# Interview: Riccardo Palmisano â?? CEO, MolMed, Italy

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*Riccardo Palmisano, CEO of MolMed, discusses the latest developments for their late-stage clinical development products, and comments on the recent approval of Strimvelis, a gene therapy developed by GSK and MolMed.*

**Can you please give our readers a brief rundown of the history of MolMed since its foundation in 1996?**

MolMed was founded in 1996 as a joint venture between Boehringer Mannheim and Science Park Raffaele to provide cell therapy services. From 2000 onwards, MolMed evolved into a biopharmaceutical development company, with a primary focus on novel cancer therapies: at the end of 2000, the company entered a new phase, beginning its transformation from service provider into a biopharmaceutical company and thus adopting a business model with greater growth prospects. Pursuant the several in-licensing agreements and out-licensing and co-development agreements signed with different parties since 2001 Molmed enlarged its portfolio with cell therapy and vascular-targeting biopharmacotherapy programs that gave rise to the products currently in late stage clinical trials, TK (Zalmoxis$^{Â®}$) and NGR-hTNF, respectively. Quite recently (March 2015) MolMed took a step in immuno-gene therapy acquiring the CAR-CD44v6 project, potentially effective for many hematological malignancies and several epithelial tumors, currently in preclinical development.

Today, MolMed is a mature company covering all functions, from discovery to proof of clinical activity, pursuing growth on four key pillars. We focus on oncology indications that require new

therapy options, aiming at fulfilling unmet clinical needs, efficiency improvement of clinical and pharmaceutical development, in-house GMP-based manufacturing of cell and gene therapy products and lastly, a diversified portfolio of strategic collaborations.

Major milestones have been achieved recently, paving the way to our growth strategy. In fact, in last December AIFA (Agenzia Italiana del Farmaco) granted the operating facility located in Milan, via Olgettina, 58 (at the San Raffaele Biotechnology Department â?? DIBIT), authorization to manufacture medicinal products to be marketed. This authorization is valid for manufacturing of medicinal products used in a specific gene therapy based on genetically modified stem cells (Strimvelis$^{Â®}$, owned by GSK), and in a specific cell therapy based on immune system genetic engineering (Zalmoxis$^{Â®}$). This authorization confirms MolMedâ??s technical-scientific and industrial quality standard in the field of gene and cell therapies: thanks to focus on innovation and technology, MolMed is the first to be ready to manufacture medicinal products of this kind for market use, both from its own or from pharma and biotech partnersâ?? pipelines.

Of course, only the marketing approval granted by the European regulatory authority for each specific therapy will make the product potentially available to a larger patient population: Zalmoxis$^{Â®}$ is in the final phase of the regulatory assessment process to obtain the Conditional Marketing Authorization, that will allow to anticipate the access to the market and to patients suffering of a life-threatening disease; Strimvelis, GSKâ??s treatment for ADA-SCID patients received the positive opinion of CHMP on the 1st of April thus representing a tangible and encouraging result of the strategic collaborations existing between GSK, the San Raffaele Telethon Institute for Gene Therapy (HSR-TIGET) and MolMed. Actually, MolMed previously produced on behalf of Fondazione Telethon the investigational gene therapy where the correct form of the ADA gene is inserted into the patientsâ?? own bone marrow derived stem cells. Since 2010, GSK took the responsibility of the clinical development of the ADA-SCID gene therapy, in collaboration with HSR-TIGET, from which they in-licensed the rights to develop and commercialize the therapy, and with MolMed for the manufacturing process optimization, standardization and characterization, as well as for the drug product supply intended to be used for compassionate treatment of patients, accordingly with agreements signed in 2011 and 2013.

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**Can you give us an overview of your product pipeline?**

MolMed is currently working on two products in Phase II/III development: TK, which has the branded name Zalmoxis, and NGR-hTNF.

Zalmoxis/TK is a cell-based therapy enabling bone marrow transplants from partially compatible donors, in absence of post-transplant immune-suppression, currently in Phase III in high-risk acute leukaemia and under evaluation by EMA for a Conditional Marketing Authorization; NGR-hTNF is a novel therapeutic agent for solid tumours which displays antitumor activity through its specific binding to blood vessels feeding the cancer and to the concentration of immune system cells into the tumour mass, currently investigated in a broad clinical programme. It is a very promising product with great results in over 1000 patients in our clinical trials. We are exploring the opportunity to submit the dossier for conditional market authorization and accelerated market access respectively in Europe and the US for the mesothelioma indication towards the end of this year.

