Licensing Opportunity for Non-Genital Wart Treatment

April 2010
Resistant Non-Genital Warts
Non-Genital Wart Market
WartPEEL® (Med-101)
Pre-clinical Data
Clinical Development
Intellectual Property
Licensing Objectives
Company Profile

- Biotechnology company
- Discovery, development, and commercialization of major pharmaceutical products
- Drug design approach
  - Combines diverse technology disciplines and an integrated organizational philosophy
  - Increased speed and success rate of new drug applications and development
- Ability to accelerate new uses of drugs which increases success rates in early development.
Management

- Thomas Swegle, CEO
- T.J. Johnsrud, President
- Craig Herman, PharmD. - Clinical Director
- Best-in-class development advisors
  - Regulatory Affairs: Stacy Suberg, Ph.D.
  - Toxicity: Michael Schlosser, Ph.D. D.A.B.T.
  - Chemistry, Manufacturing and Control: Rolland Poust, Ph.D.
  - Clinical: Benjamin Schwartz, M.D., Ph.D.
MedCara

Resistant Non-Genital Warts

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Overview

- Non-genital warts are caused by the Human Papilloma Virus (HPV)
- 7-10% of the general population have non-genital warts
  - Incidence peaks between ages 12-16
  - Only 23% regress spontaneously within 2 months
- Most commonly seen by doctors are the common wart and plantar warts
- 60% of patients have recurring warts
- Over time, many patients will have warts that enlarge, spread and become more resistant to treatment
# Current Treatment Algorithm

<table>
<thead>
<tr>
<th>First line</th>
<th>Second Line</th>
<th>Third Line</th>
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</thead>
<tbody>
<tr>
<td><strong>Common Warts</strong></td>
<td><strong>Plantar Warts</strong></td>
<td></td>
</tr>
<tr>
<td>• Salicylic acid</td>
<td>• Salicylic acid</td>
<td></td>
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<tr>
<td>• Cantharidin</td>
<td>• Cryotherapy,</td>
<td></td>
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<tr>
<td>• Cryotherapy</td>
<td>• Intralesional immunotherapy</td>
<td></td>
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<tr>
<td>• Bleomycin (Blenoxane)</td>
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<td>• Intralesional immunotherapy</td>
<td>• Bleomycin (Blenoxane)</td>
<td></td>
</tr>
<tr>
<td>• Pulsed dye laser therapy</td>
<td>• Surgical excision</td>
<td></td>
</tr>
</tbody>
</table>
Treatment Characteristics

Salicylic acid
- OTC
- Inexpensive
- Easy

Cryotherapy
- Single Treatment

Bleomycin
- Painful
- Skin color changes
- Nail Damage
- Long Course of Treatment
- Many warts do not respond
- Painful
- Scarring
- Numerous in-office treatments
- Expensive

Current treatment options are ineffective and inconvenient for patients.
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Market Opportunity

• Approximately 12 million patients have warts resistant to first line therapy
• Current treatment options are painful with repeated office visits
• Once receiving the NDA, WartPEEL would be the first and only topical FDA approved product for this indication
• Market potential for resistant warts is approximately $1 billion
• Fractured market due to lack of effective treatment
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**Overview of WartPEEL**

- Patented formulation of 2% 5-fluorouracil and 17% Salicylic Acid
  - FDA has previously independently approved both active ingredients for human use
  - Known safety profile for both components
- Excipients are all either GRAS or commonly used excipients in topical applications as stated in the Handbook of Pharmaceutical Excipients
- Proprietary semisolid preparation with properties ideal for administration over a potentially small surface area
- Adhesive and prolonged contact of medication will allow WartPEEL to become the first once-daily treatment for non-genital warts
Rational for Selection of Active Ingredients

• Salicylic Acid
  – FDA approved for treatment of warts
  – Produces desquamation of hyperkeratotic epithelium via dissolution of the intercellular cement

• 5-fluorouracil
  – Functions as an antineoplastic agent
  – Blocks methylation reaction of deoxyuridylic acid to thymidylic acid and interferes with DNA and RNA synthesis
  – Topical, intraregional, and intradermal administration is an effective treatment for genital warts

• Combination enhances the overall effectiveness in the treatment of non-genital warts
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Pre-Clinical Data

• Absorption
  Peak Plasma level of 4.25 mg/mL in study with co-administration 0.3mg/kg (11.1 mg/m²) of 5-FU and 0.6 mg/kg (22mg/m²) of SA (maximum dose)

• Distribution
  –Local distribution of 5-FU may be enhanced due to epithelial barrier disruption by SA
  –Co-administration does not appear to noticeably affect plasma levels of 5-FU

• Metabolism
  –SA and 5-FU are cleared by different enzyme systems
  –Half-life of both SA and 5-FU are short at the low systemic concentrations after topical administration
  –Metabolism of each drug is not expected to affect the metabolism of the other
Pre-Clinical Data

• Excretion
  – SA and 5-FU are excreted through different mechanisms
  – Excretion of each drug is not expected to affect the excretion of the other

• Safety
  – Well characterized
  – No serious adverse events
  – Low potential for acute toxicity after topical administration of combination SA and 5-FU
  – Although acute toxicity of high doses of SA and 5-FU in combination have not been studied, these studies are not needed to support the upcoming Phase I program
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Clinical Development

Clinical Pathway is short, low-risk, and straightforward with anticipated NDA approval 2014

- Pre-Phase I FDA Meeting COMPLETED
- Patent Issued
- End-Phase II FDA Meeting
- NDA Filing
- NDA Approval

2008 2009 2010 2011 2012 2013 2014

Regulatory

Clinical

CMC

Formulation and Product Development

Clinical Supplies Scaling

Commercial Scaling

1st Pivotal Phase III

2nd Pivotal Phase III

Phase I/II PoC Study

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Phase I/II PoC Study
## Prior Clinical Experience

<table>
<thead>
<tr>
<th>Study sponsor</th>
<th>Study formulation</th>
<th>% with unsuccessful prior treatment</th>
<th>% reporting “completely gone” or “almost gone” after treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mayo Clinic*</td>
<td>WartFILM (Research Formulation of WartPEEL®)</td>
<td>83%</td>
<td>61%</td>
</tr>
<tr>
<td>NuCara Pharmacy</td>
<td>WartPEEL®</td>
<td>100%</td>
<td>77.1%</td>
</tr>
<tr>
<td>NuCara Pharmacy</td>
<td>WartPEEL®</td>
<td>100%</td>
<td>82.8%</td>
</tr>
</tbody>
</table>

*Study was published - JEADV 2006, 20, 214–238 © 2006 European Academy of Dermatology and Venereology
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• Issued Patent: 7,655,668
  – Composition for treatment of Warts
  – Patent filed in January 2005
  – Additional time on 20 Yr Patent providing coverage through 2027

• Divisional patent application filed on method of use

• Patents on two active ingredients have long expired
  – 5-fluorouracil
  – Salicylic acid
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Destum Partners has been retained by MedCara Pharmaceuticals to identify and secure a partner for WartPEEL®

For information regarding the timelines of key events pertaining to the licensing of WartPEEL®, please refer to the accompanying Licensing Process Guide.

For More Information Please Contact:

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