

# Development of A Topical Anti-Infective An Ultra-Safe Drug with Added Benefits

## DPK-060



### TECHNOLOGY

Therapeutic peptide, derived from human sequence

Pharmaceutical drug product for local application against skin infections

### STAGE

Phase I/II trial completed  
Next trial (Phase IIb) to be conducted with future strategic partner

### MARKET POTENTIAL

World-wide peak sales potential of €150 - €200 million

### PATENT PROTECTION

Several granted and pending patent families with protection beyond 2027

### CONTACT

Subhash Chander, President  
Phone: + 1 845 598 6701  
schander@transdermalTT.com



## The Company and The Business Area

Company is a Swedish clinical-stage R&D company located on the campus of Karolinska Institutet. The company is focusing on early stage clinical development of state-of-the-art products based on **therapeutic peptides**, for local or topical application in **wounds** and skin- and soft-tissue infections. The current development pipeline includes **three candidate products**.

These peptides address infections, scarring and healing of skin lesions. The company is currently seeking **strategic partnerships** in several of its programs.

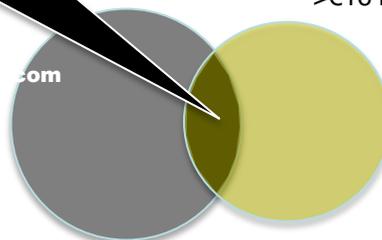
One of these pharmaceuticals is DPK-060 which is a short synthetic peptide with multiple properties. Preliminary evidence suggests that this peptide is effective in the treatment of bacterial infections in eczema patients. Company is currently seeking a collaborative partner for the development of a product addressing uncomplicated skin and skin structure infections.

Company deems that the annual market potential for such a product would be €150 - €200 million in NA, EU and JP.

The DPK-060 program has a peak sales potential of > €150 MM annually

**Infections**  
€20 billion

**Dermatology**  
>€16 billion



Estimates from Datamonitor, 2012

A future product is aimed to replace the use of conventional topical antibiotics such as fucidic acid, mupirocin and retapamulin. Company's management team envisions that the initial patient target segment is secondary infections in eczema (atopic dermatitis and nummular eczema). Thus, the primary target prescribers are dermatologists. Subsequently, further segment broadening may involve other uncomplicated skin and skin structure infections such as impetigo, infected traumatic lesions, external otitis and also prophylactic use.

## The Market Opportunity

Atopic dermatitis and nummular eczema are chronic inflammatory skin diseases, which are characterized by intense itching, skin damage, dry skin, redness and exudation. Skin eczema is a widespread disease in all of the developed pharmaceutical markets, afflicting 10-20% of children and 2-3% of adults. Current treatments for moderate to severe eczema are confined to **topical steroids** and **immunosuppressant** drugs. These drugs are restricted to short-term or intermittent use due to safety issues and cost.

A significant proportion of patients with eczema experience recurrent infections with *Staphylococcus aureus* that aggravates the disease. The bacteria produce super-antigens, which are potent inducers of strong unspecific immune reactions and are a cause of **pruritus** (itching). Importantly, expression of endogenous antimicrobial peptides in patients with infected skin lesions is substantially depressed. There are currently no topical antibiotics that are **suitable for long-term use**. This is an unmet medical need that can be addressed by DPK-060.

# Development of A Topical Anti-Infective An Ultra-Safe Drug with Added Benefits



## The DPK-060 Program & Technology Platform

DPK-060 is a 20 amino acid peptide that is derived from **human kininogen** and is optimized in terms of its biopharmaceutical properties. The peptide is **multifunctional** and potently **eliminates bacteria and fungi** from the skin.

Key properties of DPK-060:

- **Broadspectrum anti-microbial**
- **Does not induce microbial resistance**
- **Suppression of bradykinin (reduction of pruritus)**

It is noteworthy that **antimicrobial peptides** such as DPK-060 are unique in that they seem to **avoid antimicrobial resistance**. This is due to their particular mechanism of targeting multiple components in the microbial membranes in an unspecific way using the intrinsic charge of the microbial membranes.

The peptide is synthesized with standard solid-phase chemistry. The company seeks a strategic partnership for the next clinical trial that would entail a Phase II b study.



### RECENT MILESTONES

- Aug 2017**  
Strategic business arrangement with TTT
- Jan 2014**  
Company engages in a EU-funded grant collaboration regarding DPK-060
- Feb 2013**  
Final Study report from Phase II trial in external otitis
- Jan 2010**  
Phase I/II trial of DPK-060 in atopic dermatitis shows that drug is safe, tolerable and effective against bacterial infections

### UPCOMING MILESTONES

A Phase II clinical trial of DPK-060 in secondary infected eczema is pending a strategic partnership

**Table: Patent Status**

Program	Status	Key Designations	Type	Expiry
DPK-060	Granted/Pending	CN, EP, IN, JP, KR, MX, US	Sequence	2027

## Clinical Development

### Phase I/II Study in Patients of Atopic Dermatitis – Study completed in 2010

- The trial was a double-blind, randomized, placebo-controlled study
- Part A investigated the safety and local tolerability of the investigational product, Part B determined the efficacy of the treatment
- The primary efficacy endpoint was microbial density (microbial CFU/cm<sup>2</sup>)

### Phase II Study in External Otitis – Study completed in 2013

- Multicenter, double-blind, randomized, placebo-controlled Phase II trial demonstrated safety, tolerability and efficacy in external otitis.

### Phase II Study in Secondary Infected Eczema – Seeking partnerships for this study

- Multicenter, double-blind, randomized, placebo-controlled Phase II proof of concept study.

This program opportunity is available for licensing . Further information is available upon signing a confidentiality agreement.