MOLOGEN

German pioneer in the field of immunotherapy

Berlin-based MOLOGEN AG is a pioneer for many reasons: Firstly, the company had already recognised the potential of the body's own immune system to fight cancer or other diseases by the 90s – long before immuno-oncology hit headlines across the globe. Secondly, MOLOGEN was one of the first German biotech companies to list on the stock market, taking this brave step shortly after its foundation in 1998. Today, MOLOGEN is a well-established clinical stage biopharmaceutical company. Its lead candidate Lefitolimod is currently tested in a pivotal phase III trial for first-line maintenance treatment of metastatic colorectal cancer and in a phase II trial with lung cancer patients. In addition, a combination study with the checkpoint inhibitor Yervoy® (ipilimumab) is ongoing. "We were among the first to recognise the potential of immuno-oncology therapies and we alone subsequently identified and developed all of our current candidates in the pipeline," says Mariola Söhngen, CEO of MOLOGEN AG.

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This experience has helped the company to reach late stage clinical phases without any partners. "We have succeed in financing our clinical development stages through the capital market," Söhngen states. Since the IPO in 1998 at the German Stock Exchange in Frankfurt/Main, MOLOGEN has raised a total of €145m in follow-on financing rounds.

The Company's roots date back to the late 90s when molecular biologists working alongside Prof. Burghardt Wittig at the Freie Universität Berlin (Free University of Berlin), Germany, developed promising new DNA technologies and undertook pioneering research with cell-based therapeutic approaches to treat cancer patients. Based on these findings, MOLOGEN was founded and the proprietary dSLIM® technologies (family of TLR9 agonists) were developed. These days, the company is focusing on its lead candidate Lefitolimod (MGN1703) which belongs to the class of immunomodulators that bind to toll-like receptors (TLRs). These receptors serve to identify pathogens such as viruses, bacteria or fungi, and initially activate the innate immune system and also, potentially activate the adaptive immune system to fight these off. "Based on treatments with more than 450 patients so far, the drug has a favourable safety profile and is well tolerated," says Söhngen. In addition to the oncology field, Lefitolimod is also being tested for the indication HIV. A phase Ib/IIa study began in 2015 and it has already been extended. Key results have been presented in August 2017. In summer 2017, MOLOGEN announced plans to cooperate with Chinese company iPharma Ltd., to develop, produce and distribute Lefitolimod in China. The final licensing agreement is to include an initial payment at signing of €3m and potential milestone payments of a total volume of up to €100m. In addition, MOLOGEN would receive low double digit royalties on sales.

MOLOGEN AG, Berlin, Germany

Established	1998
Headquarters	Berlin
Field of activity	Immunotherapies to treat colectoral cancer, lung cancer and HIV that trigger the innate immune system; immunomodulators which bind to toll-like receptors (TLRs)

Employees (2017)	50
Turnover (2016)	–
Market capitalisation | 4 Oct 2017	€107.96m

Year of IPO | German Stock Exchange	1998
Raised capital via IPO | Frankfurt	€5.1m
Raised capital via follow-on financings	€130.5m
Major shareholders | 30 September 2017 (estimates)	Global Derivative Trading GmbH (<25%), Deutsche Balaton Aktiengesellschaft (5%), SIGNAL IDUNA Krankenversicherung a.G. (4%), Baloise Holding AG (4%)

Interview

Dr Mariola Söhngen *joined the Executive Board of MOLOGEN AG in November 2015. She has acquired a wealth of experience in the biotechnological and pharmaceutical industry. She is co-founder of both PAION AG and PAION Deutschland GmbH and served as a Managing Director since the foundation. In addition, from 2004 to 2015 she held the position of Chief Medical Officer (CMO) of PAION AG. In this function, she was responsible for clinical drug development Phase I–IV, Regulatory, Drug Safety, Quality Assurance and other areas. Prior to that, Dr Söhngen held several positions in the pharma industry. Following her medical degree in 1987, Dr Söhngen obtained both a PhD in Medicine, a Diploma in Pharmaceutical Medicine (DGPharMed) and Master of Business Communication.*

Your listing on the German stock exchange in Frankfurt already dates back 20 years. Are you satisfied with being a European listed company?

Yes, the capital markets here in the EU have supported the growth of the company over a long time. Given the further development of the company, we are now also looking into other markets and have just attracted a US investor in our last financing round.

Globally, there are quite a few companies active in the field of immunotherapy. What makes MOLOGEN AG unique?

We have been working in this field since 1998. Based on our experience, we have developed our technologies and identified promising drug targets. All of the candidates in our pipeline are the result of our own R&D activities and we have succeeded thus far in bringing our most advanced project, Lefitolimod, to a clinical stage III trial.

What is the current state of your most advanced candidate Lefitolimod?

The safety profile after more than 450 patients shows that Lefitolimod is a well-tolerated drug. It is well tolerated compared to other immunotherapies. The IMPALA phase III trial is running according to our expectations for patients with metastatic colorectal cancer. Here, we are testing the candidate

as first-line maintenance. We reached our goal to include 540 patients in mid-May 2017. The analysis of this trial is expected for 2019. The results of our explorative phase II study IMPULSE recently demonstrated that we are on the right track. They gave us an initial idea of the efficacy of Lefitolimod for some subgroups of lung cancer patients. For many experts, these results were kind of an eye opener because to date there has been almost no therapeutic success for this difficult indication. Our results, however, were considered as a very positive sign for specific subgroups and will help us to define such groups for studies relevant for approval.

What is your next step?

We are currently focusing on out-licensing or partnering for our lead candidate Lefitolimod and on preparing for its possible market approval. We are looking for global and also for regional partners, especially in Europe, North America and East Asia to develop Lefitolimod further. We are particularly interested in finding a financially strong company which could initiate further clinical trials. The first important step will be an agreement with Chinese company iPharma Ltd., to develop, produce and distribute Lefitolimod in China, for which MOLOGEN signed a binding term sheet this summer.

Which partners would be most interesting for Lefitolimod?

From our perspective, there are three groups of companies which would profit the most. Firstly, there are big pharma companies which want to close a gap in immunotherapy or strengthen their portfolio with an advanced product. Secondly, our drug could be a fit for companies already working in the immunotherapy field, with checkpoint inhibitors, for example, but which need a complementary candidate to offer combination therapies to differentiate from other checkpoint inhibitors. Thirdly, our product would be interesting for one-product-companies which want to test their therapy in a combination study.

Which mode of action would suit most in combination with Lefitolimod?

The candidate not only works with checkpoint inhibitors, but it may also improve the efficacy of chemotherapeutics, therapeutic cancer vaccination or oncolytic viruses. This is because, unlike many others, our drug works on the proximal part of the immune cascade. Lefitolimod binds to suitable TLR9 receptors within specific immune cells mainly in so called plasmacytoid dendritic cells which trigger the immune system to fight against cancer cells. For this reason, a combination of our immune surveillance reactivator with a more targeted cancer approach would make perfect sense.

DOs

Establish strong and experience management!

Prepare financial reporting, control systems and compliance system!

Identify and select strong partners, e.g. legal and financial advisors, investment bank!

Establish and empower investor relation!

Define and communicate convincing equity story!

Tell uniqueness of the company!

Deliver your goals on time and ensure quality!

DON'Ts

Don't oversell equity story!

Don't plan with a too tight time schedule!

Don't underestimate costs and resources needed!

Don't start without a backup or Plan B!