OP95

PREGNANCY OUTCOMES IN MATERNAL EXPOSURE TO GUSELKUMAB: REVIEW OF CASES REPORTED TO THE COMPANY'S GLOBAL SAFETY DATABASE

Uma Mahadevan,[1] Millie Long,[2] Mette Julsgaard,[3] Connie Lin,[4] Anja Geldhof,[5] Mauricio Rosas Ballina,[6] Hewei Li,[7] Javier P. Gisbert,[8] María Chaparro[8]

[1]University of California, San Francisco, CA, USA; [2]University of North Carolina, Chapel Hill, NC, USA; [3]Department of Hepatology and Gastroenterology, Aarhus University Hospital, Aarhus, Denmark; [4]Johnson & Johnson, Horsham, PA, USA; [5]Johnson & Johnson, Diegem, Belgium; [6]Actelion Research & Development, Basel, Switzerland; [7]Johnson & Johnson, Titusville, NJ, USA; [8]Hospital Universitario de La Princesa, Instituto de Investigación Sanitaria Princesa (IIS-Princesa), Universidad Autónoma de Madrid (UAM), and Centro de Investigación Biomédica en Red de Enfermedades Hepáticas y Digestivas (CIBEREHD), Madrid, Spain

DDW2026
Digestive Disease Week®
MAY 2–5, 2026 | CHICAGO, IL
EXHIBIT DATES: MAY 3–5, 2026
@DDWMeeting | #DDW2026

Sponsored by Johnson & Johnson

Disclosure information

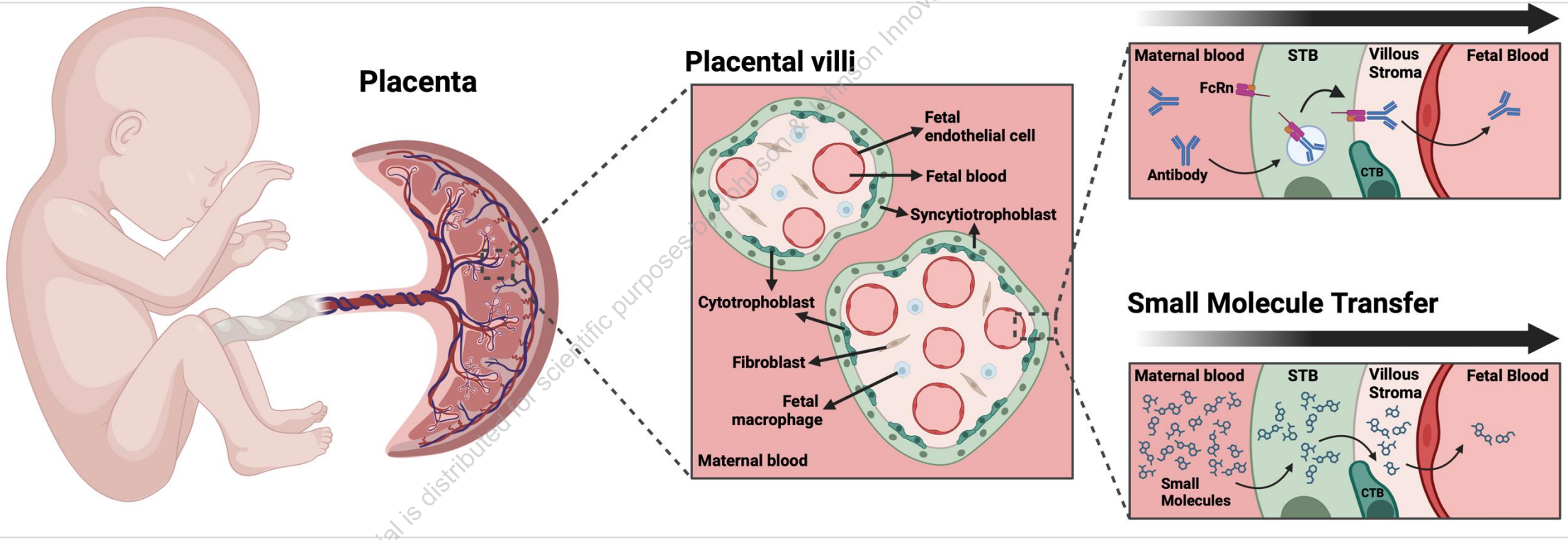
Uma Mahadevan

I disclose the following financial relationship(s) with a commercial interest:

I have served as a consultant and an advisory board member for AbbVie, Abivax, Bristol Myers Squibb, Celltrion, Disc, Enveda, Genentech, Gilead, Johnson & Johnson, Lilly, Merck, Pfizer, Sanofi, Takeda, and Trex.

