



an integrated
strategy
to cure cancer



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Director Operations,
Qualified Person

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Director Clinical Development

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Shareholders' Information

MolMed (Milan:MLM) is a public
company listed on the Milan
Stock Exchange, on the MTA
(standard segment, class I)
managed by Borsa Italiana

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MolMed is a late-stage biotech
company focused on oncology,
with two investigational
therapeutics in Phase III.

MolMed's pipeline is unique,
with diversified therapeutic
approaches and technology
platforms.

MolMed's investigational therapeutics are
both new, completely original, first-in-
class candidate products building up new
therapeutic classes, based on two
different biotech-based approaches: cell
therapy using genetically engineered
cells, and vascular targeting biologics.

MolMed's staff includes 87 highly skilled
employees. 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 &
gene therapy services

1999: Acquisition of Boehringer's equity
stake by 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* and
Delfin

2007: Overall capital increase of € 26
million since 2005

2008: IPO of 25% of shares (€ 56 million
gross proceeds)

2010: Share capital increase with option
right (€ 58 million gross proceeds)

Strategy

- Focus on oncology indications with
high unmet need
- 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 2010-1H 2011

- Start of Phase III trial of NGR-hTNF for
mesothelioma and IND clearance by
the FDA to conduct the trial in the US
- IND clearance by the FDA to conduct
Phase III trial of TK for high-risk
leukaemia in the US
- Evidence of anti-tumour activity of
NGR-hTNF in six different types of
solid tumours, observed in Phase II
trials
- First promising data of a randomised
Phase II trial of NGR-hTNF for non-
small-cell lung cancer, in combination
with platinum-based regimens
- Start of two new randomised Phase II
trials of NGR-hTNF, in ovarian cancer
with PLD and in mesothelioma as
maintenance treatment

Clinical development pipeline



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 TK, 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 trials status

- Completed Phase II trial for high-risk leukaemia: the 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 ongoing in Italy, planned to become a multicentric trial in Europe and in the US in 2011
- Phase I trials for leukaemia started in Japan conducted by partner Takara Bio Inc, that in-licensed TK for most Asian markets

NGR-hTNF

Vascular targeting agent to treat solid tumours

NGR-hTNF is a first-in-class vascular targeting agent (VTA), a fusion protein obtained from the combination of a tumour homing peptide (NGR) with the human cytokine Tumour Necrosis Factor (hTNF). NGR-hTNF targets the blood vessels feeding the tumour through specific binding of both moieties of the molecule to the neovasculature endothelium. NGR-hTNF has a broad therapeutic potential for the treatment of very different types of solid tumours, including rare and common conditions.

NGR-hTNF has Orphan Drug designation, both in the EU and in the US, for the treatment of mesothelioma (2008) and for the treatment of liver cancer (2009).

Clinical trials status

NGR-hTNF is in clinical development both as single agent and in combination with different chemotherapeutic agents, for seven different types of solid tumours.

Completed Phase II trials include:

- Phase II trials as single agent for colorectal cancer, liver cancer and mesothelioma
- Phase II trials in combination therapy, for colorectal cancer with Xelox, for small-cell lung cancer and ovarian cancer with doxorubicin

Ongoing trials include:

- Phase III trial for mesothelioma in second line
- Randomised Phase II trial for mesothelioma as maintenance therapy
- Randomised Phase II trials in combination therapy, for non-small-cell lung cancer with platinum-based regimens and for ovarian cancer with PLD
- Randomised Phase II trial for soft tissue sarcomas, as single agent or in combination with doxorubicin

Product	Indication	Trial code	Phase I	Phase II	Phase III
TK	High-risk leukaemia	TK007, TK008 <i>random.</i>			
	<i>Leukaemia (Japan/Takara Bio)</i>				
NGR-hTNF	Solid tumours → MTD	EORTC 16041			
	Solid tumours - low dose	NGR002			
	Solid tumours - high dose	NGR013			
Monotherapy	Colorectal cancer	NGR006			
	Liver cancer	NGR008			
	Mesothelioma	NGR010, NGR015 <i>random.</i>			
	Mesothelioma/maintenance	NGR019 <i>random.</i>			
+ doxorubicin	Solid Tumours	NGR003			
	Lung cancer/SCLC	NGR007			
	Ovarian cancer	NGR012			
	Ovarian cancer	NGR018 <i>random.</i>			
	Soft tissue sarcomas	NGR016 <i>random.</i>			
+ Xelox	Colorectal cancer	NGR005			
+ cisplatin	Solid tumours	NGR004			
	Lung cancer /NSCLC	NGR014 <i>random.</i>			

ongoing recruitment completed completed