



an integrated
strategy
to cure cancer



MolMed S.p.A.

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Director Drug Development

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Director Operations, Qualified
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Shareholder Information

MolMed (Milan:MLM) is a public company listed at the Milan Stock Exchange, on the Standard segment (class I) of the *Mercato Telematico Azionario* managed by Borsa Italiana

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MolMed is a medical biotechnology company with a primary focus on developing novel and effective therapies for treating tumours.

MolMed is building up an integrated strategy, by the development of both effective targeting of the tumour mass in the acute stage, and highly selective therapies to eliminate residual disease.

MolMed has a strong pipeline, with 2 products in several different clinical trials, and 3 leads in preclinical or R&D stage, based on different biotech-based approaches: cell-based therapy with genetic engineering, and vascular targeting.

MolMed has 90 highly skilled employees in a total staff of 110. Its management team combines scientific excellence with industrial and management expertise.

MolMed is located in Milan (Italy), within the San Raffaele Biomedical Science Park, the leading Italian biomedical research institution.

Corporate History

1996: Incorporation as a joint venture between Boehringer Mannheim and Science Park Raf, to provide cell therapy services

1999: Acquisition of Boehringer by Roche, which sells its equity stake to the investment fund EDCP (now AIRAIN)

2000: Evolution from service to product company

2002: Acquisition and incorporation of the research company Genera S.p.A.

2004: Entrance of 3 new shareholders through a capital increase of € 20 million: *Fininvest*, *H-Equity SICAR* and *Delfin*

2007: Overall capital increase of € 26 million since 2005

2008: IPO of 25% of shares, resulting in € 56 million of proceeds. Shares are traded on the Milan Stock Exchange since March 5, 2008

Strategy for growth: a full industrial project built on a sound science basis

- Focus on oncology indications needing new options
- Efficient clinical & pharmaceutical development, independently or with partners
- In-house GMP manufacturing of cell/gene therapy products
- Diversified pipeline to create value for shareholders

Highlights 2008

- Start of Phase III trial of TK therapy in high-risk acute leukaemias
- Orphan Drug designation to NGR-hTNF for the treatment of mesothelioma in both EU and US
- Promising clinical results for NGR-hTNF in Phase II trials as single agent in 3 indications: colorectal and liver cancer, and mesothelioma
- Ongoing Phase II trials of NGR-hTNF in combination therapy: with Xelox in colorectal cancer, and with doxorubicin in small-cell lung cancer and in ovarian cancer

TK

Therapy enabling safe and effective haplo-HSCT

TK is the only therapy that specifically addresses the issue of enabling safe and effective haematopoietic stem cell transplantation from a partially compatible donor (haplo-HSCT) to treat high-risk leukaemia patients, without elimination of donor T cells. Haplo-HSCT is normally hampered by a severe immune reaction against patient's tissues, known as GvHD, mediated by donor T cells. The standard way to prevent GvHD is the elimination of donor T cells from the graft, but this procedure heavily reduces the effectiveness of the transplant, because donor T cells have key therapeutic effects, since they protect the patient from infections and from residual leukaemia cells, while the immune system reconstitutes from the transplanted stem cells. With the TK therapy, patients can receive donor T cells as add-backs to haplo-HSCT: this is made possible by genetic engineering of donor T cells with insertion of the TK gene, allowing to control and abrogate GvHD in case of onset, through the simple administration of ganciclovir.

TK was granted Orphan Drug designation both in the EU (2003) and in the US (2005).

Clinical development: completed and ongoing trials

- Phase I/II trial in Europe for high-risk leukaemia: the completed study showed the safety of TK therapy, and a great improvement in patients' survival, thanks to rapid and sustained immune-reconstitution
- Phase III trial for high-risk leukaemia: started in Italy in 2008, planned to become a multicentric trial in Europe and in the US
- Phase I trial for leukaemia: started in Japan in October 2008, conducted by Takara Bio Inc, MolMed's Asian partner for cell and gene-based therapies

NGR-hTNF

Vascular targeting agent to treat solid tumours

NGR-hTNF (ARENEGYR) is a first-in-class vascular targeting agent (VTA): it is a fusion protein obtained from the combination of a tumour homing peptide (NGR) with the human cytokine Tumour Necrosis Factor (hTNF). While anti-angiogenesis agents inhibit the growth of new tumour blood vessels, NGR-hTNF targets existing blood vessels feeding the tumour, through specific binding of the NGR peptide to the tumour vessel endothelium. NGR-hTNF is currently in clinical development either as single agent or in combination with different chemotherapeutic agents, for 5 types of solid tumours.

In 2008, NGR-hTNF was granted Orphan Drug designation for the treatment of mesothelioma, both in EU and in the US.

Clinical development: ongoing trials

- Phase II trials as single agent, for colorectal and hepatocellular carcinomas, and for malignant pleural mesothelioma
- Phase II trials in combination with doxorubicin, for small-cell lung and ovarian carcinomas;
- Phase II trial in combination with Xelox, for colorectal carcinoma
- Phase I trial as single agent at high doses
- Phase I trial in combination with cisplatin

NGR-IFN γ and NGR-IL12

MolMed's VTA programme includes two additional molecules, combining the tumour homing peptide NGR with the cytokines interferon-gamma (NGR-IFN γ) and interleukin 12 (NGR-IL12): the two projects are in the preclinical and discovery stage, respectively.

Product	Indication (trial code)	Res	Precl	Phase I	Phase II	Phase III	
TK	High-risk leukaemia (TK007, TK008)	■	■	■	▶		
NGR-hTNF	Solid tumours [→MTD] (EORTC)	■	■	■			
	Solid tumours [low dose] (NGR002)			■			
	single agent	Colorectal cancer (NGR006)				▶	
		Hepatocarcinoma (NGR008)				▶	
		Mesothelioma (NGR010)				▶	
		Solid tumours [high dose] (NGR013)			▶		
		Small cell lung cancer (NGR007)				▶	
	+ doxorubicin	Solid tumours (NGR003)		■	■		
		Ovarian cancer (NGR012)				▶	
	+ XELOX regimen	Sarcomas				▶	
Colorectal cancer (NGR005)					▶		
+ cisplatin	Solid tumours (NGR004)		■	■			
	Lung cancer/NSCLC				▶		
NGR-IFNγ	Solid tumours	■	■				
NGR-IL12	Solid tumours	■					

Legenda for clinical trials: ■ completed ▶ ongoing ▷ planned