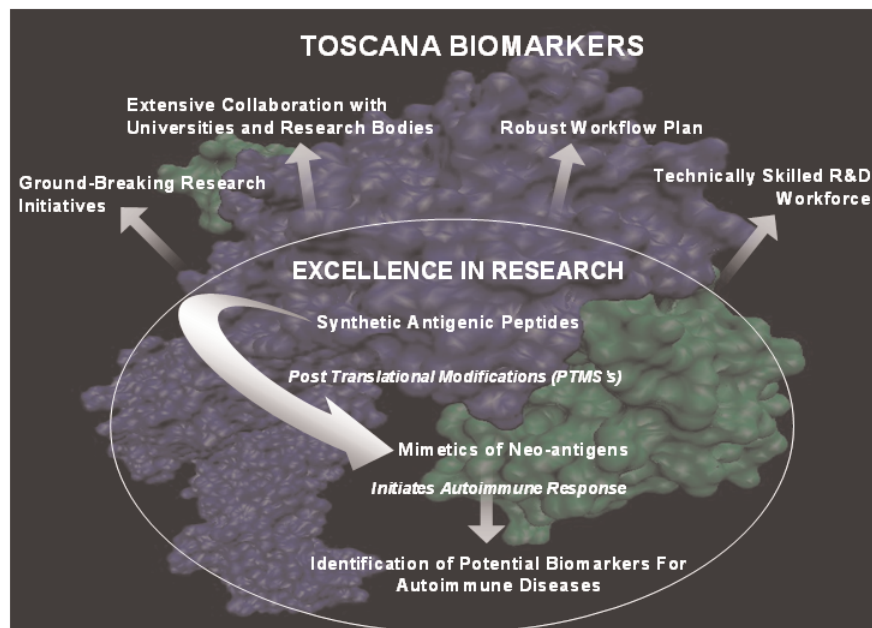
The 2008 Frost & Sullivan Excellence in Research Award in the European autoimmune disease diagnostics market is presented to Toscana Biomarkers. The company is recognised for its outstanding contributions to the research and development (R&D) of novel biomarkers for the diagnosis of autoimmune diseases. Started in 2007 and incubated by the recently born Toscana Life Sciences park in Siena, Toscana Biomarkers is dedicated to the discovery and validation of novel diagnostic and prognostic tests for autoimmune diseases.

Primary Focus

Biomarkers are basically, proteins or peptides which can serve as a facet or a component in determining the state and progression of a particular disease. Presently there has been a perplexing array of biological markers being developed for disease diagnosis and prognosis. On a research perspective, the applications of these biomarkers have been extensively used in the genetic and molecular analysis of relatively rare complications such as autoimmune diseases. Toscana Biomarkers' primary focus revolves around the identification of specific biomarkers detectable in patients' serum samples and validation of the same with respect to the disease progression and activity. Antigenic peptides, which can selectively and specifically recognise autoantibodies can be used in immunoenzymatic assays to detect disease biomarkers. In this perspective, the company aims at developing robust biomarkers panel for the diagnosis of autoimmune diseases ranging from rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE) to more complex diseases such as multiple sclerosis (MS) and systemic sclerosis.

Chart 1.1 displays the research strategy adopted by Toscana Biomarkers in the European autoimmune disease diagnostics market in 2008.

Chart 1.1: Autoimmune Disease Diagnostics Market: Research Strategy employed by Toscana Biomarkers (Europe), 2008



Source: Frost & Sullivan

Excellence in Research

Toscana Biomarkers, headed by a multi-disciplinary group of research scientists of the Universities of Florence (Interdepartmental Laboratory of Peptide and Protein Chemistry and Biology, PeptLab) and Pisa (Clinical Immunology Unit) has primarily concentrated its research under three diseases, namely RA, MS, and SLE. Complementing its focus in the development of novel disease biomarkers, the company is also engaged in the development of in-vitro diagnostic assays, especially the enzyme linked immuno sorbent assay (ELISA) for autoimmune diseases.

The central dogma to the company's R&D revolves around a peptide-based reverse approach (chemical reverse approach - CRA) to detect biomarkers for autoimmune complications. The "reverse" approach indicates that the screening of antigenic probes is primarily guided by the antibodies circulating in a patient's biological fluids. The circulating auto-antibodies aid in recognising and optimising the molecular ("chemical") structure of defined and pre-disposed peptide libraries. The synthetic post-translationally modified peptides basically get well recognized by the auto-antibodies effectively mimicking the neo-antigenic epitopes. These peptides could be further screened and employed as antigenic probes for the detection of potential biomarkers for the disease.

Taking advantage of the potential post-translational modifications (PTM's) associated with the pathogenesis of autoimmune diseases, the R&D team at Toscana Biomarkers aims at providing novel diagnostic solutions employing disease biomarkers. PTMs such as lipidation, citrullination, and glycosylation play a fundamental role in antigen recognition as they are known to alter its immunogenicity and function. Such modifications alter the antigens structural integrity making them "neo-antigens" triggering an immune response (autoimmune). Researchers are now in the process of introducing synthetically developed antigens subjected to chemical modification employing appropriate PTMs. Such synthetic peptides that are developed mimic the native neo-antigens.

Conclusion

The company through its ground breaking research initiatives has clearly demonstrated the ability of incorporating synthetically modified peptides for the validation and discovery of biomarkers for the effective diagnosis of autoimmune diseases. The researchers at Toscana Biomarkers are determined to explore the possibilities of adopting robust approaches in identifying novel diagnostic solutions within the autoimmune diseases diagnostic space. By virtue of these cumulative factors Toscana Biomarkers has been recognized by Frost & Sullivan for its outstanding achievements in biomarker research and discovery and is the worthy recipient of the 2008 Frost & Sullivan Excellence in Research Award in the European autoimmune disease diagnostics market.

About Best Practices

Frost & Sullivan Best Practices Awards recognize companies in a variety of regional and global markets for demonstrating outstanding achievement and superior performance in areas such as leadership, technological innovation, customer service, and strategic product development. Industry analysts compare market participants and measure performance through in-depth interviews, analysis, and extensive secondary research in order to identify best practices in the industry.



About Frost & Sullivan

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