RAPID SURVEILLANCE STUDY TO EVALUATE THE SAFETY OF RESPIRATORY SYNCYTIAL VIRUS (RSV) VACCINE (ABRYSVO™) EXPOSURE DURING PREGNANCY IN THE UNITED STATES

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BACKGROUND

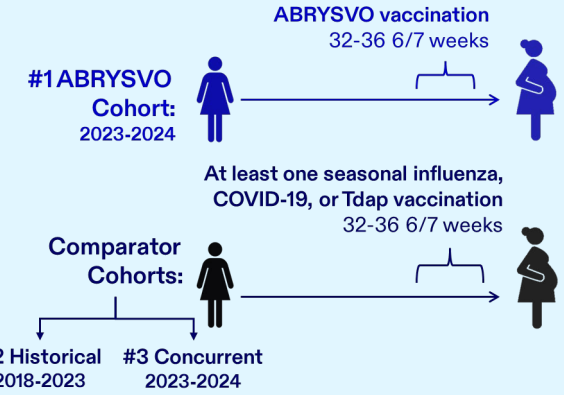
- ABRYSVO™ (RSVpreF) is a vaccine administered during pregnancy to prevent RSV-associated lower respiratory tract disease in infants.
- Rapid cycle analyses (RCA) are ongoing for **early detection of potential safety risks**: Cumulative data through 4 of 5 planned tests are presented.
- The RCA is a US FDA post-marketing requirement

OBJECTIVE

To rapidly monitor incidence proportions of 10 prespecified safety outcomes following ABRYSVO and comparator maternal vaccination

METHODS

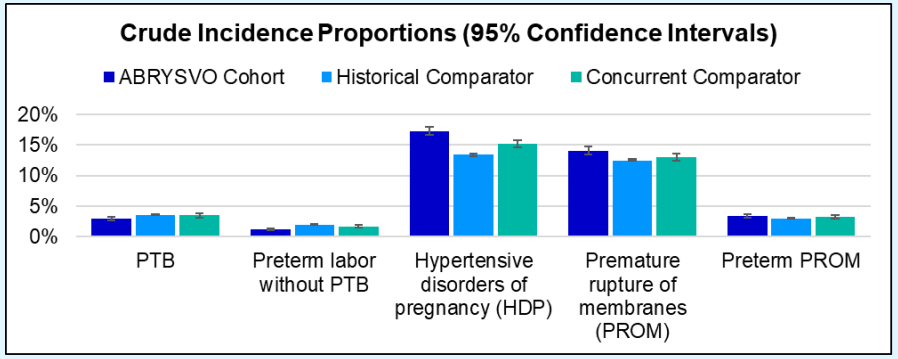
- **Data Source:** Health insurance claims data held by Research Partners (RPs; N=5) participating in the US FDA's Sentinel System
- **3 cohorts of pregnant individuals 15-54 years:**

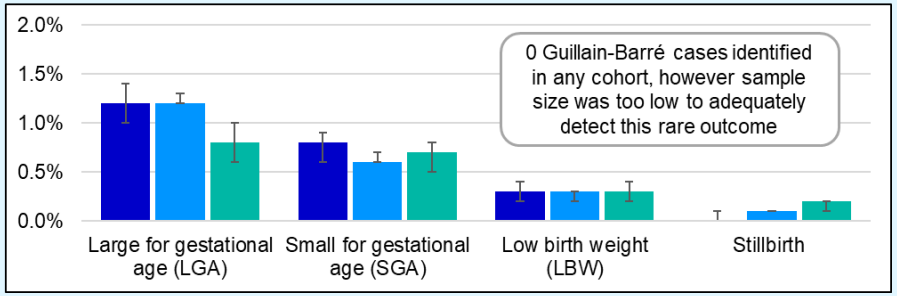


- Outcome incidence assessed using maximized Sequential Probability Ratio Tests
- Confounding variables *(included as feasible given prevalence of each outcome):* RP, maternal age, season, gestational age at vaccination, and evidence of high-risk for preterm birth (PTB)

Results

- ABRYSVO Cohort **(n=13,467)**; Concurrent Comparator **(n= 13,839)**; Historical Comparator **(n=143,459)**
- ABRYSVO cohort tended to be older, receive their index vaccine later in pregnancy, have ≥2 encounters coded for a high-risk pregnancy, and have greater health-seeking behavior





Outcome	Statistical Signal Identified (Estimated Risk Ratio [RR])*	
	Historical Comparison	Concurrent Comparison
PTB	*No (RR <1.20)*	Testing ongoing
Preterm labor w/o PTB	*No (RR <1.30)*	Testing ongoing
HDP	*Yes (RR ≥1.10)*	*Yes (RR ≥1.10)*
PROM	*Yes (RR ≥1.10)*	*Yes (RR ≥1.10)*
PPROM	*Yes (RR ≥1.20)*	Testing ongoing
LGA	*No (RR <1.35)*	Testing ongoing
SGA	*No (RR <1.50)*	*No (RR <1.75)*
LBW	*No (RR <2.00)*	*No (RR <2.50)*
Stillbirth	Testing ongoing	Testing ongoing

**Assuming no residual bias (strong assumption)*

CONCLUSIONS

- **No increased risk of PTB observed after ABRYSVO administration (32-36 6/7 wks)** in the historical comparison; testing is ongoing in concurrent comparison
- **In this RCA, a potential increased risk of HDP, PROM, and PPROM after ABRYSVO administration (32-36 6/7 wks) cannot be ruled out**
  - Residual confounding may explain the findings
- Upcoming cohort study to include additional confounders and improve potential misclassification in PPROM algorithm (Interim Report: Aug 2025; Final Report: 2029)

DISCLOSURES

This study was funded by Pfizer, Inc. Some co-authors are employed at organizations which conduct work for government and private organizations, including Pfizer, Inc. and other pharmaceutical companies.