Background

- The Global Consensus Consortium published a statement on the management of pregnancy in inflammatory bowel disease suggesting women can continue treatment with IL-23 inhibitors throughout pregnancy[1]



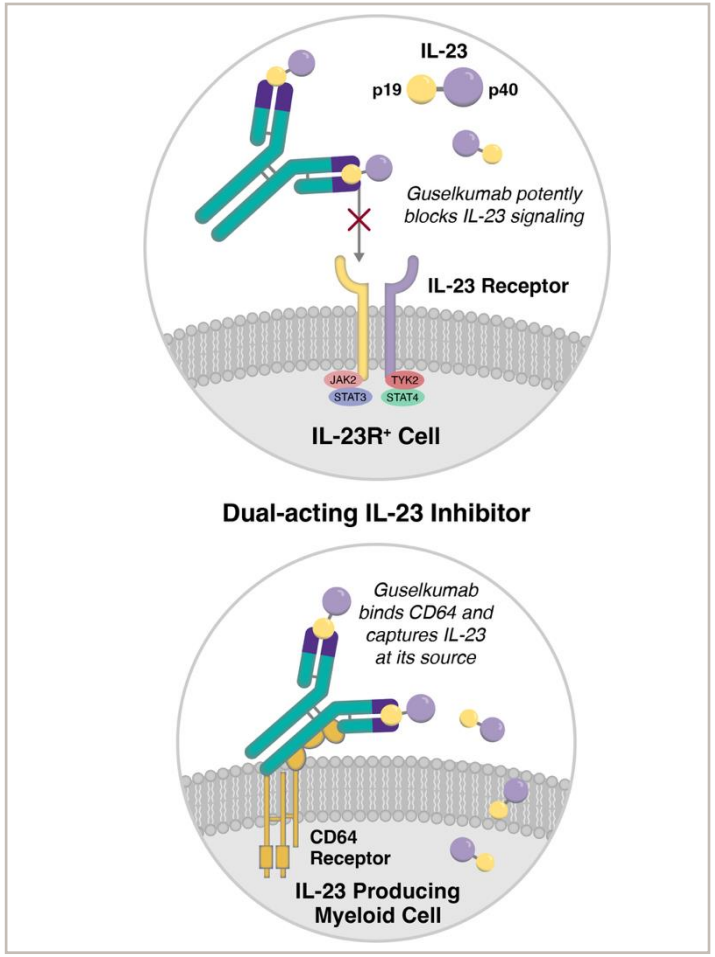
1. Mahadevan U, et al. *J Crohns Colitis*. 2025;19:jjaf129. From PIANO website: https://pianostudy.org/. **IL**=interleukin.

Background & Objective

- GUS is a dual-acting, selective IL-23p19 subunit inhibitor that blocks IL-23 and binds to CD64, a receptor on immune cells that produce IL-23[1]
- GUS has received FDA approval for the treatment of:[2]
  - Moderate-to-severe plaque PsO (in 2017)
  - Active PsA (in 2020)
  - Moderately to severely active UC and CD (in 2024 and 2025, respectively)

Objective

- We report data on pregnancy cases with known outcomes in women exposed to GUS during pregnancy from the Company Global Safety Database



1. Sachen KL, et al. *Front Immunol*. 2025;16:1532852. 2. TREMFYA. Package insert. Janssen Biotech, Inc.; 2025. **CD=**Crohn's disease, **GUS=**guselkumab, **PsA=**psoriatic arthritis, **PsO=**psoriasis, **UC=**ulcerative colitis.

