

A large, semi-transparent orange graphic with a rounded, teardrop-like shape is positioned on the left side of the image. It contains the main title and subtitle in white text.

From Innovation to Implementation

The Journey of a New
Shingles Vaccine



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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

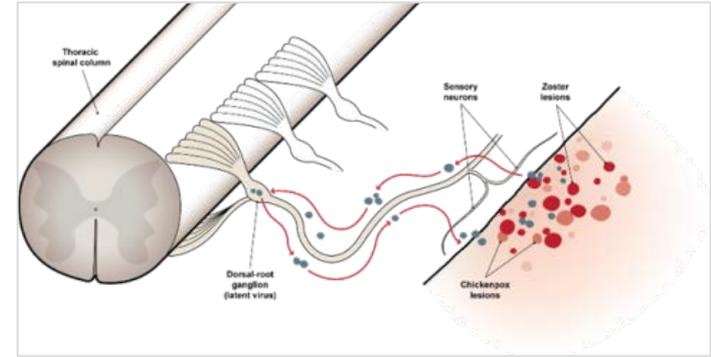


- Shingles: disease and risk factors
- SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted): innovative design, indication
- Bringing SHINGRIX to market: new territory for shingles and adult vaccination
 - ACIP recommendations
 - Rapid and broad vaccine access
 - Vaccine demand
 - Early reports and response 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)¹⁻³



- Shingles presents as a unilateral, vesicular rash – with skin lesions typically spread across the chest, abdomen, or face²
- PHN, pain persisting ≥ 3 months after the onset of a rash, is a common complication of shingles¹⁻³
- Herpes zoster of the eye occurs in 10%-25% of patients²



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Courtesy of MN Oxman, UCSD.

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



Address population-specific challenges¹:

- Age-related decline in immunity
- Immunocompromised patients

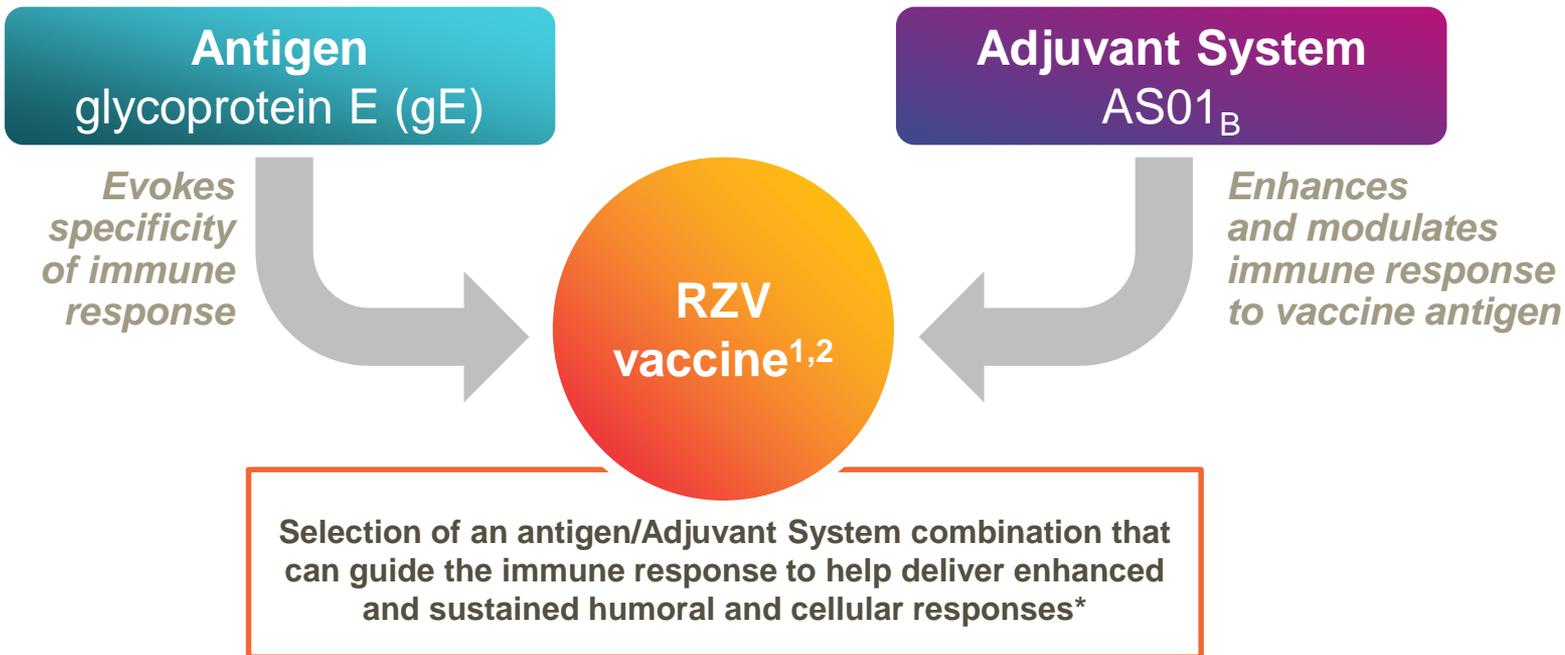
Utilize vaccine technology to generate a durable immune response against VZV:

- Target the decline in VZV-specific cellular immunity (associated with increased risk of shingles)



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



SHINGRIX (Zoster vaccine recombinant, adjuvanted) licensed by FDA on October 23, 2017



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).

