Mr. **Nimrod Leuw**

MediWound

INNOVATING SOLUTIONS FOR WOUND & BURN CARE

Mediwound latest inspection experience

March 2023

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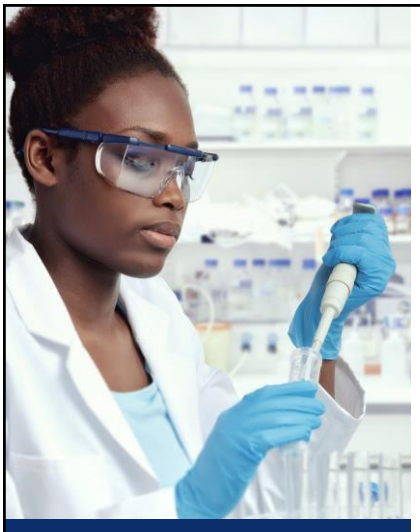

Committed to innovation; developing breakthrough therapies, dedicated to improving patient care

Innovative Biotherapeutic Company

Next generation non-surgical solutions for tissue repair and regeneration

Proprietary enzymatic technology platform
Clinically and commercially validated bioactive therapies;
100+ peer reviewed publications, 13 successful clinical studies, approved in 41 countries

Diversified and differentiated portfolio
Targeting unmet medical needs; multi-billion$ addressable markets

Supported by strategic collaborations
BARDA, Vericel (US), and Kaken (Japan)

cGMP certified sterile manufacturing facility

Proven management team with vast pharmaceutical experience and extensive capabilities

Solid balance sheet; Strong investor base

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Portfolio of Advanced Therapies

NexoBrid®
Disruptive therapy for burn care

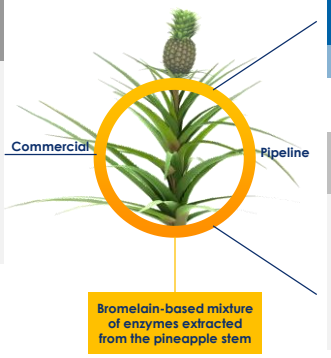
Indication: Eschar removal of deep partial and full thickness burns

Classification: Orphan biological drug

Target users: Hospitalized patients

Substantial U.S. government support

Development status: EU and international market approvals in hand; registration-stage in U.S.



EscharEx®
Next-gen enzymatic therapy for wound care**

Indication: Debridement of chronic/hard-to-heal wounds

Classification: Biological drug candidate

Target users: Outpatient setting

Development status: Phase II studies completed

MW005
Biotherapy for non-melanoma skin cancers**

Indication: Treatment of non-melanoma actinic skin cancers

Classification: Biological drug candidate

Target users: Outpatient setting

Development status: Phase I/II study underway

*TAM - targeted addressable market; source: Oliver Wyman market research
**Investigational Drug; not approved in any jurisdiction

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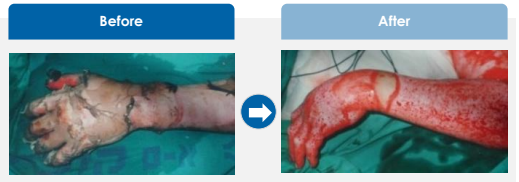
NexoBrid®

Concentrate of proteolytic enzymes enriched in bromelain

NexoBrid is indicated for removal of eschar with deep-partial and full-thickness thermal burns

- Orphan biological product
- Bromelain-based biological product containing a sterile mixture of proteolytic enzymes
- Easy-to-use, topical application at the patient's bedside
- Effectively and selectively removes burn eschar within a single 4 hours application without harming surrounding viable tissue or blood loss
- Allows for early visual assessment of the wound
- Approved in 41 countries (EU and ROW); registration stage in the U.S. and Japan
- Significant IP protection: patent portfolio, orphan and biologic exclusivities in the U.S.



Marketing approvals: EU, Israel, Russia, Ukraine, Peru, Argentina, Taiwan, South Korea, UAE

NexoBrid® | MediWound

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Preparations:

- MediWound Issued a “FDA audit preparation project”
- The project handled by an external consultant
- Internal Excel with tasks to perform according to criticality
- “Front” / “Back” room preparations
- SME’s

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FDA audit preparations

Regulatory audits during year 2022

- June - PAI by PMDA (Japanese Health Authorities)
- August – Routine GMP Re-Inspection by the Israeli MOH
- September – Routine GMP Re-Inspection by EU QP
- October – FDA PAI at CBC , Taiwan
- November –FDA PAI at MediWound , Israel

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FDA audit

Before

- A teams meeting pre-inspection with the Lead auditor – coordination of expectations
- A detailed manufacturing program including : cleaning , EM , IPC was sent to the lead auditor before the audit

During

- 7 days with 3 auditors

The inspection included going down to production rooms throughout the entire process (live activities):

- Preparations
- EM
- Cleaning
- DS production
- DP production
- Packaging area activities (leak test, visual inspection)
- Smoke tests , Media fill , real filling process (Camera)

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FDA audit continuous

- The inspection included QC and Micro tests review
- Data integrity for a lab instrument

Documents review:

- SOP's
- Validation performances of all sterilization equipment (SIP, Autoclave and etc)
- Validation performance of all relevant storage equipment
- Deviations
- Change Controls
- Aseptic production documents
- Batch documents
- Laboratory documents

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FDA audit summary

- Response to FDA 483 within 14 working days
- The response is sent the lead auditor as well as to the compliance group
- The compliance group is an independent group that was not part of the CMC review or GMP Inspection

Subjects

1. LAL method
2. Disinfection efficacy re-validation study
3. Aseptic behavior within the filling room (Grade A/B)
4. E.M Cleanroom

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Thank You