From Innovation to Implementation

The Journey of a New Shingles Vaccine
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National Vaccine Advisory Committee Meeting, September 13, 2018

Employed by GSK where I am a vaccine research physician

Industry Representative Member, National Vaccine Advisory Committee

Presentation at the invitation of National Vaccine Program Office

Presentation is for instructional purposes only; this is not a sales, marketing or promotional presentation
From innovation to implementation: The journey of a new shingles vaccine

- Shingles: disease and risk factors
- SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted): innovative design, indication
- Bringing SHINGRIX to market: new territory for shingles and adult vaccination
  - ACIP recommendations
  - Rapid and broad vaccine access
  - Vaccine demand
  - Early reports and response related to storage, reconstitution and administration
  - Vaccine supply and managing unprecedented demand
  - Programs to support series completion
- Considerations for NVAC
Shingles: common, painful disease can lead to serious complications, including Postherpetic Neuralgia (PHN)\textsuperscript{1-3}

- Shingles presents as a unilateral, vesicular rash – with skin lesions typically spread across the chest, abdomen, or face\textsuperscript{2}
- PHN, pain persisting $\geq 3$ months after the onset of a rash, is a common complication of shingles\textsuperscript{1-3}
- Herpes zoster of the eye occurs in 10\%-25\% of patients\textsuperscript{2}

Development objective: design a herpes zoster vaccine to address immunosenescence, immunocompromised

Address population-specific challenges:\(^1\):
- Age-related decline in immunity
- Immunocompromised patients

Utilize vaccine technology to generate a durable immune response against VZV:
- Target the decline in VZV-specific cellular immunity (associated with increased risk of shingles)


VZV, varicella zoster virus.
Selection of an antigen/Adjuvant System combination that can guide the immune response to help deliver enhanced and sustained humoral and cellular responses.

The GSK RZV vaccine (SHINGRIX) – innovative combination of antigen and adjuvant system

Antigen: glycoprotein E (gE)

Evokes specificity of immune response

RZV vaccine

Adjuvant System: AS01B

Enhances and modulates immune response to vaccine antigen

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RZV, recombinant zoster vaccine.

* Clinical Significance has not been established

Indication

- SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older.

- SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

See Full Prescribing Information at SHINGRIXHCP.com
Important Safety Information

• SHINGRIX is contraindicated in anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX

• Review immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX

• Solicited local adverse reactions in subjects aged 50 years and older were pain (78.0%), redness (38.1%), and swelling (25.9%)

• Solicited general adverse reactions in subjects aged 50 years and older were myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%)

• SHINGRIX was not studied in pregnant or lactating women, and it is unknown if it is excreted in human milk. Therefore, it cannot be established whether there is vaccine-associated risk with SHINGRIX in pregnant women or if there are effects on breastfed infants or milk production/excretion

• Vaccination with SHINGRIX may not result in protection of all vaccine recipients
Bringing SHINGRIX to market has been a unique journey

New territory for shingles and adult vaccination

New Science

Efficacy Regardless of Age

>90%

Recommendation

Unprecedented Demand

See Full Prescribing Information at SHINGRIXHCP.com
FDA approval and ACIP recommendation
Occurred within days of each other

- October 23, 2017 – FDA approval of SHINGRIX for adults ages 50 and older
- October 25, 2017 – ACIP Recommendations for use SHINGRIX:
  - Recommended for the prevention of herpes zoster and related complications for immunocompetent adults aged ≥50 years
  - Recommended for the prevention of herpes zoster and related complications for immunocompetent adults who previously received zoster vaccine live (ZVL)
  - Preferred over ZVL for the prevention of herpes zoster and related complications

On our way to vaccinating millions with SHINGRIX

~115m adults eligible to receive SHINGRIX based on ACIP recommendations
Broad access just ~4 months after FDA approval

>90% Medicare Pharmacy Coverage
>90% Commercial Medical Coverage
>90% of Pharmacy Chains have Stocked SHINGRIX
Vast majority of providers report their next order will be SHINGRIX

Source: MMIT, IQVIA, GSK Awareness Trial and Usage Survey, Access as of March 2018
Pace of uptake and volume of demand for SHINGRIX has been unprecedented

Market is currently many times larger than Zostavax last year, driven early on by pharmacies. HCPs are still ramping up.

98% market share in 5 months, faster than other vaccines and generic drug curves.

70% of Shingrix use has been in naïve patients.

Pharmacies primarily serve 65+ patients and HCPs primarily treat 50-64 patients.

>98%
SHINGRIX to market 10 years after ZVL

We had to educate providers on proper use

SHINGRIX and ZVL:

- Different storage
- Different reconstitution
- Different administration

Early reports of storage, reconstitution and administration errors

See Full Prescribing Information at SHINGRIXHCP.com
Zostavax PI: merck.com/product/usa/pi_circulars/z/zostavax/zostavax_pi2.pdf
A comprehensive approach to education

Partnerships across the healthcare system

GSK Education

Working with Retailers & Systems

Working with other 3rd Parties Associations

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360 degree approach to educational resources

Video, digital, paper, in-person, on-demand

3rd Party Assets

Speaker Programs And Webinars

Sales Aid

Administration Reference Guide

Field Team Slide Decks

Packaging Labeling

Pocket Guide

Zoe 50/70

2 Dose Reminder Cards & Elasti-tags

3rd Party Assets

SHINGRIXhcp.com Website

Reconstitution Video

“What To Expect” Fact Sheet

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Managing unprecedented demand

SHINGRIX supply to immunize more adults than ever before

1H 2018 > All of 2017

2H 2018 > 1H 2018

Ongoing:
Large Resupplies every 2-3 weeks
GSK’s guiding principles to manage available inventory

- Demonstrate our openness, transparency and commitment to meeting long-term demand for SHINGRIX and explaining the supply situation
- Allocate new doses in a fair and equitable way that is aligned with immunizer’s zoster vaccination behavior
- Support 2nd dose series completion and then focus on new starters
- Work with Wholesalers/Distributors to share our allocation goals, with the goal of maintaining HCP immunizers’ channel preference
Programs are in place to support series completion with SHINGRIX

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<th>Message Source</th>
<th>Point of Care (Doctor or Pharmacist)</th>
<th>Pharmacy/Retailers</th>
<th>GSK Direct to Patients</th>
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**Programs**

- Electronic Health Records (EHRs)
- Reminder Card
- "What to Expect" Fact Sheet
- Text Message
- Pre-Recorded Phone Call
- Direct Mail & Pharmacy Reminders
- Email

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SHINGRIX: A unique journey

Considerations for NVAC: new learnings adult vaccines

• Breakthrough vaccine innovation for adults brings strong and immediate provider, healthcare system, retail pharmacy and patient demand

• Adult vaccination infrastructure:
  o Improving; Medicare Part D financial and access challenges remain
  o Centralized in large systems
  o Retail pharmacies important destination

• Recipe for success in effectively addressing issues in real time, and keeping the focus on the patient:
  o Transparency and collaboration with vaccine system partners and patients
  o Sharing best practices