SHINGRIX (Zoster vaccine recombinant, adjuvanted)



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

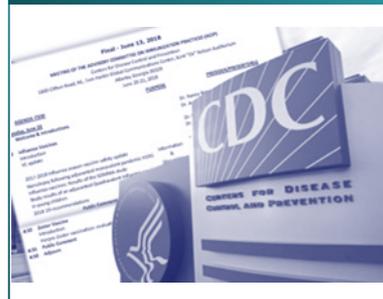
New Science



Efficacy Regardless of Age

>90%

Recommendation



Unprecedented Demand



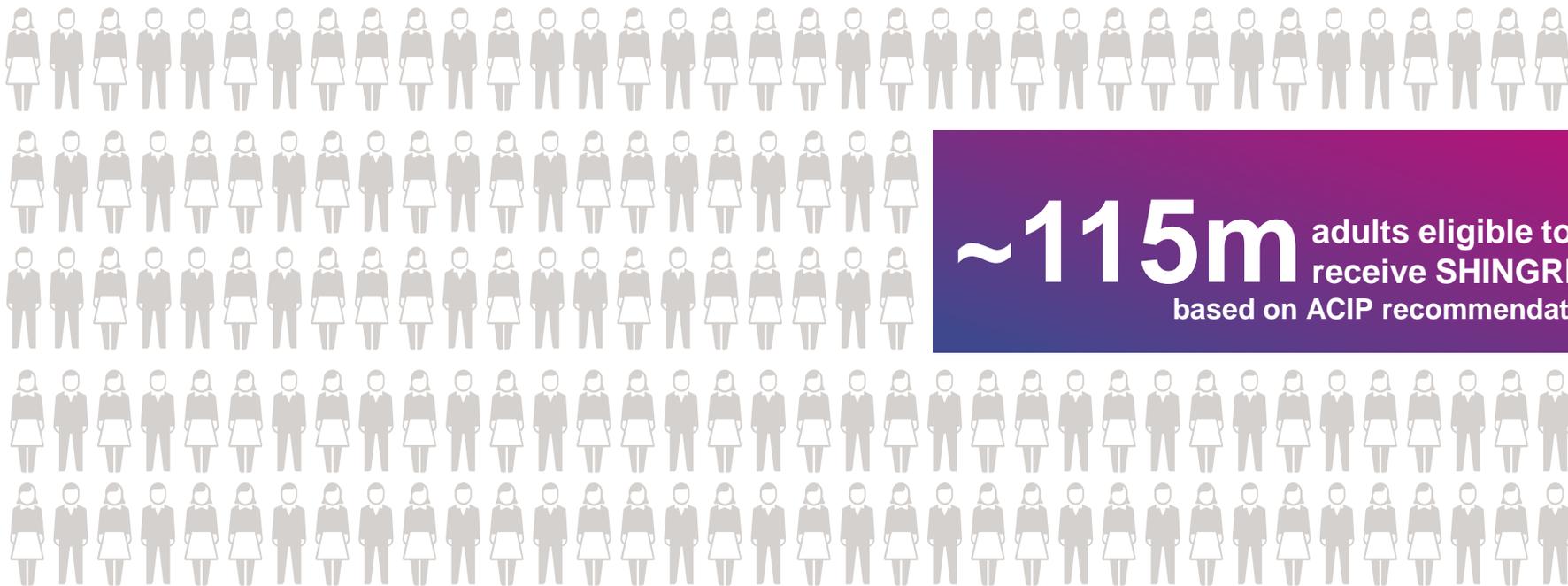
FDA approval and ACIP recommendation



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



Broad access just ~4 months after FDA approval



**ACIP
Recommendation**



**>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**

Pace of uptake and volume of demand for SHINGRIX has been unprecedented



X_x

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

>98%

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.

