

Novel Diagnostic Tests for Autoimmune Disease Treatment Strategies



Dr. Stefan Muellner
CEO
Protagen AG

CEOCFO: Dr. Muellner, what is the basic concept behind Protagen?

Dr. Muellner: At Protagen, we are dedicated to the development of novel diagnostic tests that aid successful therapeutic development and better treatment strategies for some of the most severe autoimmune diseases.

We have developed a multi-marker assay technology called SeroTag® that is based on one of the largest human recombinant protein expression libraries in the world. We maintain all of these proteins, clones and expression capabilities in-house. With our SeroTag biomarker platform, we have the power to identify novel biomarkers for improved diagnostics. Being ISO 13485 certified we have now everything under one roof – from discovery through to the CE-mark test development.

CEOCFO: What is different about your platform? What are you able to do that perhaps others cannot?

Dr. Muellner: In autoimmunity, the immune system directs its activity against the own body. Currently there are around 100 defined autoimmune diseases according to the American Association of Autoimmune Diseases. However, there are less than 50 diagnostic markers that are useful for diagnosing those diseases or differentiating them from other autoimmune diseases. Thus, there is a clear, unmet diagnostic need in this field. Unlike earlier, often unspecific approaches to diagnostics, our SeroTag® platform systematically analyses human serum samples for specific autoantibody signatures. Our understanding of disease-specific autoantibody profiles and their application to the development of novel, robust diagnostic tests means that we are exceptionally well positioned to create products that will enable earlier diagnosis with improve sensitivity and specificity, and therefore the subsequent treatment of autoimmune disease.

CEOCFO: Why the decision to go in this direction? Why is it a better way for the company?

Dr. Muellner: Previous attempts have often been limited by the fact that they could not define the specific protein target even if they saw a response on the tissue slide. This has had significant implications for test development, sensitivity and specificity. With our SeroTag® approach, we can directly identify the targets to be used in diagnostic tests. Overall, it is much easier to develop a specific product when you have a defined biomarker protein – this also improves the market take-up of such a product.

CEOCFO: What has been the reception from the research community?

Dr. Muellner: So far, it has been extremely positive. The business community still has to be convinced a little more, but I think that further market education can solve this – especially when it comes to Companion Diagnostics (CDx) in the autoimmune diseases field. For example, while some of the big pharma companies are positive towards us, others are failing to see a reason to invest in new diagnostics in this field. Currently, it is not like oncology where the FDA and the pharma companies have already accepted the necessity of biomarkers in stratifying patients for more successful drug development programmes. In fact, there is quite a degree of reluctance towards novel biomarkers because they might split the available treatment market.

However, existing novel biologic treatments are very expensive and have a response rate of around 50%, thus the cost pressure from payers will ultimately guide pharma to novel markers. We strongly believe that we are currently in the 'sweet spot' with our approach: although we are not yet doing business at full steam, our work is based on excellent science that has already been accepted by the clinicians. This will greatly help our market penetration.

CEOCFO: How do you educate the business community and get them to pay attention?

Dr. Muellner: We listen to their preferences and their arguments. As a small company, we are focusing on some of the most relevant autoimmune diseases, such as Rheumatoid Arthritis (RA), Systemic Lupus Erythematosus (SLE) and

Systemic Sclerosis (SSc). This has led to the development of NavigAID SLE, which we launched in April this year. This is pharma product to support the clinical development of novel SLE therapies.

We also go to the typical conferences like EULAR (the European League against Rheumatism) and ACR (the American College of Rheumatology). We do also use more direct ways, i.e. making use of my network – having come from a pharma background – to convince the public, pharma, payers and ultimately patients that it is worthwhile to work with and invest in Protagen.

CEO CFO: Would you tell us about your first CE marked product?

Dr. Muellner: We recently received our ISO 13485 certification. As a part of the certification process, and to fast track the process, we developed a generic marker and compared this to other products from a peer group. The results successfully proved that we could deliver the same or even better performance with our own product compared to marketed products. We are now developing our first proprietary marker for the diagnosis of SSc – an autoimmune disease with high morbidity and mortality – as an ELISA (Enzyme-Linked Immunosorbent Assay) plate. Developing novel proprietary markers is challenging since there are no benchmarks or predicate devices. We should complete that development by the end of the year with the first novel, proprietary CE-marked test from Protagen. In parallel, we have also already started development of a novel diagnostic for SLE, and expect it to be CE-marked in 2016. There is also rich pipeline of novel immune diagnostic products still to come.

“We are the only company in the world with this technology and we are the only company providing new content to the autoimmune diagnostic world.” - Dr. Stefan Muellner

CEO CFO: With so much opportunity, how do you decide where to focus?

Dr. Muellner: Our SeroTag® approach is focused on autoantibody profiles, and given the importance of autoantibodies for the diagnosis of autoimmune diseases, this focus area seems justified. Yet with so many autoimmune diseases, we have to concentrate on a limited number of indications. There was a small opportunistic drive here since we already had a very good clinical network in rheumatology from previous government funded projects. One of the key opinion leaders on these projects more or less fell in love with our technology and helped us confirm that we should stay in the areas of RA, SLE and related diseases.

Given that we are dependent upon good clinical samples for our discovery and validation work, this valuable connection opened the door for us to the rheumatology space. Having said that, our SeroTag® platform is almost indication-agnostic, and can be applied to other indications and therapeutic areas such as neurology, e.g. multiple sclerosis, gastroenterology, e.g. inflammatory bowel disease, and others. So, there is still plenty of work and potential ahead of us.

CEO CFO: Are you funded for the next steps or will you be seeking additional funding or investments?

Dr. Muellner: We are currently looking for additional funding, having a runway until the end of the year. The additional funding may come from VCs or strategic partners. Regardless of the source, the new funding will give us the security to develop our full pipeline of products. It is my personal opinion that it is now time to collaborate with big companies in the field and forge strategic alliance(s) for our diagnostic product portfolio.

CEO CFO: Why pay attention to Protagen today?

Dr. Muellner: We are the only company in the world with this technology and we are the only company providing new content to the autoimmune diagnostic world. There is currently no other company with this potential. There is ongoing research in academia but there is no company at the moment that has a similar technology to ours and that has the complete value generation chain from discovery to final product under one roof. This makes us unique and gives us a first-mover advantage in this field.

Interview conducted by: Lynn Fosse, Senior Editor, CEO CFO Magazine

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