At the same time, we are developing other assets: CAR-CD44v6, an immuno-gene therapy project that is currently in a pre-clinical stage. Based on the peculiarity of the product it can be used for hematologic tumors (e.g. leukemia and multiple myeloma) and also for several solid tumors, including breast, lung and colon. Leveraging on our expertise in developing cell and gene therapies,

we are committed and confident to increase the value of this product and to bring this product to patients in a few years.

**MolMed has its headquarters at the San Raffaele Biotechnology Department, one of the best-known centers for gene therapy in Europe. What is the importance of securing third-party collaboration to MolMedâ??s business model?**

We are indeed engaged in third-party manufacturing, a capability we have acquired since our inception and initially during the development of our own therapies, being resilient and confident, in a period when cell and gene therapy was considered an obscure field, at least.

Based on our capabilities we are attracting numerous partners: we have agreements with GSK, the Telethon Institute, Genenta Science, and are finalizing another potential collaboration with a multinational partner that I cannot disclose at this moment. Today we have a facility that covers 1400 square meters at the San Raffaele hospital, the first facility in Europe that is approved for manufacturing of cell and gene therapy (Strimvelis and Zalmoxis) for the market. In 2013, MolMed started an important project aimed at expanding its production capacity at the scientific park â??Open Zoneâ?• in Bresso (Milan). We invested a huge amount of money into this facility, which includes laboratories, clean rooms, development and manufacturing spaces. With this new facility, today completed and waiting for the final authorization by AIFA, MolMed will gain an additional 3,300 sqm of fully compliant production capacity, meeting the same quality standards and technological expertise already endorsed at the manufacturing site located at DIBIT.

**What is your vision for the future of MolMed?**

In the near term, we want to find partners for co-develop and co-marketing our products. We may consider commercializing Zalmoxis ourselves but for NGR-hTNF we do not have the adequate footprint to do so. At the same time we are selecting partners for the co-development (in indications other than mesothelioma) and manufacturing of it: we are looking for knowledge partners, licensing and/or patent agreements and more.

In the medium-term we want the business model to consider not only out-licensing but in-licensing as well.

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We have to initiate the search for products to enlarge our own early stage pipeline. Compared to our peers in the industry MolMed is rather unusual: we have two products in late stage clinical development and one product in the pre-clinical stage whereas our peers have plenty of products in the pre-clinical stage but no products in phase II/III. While we are now fully dedicated to bring Zalmoxis and NGR-hTNF to patients, we certainly have to increase our pipeline, which must be enrich for the long-term.

We have three clear missions. The first one is to provide innovative therapies to patients. The second one is to generate return on investment for our investors who supported and trusted in our science from the very beginning. Thirdly, we want to demonstrate that in Italy, you can still build a science-based biotech company that will not be sold to multinational players. In the recent past we have seen very successful stories of biotech companies that were ultimately acquired by bigger players but I do not think that it is too late to build an Italian Actelion or Genzyme. We have to be resilient on this path.

**In this pursuit, what makes MolMed the partner of choice?**

Firstly, we are a top player in the development and manufacturing of cell and gene therapies. We are one of the only companies that can create value to cell and gene pre-clinical therapies to our potential partners. We are in discussion with big pharmaceutical companies who have chosen us over our competitors

Secondly, we are very strong in the quality of work we produce. R&D and manufacturing are important but it is crucial to invest in quality, which is a key differentiator for MolMed.

On the commercial side, we have two innovative therapies close to the market in need of additional resources to complete full authorization. With Zalmoxis, there is an opportunity to create and shape a market without having to worry about competition at all.

**What is your final message to the readers of PharmaBoardroom and Pharmaceutical Executive?**

MolMed sets the standard of excellence in cell and gene therapy. We are preparing to be ready from research and development to the market place, looking for partners to support us in this pursuit. We are asking the institutions to support us with the punctual authorization of our processes and products to bring innovative treatments to patients around the world, which will also enable to increase the number of partnerships in our new facility.

Biotechnology is a field where we see a lot of developments and investments and Italy surely wants to play a role in this field in the future. On a broader scale, we are talking about leveraging Italian abilities, for example the excellence in vaccines with GSK, the excellence in cell and gene therapy with MolMed and the excellence in regenerative medicines with Chiesi.

As President of Assobiotec, the Italian biotech companies trade association, Iâ??m cooperating with Italian Institutions too, in order to build a kind of incubator/accelerator where smaller biotech companies could find the necessary resources they do not have on their own to develop and launch future products. I am sure that MolMed could, and should, play a relevant role in such innovative public-private collaboration too.

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