Methods

Pregnancy cases that were reported to the Company Global Safety Database through July 12, 2025 were analyzed

Reporting sources:

Interventional

- Data reported from clinical trials

Non-interventional

- Data reported from registries (eg, observational studies)

Spontaneous reporting

- Physician or self-reported (eg, unsolicited)

Timing of reporting:

Prospective data

- Collected from pregnancies with GUS exposure reported before outcomes were known

Retrospective data

- Included simultaneous reports of pregnancies and outcomes

Methods

Pregnancy cases that were reported to the Company Global Safety Database through July 12, 2025 were analyzed

Therapeutic indications were categorized as:

- Psoriatic disease
- CD
- UC
- Other/not reported

Maternal GUS exposure occurred:

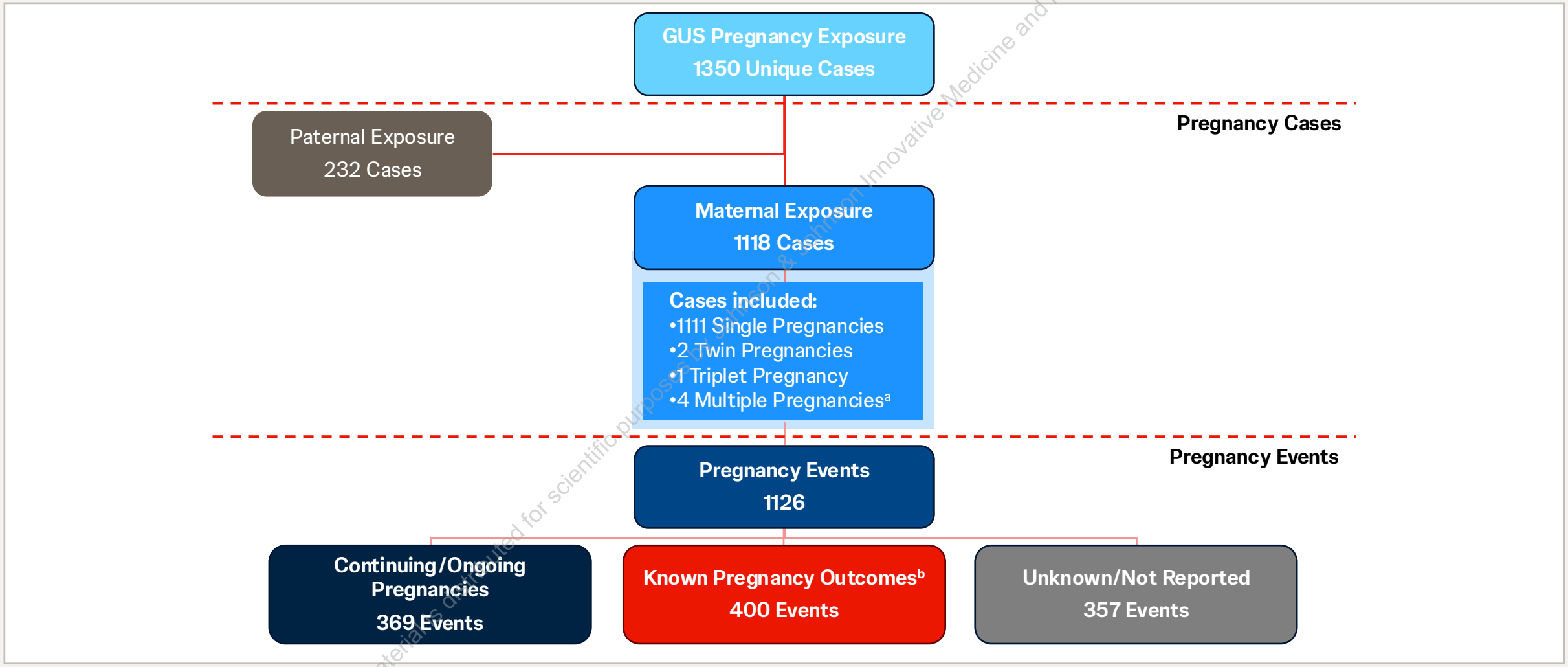
- Preconception only
- Any T1: any exposure during the 1st trimester (T1 only; T1+T2; T1-T3)
- T2+T3: after 1st trimester
- T3 only: 3rd trimester exposure only
- NR: not reported

