Molteni therapeutics srl:
Company and Products Overview

Molteni Therapeutics, where the light shines

ver. 2.0 – Sept 2015
• Molteni Therapeutics Company Overview

• Photo Dynamic Therapy Key Facts:
  Wound Healing
  Mode of Action
  Advantages
  Therapeutic Areas

• VULNOFAST® products

• VULNOLIGHT®

• What MT is looking for?
Molteni Therapeutics (MT)

Founded in November 2006 as a spin-off of Molteni Farmaceutici, an Italian company with more than one century of pharmaceutical experience.

MT is a product driven company dedicated to the development of innovative Drugs and Medical Devices, principally based on the Photodynamic Therapy technology, to meet unmet medical needs.
More than 200 m² of facilities (offices and laboratories).

Top level analytical instrumentation to aid the processes of Research and Design & Development of new products.

Network with the scientific park of Toscana Life Science (Siena).

Qualified staff: employees with strong pharmaceutical background (education: M.Sc. > 80%; Ph.D. 25%).

Competences to support the development from the lab to the market (New Chemical Entities and New Products), with focus on topical dosage forms.
MT Certifications

To ensure that all our activities, carried out internally or outsourced, are done in the best way MT has voluntarily decided to certify the company Quality Management System (QMS) according to the highest standards.

The QMS of Molteni Therapeutics is certified by TÜV Italia for:

“Design and development, management of production and trade of medical devices for topical use, focused on photodynamic treatments. Trade of photodynamic therapy equipments”

according to the following International Standards:

• UNI EN ISO 9001:2008 (Quality management systems - Requirements)

• UNI EN ISO 13485:2012 (Standards for Quality Management System on Medical Devices)
Presentation Out line

• Molteni Therapeutics Company Overview

• Photo Dynamic Therapy Key Facts:
  Wound Healing
  Mode of Action
  Advantages
  Therapeutic Areas

• VULNOFAST® products

• VULNOLIGHT®

• What MT is looking for?
• Photo Dynamic Therapy (PDT) is a bimodal therapeutic strategy based on the physical action of an agent (photosensitizer) activated by visible light.

• MT had been a pioneer in exploiting the PDT technology for antimicrobial purposes, developing topically administered products for the treatment of infected ulcers and skin lesion.

• The photosensitizers activity depends on the production of singlet oxygen ($^1\text{O}_2$) or other Reactive Oxygen Species (ROS) which rapidly restore the micro-environment of the lesion where have been released, promoting a wound healing effect.
PDT is a result of the combined effect of three intrinsically non-toxic agents

- Photosensitizer (PS)
- Light
- Oxygen
PDT Key Facts: Advantages

- **Immediate reduction of the bacterial load**, restoring the proper micro-environment to facilitate the natural healing/tissue repair processes
- **Proven wound healing of the infected lesions**
- Photosensitizer is applied locally (negligible systemic exposure)
- Co-adjuvant of systemic antibiotic regimens (in clinically required)
- Excellent safety and tolerability profile, safe for host tissues
- **Broad spectrum of antimicrobial activity**, including wild type and resistant strains
- Proven inhibition of bacterial re-growth
- **No induction of resistance** in vitro by multiple antimicrobial PDT treatments
- No interference with normal bacterial flora outside the lesion
PDT technology can be applied in different therapeutic areas. Three lead compounds (RLP068, MRLP98, MRLP164) are currently being investigated by MT and ready for further developments.