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

A comprehensive approach to education



Partnerships across the healthcare system

GSK Education



Working with Retailers & Systems



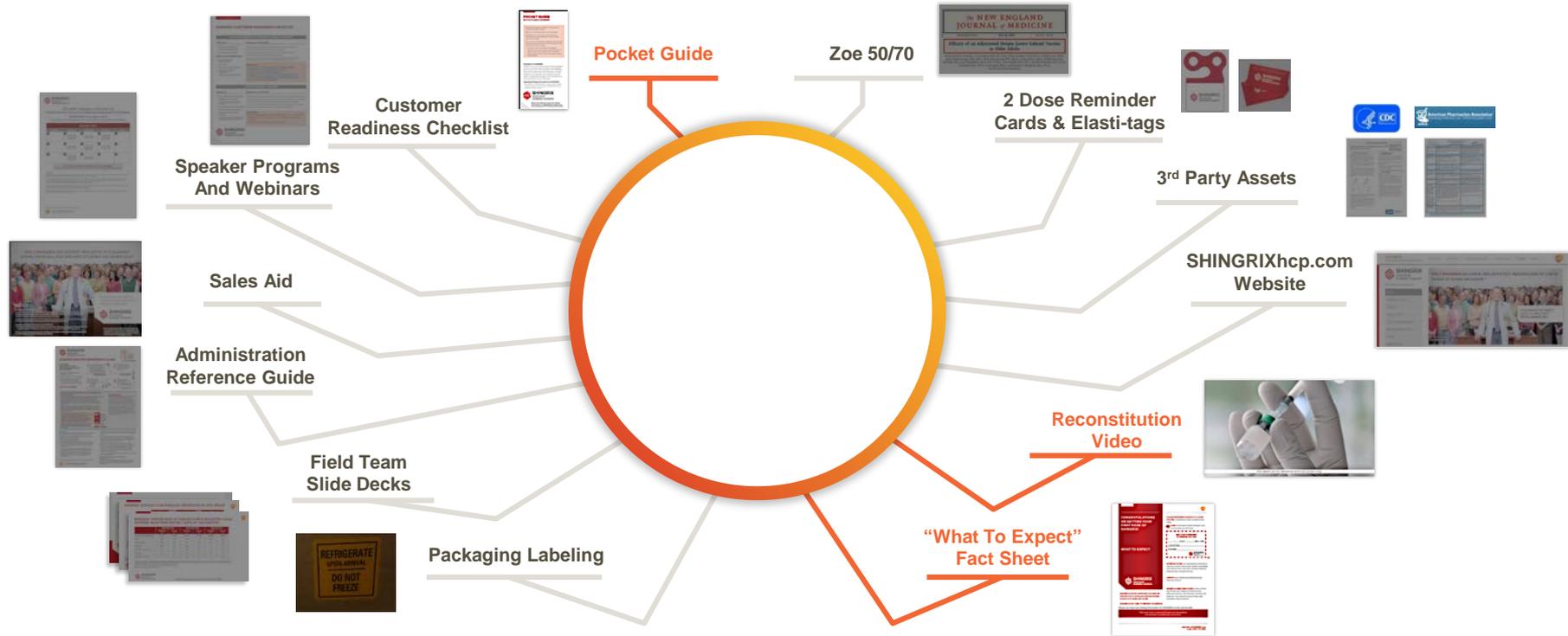
Working with other 3rd Parties Associations



360 degree approach to educational resources



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



Managing unprecedented demand



SHINGRIX supply to immunize more adults than ever before



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



Message Source	 Point of Care (Doctor or Pharmacist)	 Pharmacy/Retailers	 GSK Direct to Patients
Patient Actions	1. Schedule follow-up appointment 2. Receive e-Rx 3. Take home educational resources	1. Automatically registered via pharmacy	1. Visit SHINGRIXreminder.com 2. Opt-in for reminders
Programs	<div data-bbox="353 489 421 554"></div> <p data-bbox="446 532 774 554">Electronic Health Records (EHRs)</p> <div data-bbox="353 590 430 631"></div> <p data-bbox="459 609 606 631">Reminder Card</p> <div data-bbox="363 663 411 729"></div> <p data-bbox="436 685 707 707">"What to Expect" Fact Sheet</p> <div data-bbox="440 729 710 893">  </div>	<div data-bbox="836 481 913 554"></div> <p data-bbox="923 503 1064 525">Text Message</p> <div data-bbox="836 568 913 631"></div> <p data-bbox="929 579 1180 601">Pre-Recorded Phone Call</p> <div data-bbox="826 656 923 762"></div> <p data-bbox="929 656 1161 707">Direct Mail & Pharmacy Reminders</p> <div data-bbox="948 732 1271 838">  </div>	<div data-bbox="1319 478 1396 551"></div> <p data-bbox="1406 503 1534 525">Text Message</p> <div data-bbox="1319 568 1396 631"></div> <p data-bbox="1406 579 1649 601">Pre-Recorded Phone Call</p> <div data-bbox="1319 656 1396 707"></div> <p data-bbox="1406 656 1456 678">Email</p> <div data-bbox="1329 751 1547 838">  </div> <div data-bbox="1561 645 1725 844">  </div>

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:
 - Improving; Medicare Part D financial and access challenges remain
 - Centralized in large systems
 - Retail pharmacies important destination
- Recipe for success in effectively addressing issues in real time, and keeping the focus on the patient:
 - Transparency and collaboration with vaccine system partners and patients
 - Sharing best practices