Measles and rubella vaccination by microneedle patch

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Disclosure

Mark Prausnitz is a co-founder and has a significant financial interest in Micron Biomedical.

This conflict of interest is managed by Georgia Tech and Emory University.
Outline

Development of the MR patch

The path to clinical trial and licensure
Dissolving microneedle patch
Dissolving microneedle patch
Dissolving microneedle patch

Green dye represents location of vaccine
Microneedle patch meets public health needs

Patient administration
- Minimally-trained personnel
- No applicator, no reconstitution
- Painless delivery, no fear of needle

1) Apply patch
2) Press to skin
3) Remove from skin
4) Vaccine is delivered
Microneedle patch meets public health needs

Patient administration
- Minimally-trained personnel
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Manufacturing
- Low-cost, scalable fabrication
Microneedle patch meets public health needs

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- No applicator, no reconstitution
- Painless delivery, no fear of needle

Manufacturing
- Low-cost, scalable fabrication

Transportation and storage
- Small package size
- Improved thermostability

100 microneedle patches
10 ten-dose vials
100 needles and syringes
biohazardous sharps waste
cold-chain storage
Microneedle patch meets public health needs

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- Minimally-trained personnel
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Manufacturing
- Low-cost, scalable fabrication

Transportation and storage
- Small package size
- Improved thermostability

Waste disposal
- Impossible reuse
- Reduced disposal volume
Micron Biomedical

Commercializing Georgia Tech microneedle patch technology

Partners
- BMGF, UNICEF, CDC
- Pharmaceutical companies

Clinical stage
- GMP manufacturing (e.g., MR patch)
- Regulatory filings

Commercial manufacturing
- Clinical trial materials
- Pilot manufacturing line designed
- Commercial manufacturing line designed
Target product profile

Indication: Measles and rubella prophylaxis

Target population: Age 9-months and older

Uses: Routine immunization
Supplementary immunization activities
Outbreak response immunization

Safety: AEs no more serious than current MR vaccines

Reactogenicity: Mild, transient erythema and pruritus

Immunogenicity: Seroconversion non-inferior to current MR vaccines
<table>
<thead>
<tr>
<th>Target product profile</th>
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<tbody>
<tr>
<td>Presentation:</td>
<td>Single dose, single use Integrated vaccine delivery system</td>
</tr>
<tr>
<td>Route of admin.:</td>
<td>Skin</td>
</tr>
<tr>
<td>Application:</td>
<td>No applicator required</td>
</tr>
<tr>
<td>User training:</td>
<td>No training, minimal instructions</td>
</tr>
<tr>
<td>Wear time:</td>
<td>1 – 5 minutes</td>
</tr>
<tr>
<td>Delivery indicator:</td>
<td>Auditory and visual</td>
</tr>
<tr>
<td>Disposal:</td>
<td>Non-sharps, biohazardous waste Reduced volume</td>
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<tr>
<td>Target product profile</td>
<td></td>
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<tr>
<td>------------------------</td>
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<tr>
<td>Stability:</td>
<td>VVM14 (2-8°C @ 24 months, 40°C @ 3 days)</td>
</tr>
<tr>
<td>Product registration pathway:</td>
<td>WHO pre-qualification</td>
</tr>
<tr>
<td>Cost per immunized child:</td>
<td>Possible increased COGS offset by programmatic savings</td>
</tr>
</tbody>
</table>
Outline

Development of the MR patch

The path to clinical trial and licensure
Timeline of MR patch development

2009  WHO grant (IPV patch)

2011  WHO and BMGF grants (IPV patch)
Timeline of MR patch development

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2013  Measles patch in cotton rats

2015  Measles patch in NHP

2018  MR patch in infant NHP
Timeline of MR patch development

- 2009  WHO grant (IPV patch)
- 2011  WHO and BMGF grants (IPV patch)
- 2013  Measles patch in cotton rats
- 2015  Measles patch in NHP
- 2017  Phase 1 clinical trial (influenza patch)
- 2018  MR patch in infant NHP

The safety, immunogenicity, and acceptability of inactivated influenza vaccine delivered by microneedle patch (TIV-MNP 2015): a randomised, partly blinded, placebo-controlled, phase 1 trial


Lancet 2017; 390: 649–58
Timeline of MR patch development

- 2009  WHO grant (IPV patch)
- 2011  WHO and BMGF grants (IPV patch)
- 2013  Measles patch in cotton rats
- 2015  Measles patch in NHP
- 2016  BMGF grant (MR patch)
- 2017  Phase 1 clinical trial (influenza patch)
- 2018  MR patch in infant NHP
- 2019  Ready for clinical trial
Phase 1 clinical trial of MR patch

Study site:
    Developing country, USA, Europe
Phase 1 clinical trial of MR patch

Study site:
  Developing country, USA, Europe

Study population:
  Adults only, adults and infants
Phase 1 clinical trial of MR patch

Study site:
   Developing country, USA, Europe

Study population:
   Adults only, adults and infants

Clinical phase:
   Phase 1, Phase 1/2
Phase 1 clinical trial of MR patch

Study site:
  Developing country, USA, Europe

Study population:
  Adults only, adults and infants

Clinical phase:
  Phase 1, Phase 1/2

Stage gate:
  ASAP, “apples-to-apples”
Risk vs. Speed
Timeline of MR patch development

Phase 1 trial
Phase 2 trial
Pilot manufacturing
Phase 3 trial
Commercial manufacturing
Licensure WHO PQ
Risk:
Invest in pilot manufacturing before clinical trial results
Timeline of MR patch development

- Phase 1/2 trial
- Pilot manufacturing
- Phase 3 trial
- Commercial manufacturing
- Licensure

Risk:
Only one clinical trial before Phase 3 trial
Risk:
Invest in pilot manufacturing before clinical trial results
Only one clinical trial before Phase 3 trial
Questions?