- Intranasal bacterial infectious disease
- Periodontal diseases
- Dermatology infectious disease
- Prosthesis infections (e.g. PJI)
- Wound Infections

Diabetic foot ulcers (DFU)
Chronic leg ulcers (vascular)
Post trauma, surgical, pressure ulcers, burns
• Molteni Therapeutics Company Overview

• Photo Dynamic Therapy Key Facts:
  Wound Healing
  Mode of Action
  Advantages
  Therapeutic Areas

• VULNOFAST® products

• VULNOLIGHT®

• What MT is looking for?
Molteni has developed a therapeutic approach for the **local treatment of skin lesions and ulcers by means of photodynamic therapy**, based on its proprietary products:

- **VULNOFAST®**: a topically delivered sterile formulation comprising a red light photosensitiser (i.e. RLP068/Cl). Two products (VULNOFAST® gel and VULNOFAST® plus) with different formulation and dose delivery system.

- **VULNOLIGHT®**: a photodynamic therapy equipment, based on the L.E.D. technology, specifically designed for the activation of the VULNOFAST® products (light dose of 60 J/cm² delivered in approximately 8 minutes).
VULNOFAST®: a new tool for ulcers and wounds topical treatment

• VULNOFAST® products are **topically administered** onto skin lesions or ulcers; after a suitable waiting time the lesion is illuminated with therapeutic red light.

• VULNOFAST® rapidly achieves a reduction of the pathogenic bacterial flora after the treatment without generating bacteria resistance.

• VULNOFAST® can be used in combination with systemic antibiotic regimens. VULNOFAST® has been designed as a **flexible and cost-effective tool to be introduced in the ulcers’ management protocols**.

• VULNOFAST® gel has been certified in the EU as a class IIb Medical Device in 2013; VULNOFAST® plus has been certified in the EU as a class IIb Medical Device in 2014.
Wound healing: a demonstrated improvement

Investigation of the efficacy of a single treatment of photodynamic therapy with VULNOFAST® gel in a methicillin-resistant S. aureus (MRSA) infected wound model in mice. VULNOFAST® gel wound healing and antibacterial activity has been compared versus placebo and a reference systemic antibiotic regimen (Teicoplanin by i.p.):

Proof of concept in humans

A randomised, double-blind, dose-response, placebo-controlled, multicenter (62 patients), phase IIA clinical study to evaluate the efficacy and safety of topical application of G.68.γ/EtOH (VULNOFAST® gel) in patients with type 1 or type 2 diabetes with infected foot ulcers.

Total bacterial load reduction assessed before the treatment (baseline, V1-pre) and immediately after illumination (V1-post) on day 1

Pathogenic bacterial load reduction assessed before the treatment (baseline, V1-pre) and immediately after illumination (V1-post) on day 1

Additional benefits of the use of VULNOFAST® products are:

• Innovative technology based on a different mode of action in comparison with the available tools for wound management
• Painless treatment
• No efforts by patient required
• All-in-one package (VULNOFAST® + VULNOLIGHT®)
• Simple procedure that can be performed by health professionals during regular doctor visits and check-ups
• Reduction in the use of topical antibiotics
• Time and cost savings due to a more rapid recovery of the hospitalized patient


Presentation Out line

• Molteni Therapeutics Company Overview

• Photo Dynamic Therapy Key Facts:
  Wound Healing
  Mode of Action
  Advantages
  Therapeutic Areas

• VULNOFAST® products

• VULNOLIGHT®

• What MT is looking for?
• Molteni Therapeutics Company Overview

• Photo Dynamic Therapy Key Facts:
  Wound Healing
  Mode of Action
  Advantages
  Therapeutic Areas

• VULNOFAST® products

• VULNOLIGHT®

• What MT is looking for?
VULNOLIGHT® at work
• Molteni Therapeutics Company Overview

• Photo Dynamic Therapy Key Facts:
  Wound Healing
  Mode of Action
  Advantages
  Therapeutic Areas

• VULNOFAST® products

• VULNOLIGHT®

• What MT is looking for?
MT is seeking an out-licensing partner for the VULNOFAST® products.

The goal is to create a business partnership for the late development and trade:
- Products are already available for the market.
- Further clinical information may be needed to support a proper marketing.

MT is open to evaluate and agree the most suitable out-licensing strategy.
Thanks for your attention