

Peripheral neuropathy prevention

-A topical repurposed drug for CIPN



A patent-protected, topical formulation of drug Rifampicin that protects peripheral nerves in cancer patients and prevents debilitating chemotherapy-induced peripheral neuropathy.

- Chemotherapy damages neurons, causing neuropathic pain called CIPN in hands and feet.
- 50% of breast cancer patients are treated with paclitaxel (taxane) + nearly **all childhood cancers** are treated with vincristine (vinca alkaloid) which cause CIPN.
- This side effect frequently results in treatment discontinuation of chemotherapeutics.
- **There is no effective treatment available for CIPN.**

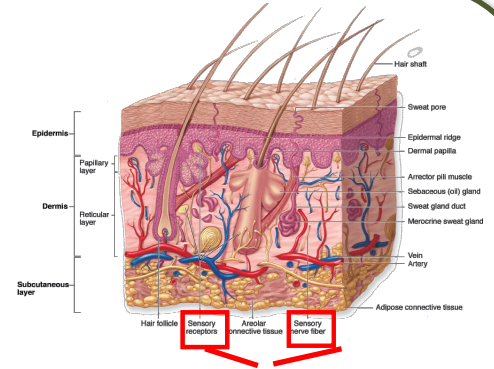


Figure 1: Sensory receptors and nerve fibers affected by chemo are the targets of this product.

The mechanism behind the idea

Rifampicin in topical formulation increases expression of a drug transporter that pumps out cancer drugs from neurons, which thus protects these cells from CIPN.

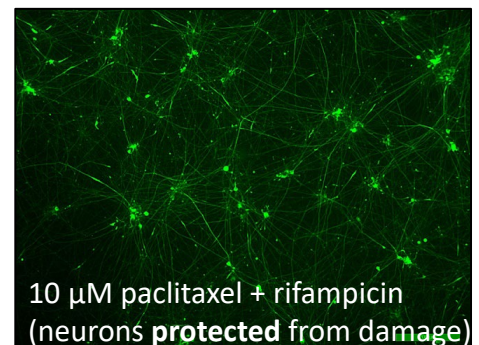
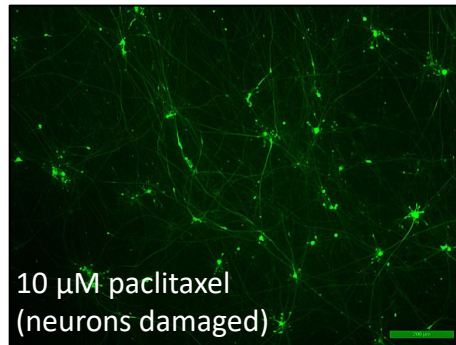
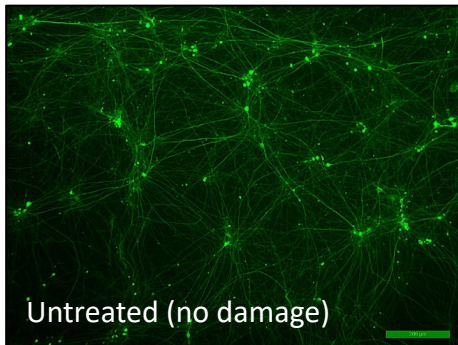


Figure 2: Sensory neurons are damaged by treatment with paclitaxel., however this damage can be prevented upon pre-treatment with our drug.

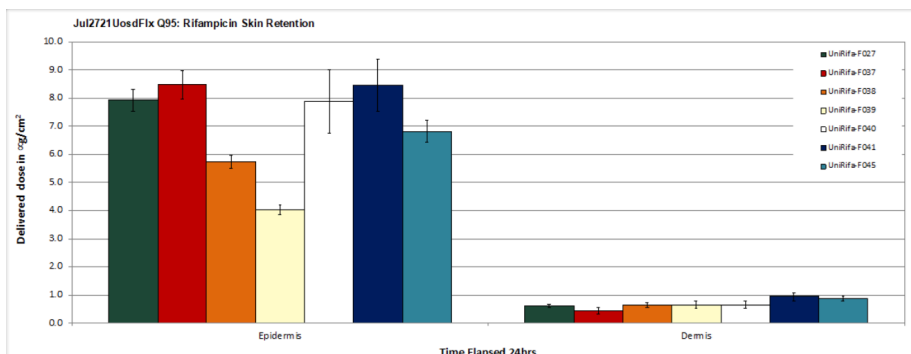


Figure 2: Rifampicin formulations can pass the epidermis and dermis.

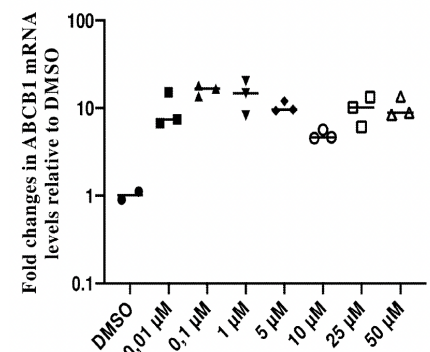


Figure 3: Rifampicin increases P-gp expression in sensory neurons.

Current state of development:

Optimization of the topical formulation and animal studies are underway, secondary animal GLP studies to follow.

Preclinical minipig studies:

- To evaluate the safety of the topical formulation with rifampicin.
- To ensure no systemic absorption of the topical formulation is detected.

We are looking for a development/commercial partner to sponsor and execute clinical studies.

Business opportunity

- **Low risk** (safety established through years of systemic use)
- **Fast-track to market** with low development costs (systemic treatment approved and marketed globally for more than 40 years)
- **Improve quality of life** among cancer patients
- **Prevents CIPN** rather than alleviation of symptoms or repair of damaged neurons.
- **Patent-protected** repurposed drug treatment, new medical use/never applied topically before).
- **No off-label use**, as our lead drug has never been formulated for topical use and rifampicin is not easily formulated for topical delivery.

Team



Tore B. Stage
Inventor
Assoc. Professor
Pharmacist, SDU



Ditte B. Iversen
Pharmacist
PhD-student
SDU



Jakob Lohmann
Patent attorney
Plougmann
Vingtoft



Niels Skjærbæk
Business developer
Marigold
Innovation ApS

Intellectual property rights

Patent no. WO2021043673 (Priority :September 2019, National: March 2022 in EU & US). Owner: University of Southern Denmark

Contact information

Business Developer, Lindsay Kellar-Madsen
Email: lkmadsen@sdu.dk