Pregnancy outcomes were classified as:

- Live births
- Spontaneous abortions
- Elective terminations
- Ectopic pregnancies
- Stillbirths

A total of 400 pregnancy events with known outcomes occurred among 396 women

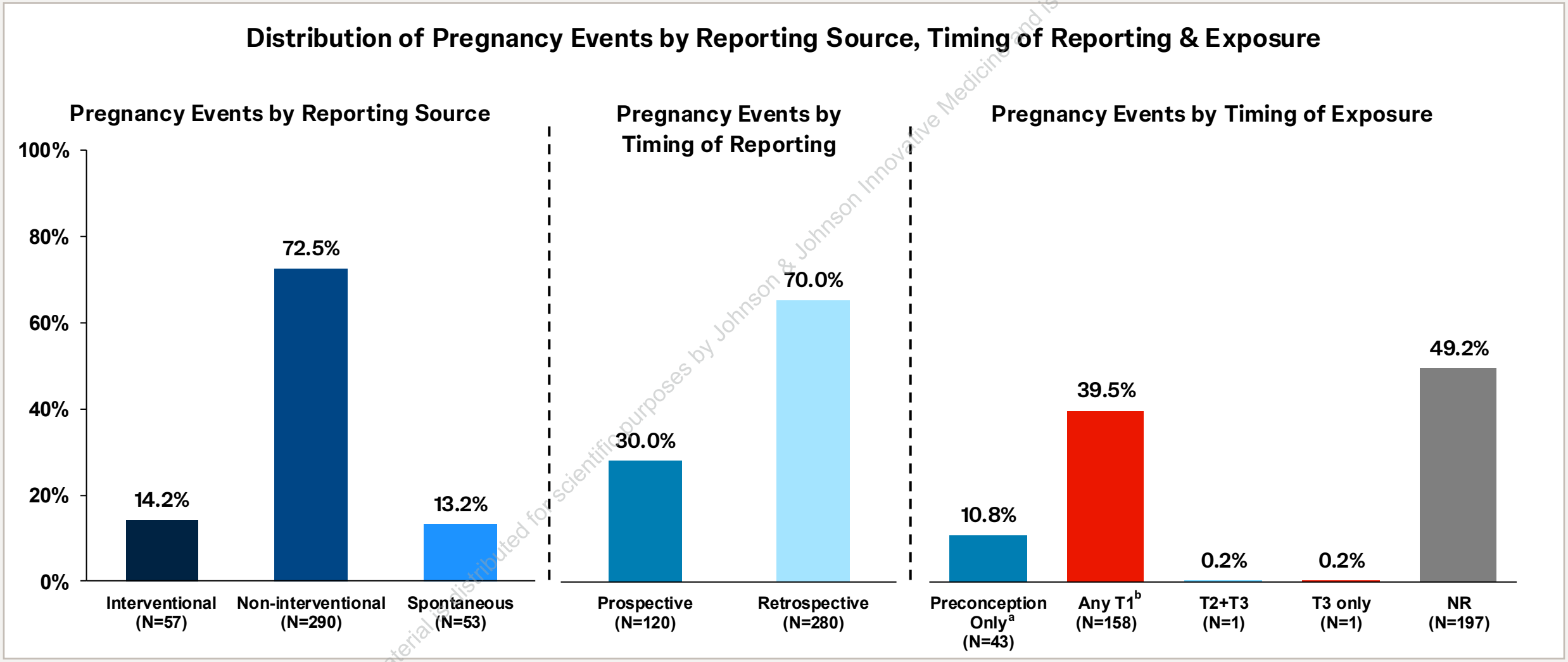
- Maternal age was reported for 67% (264/396) of women; the mean maternal age was 32 years



[a]Four women had two single pregnancies each. [b]These 400 events were from 287 medically confirmed pregnancies and 109 medically unconfirmed pregnancies.

Most pregnancy events were from retrospective reports and non-interventional settings

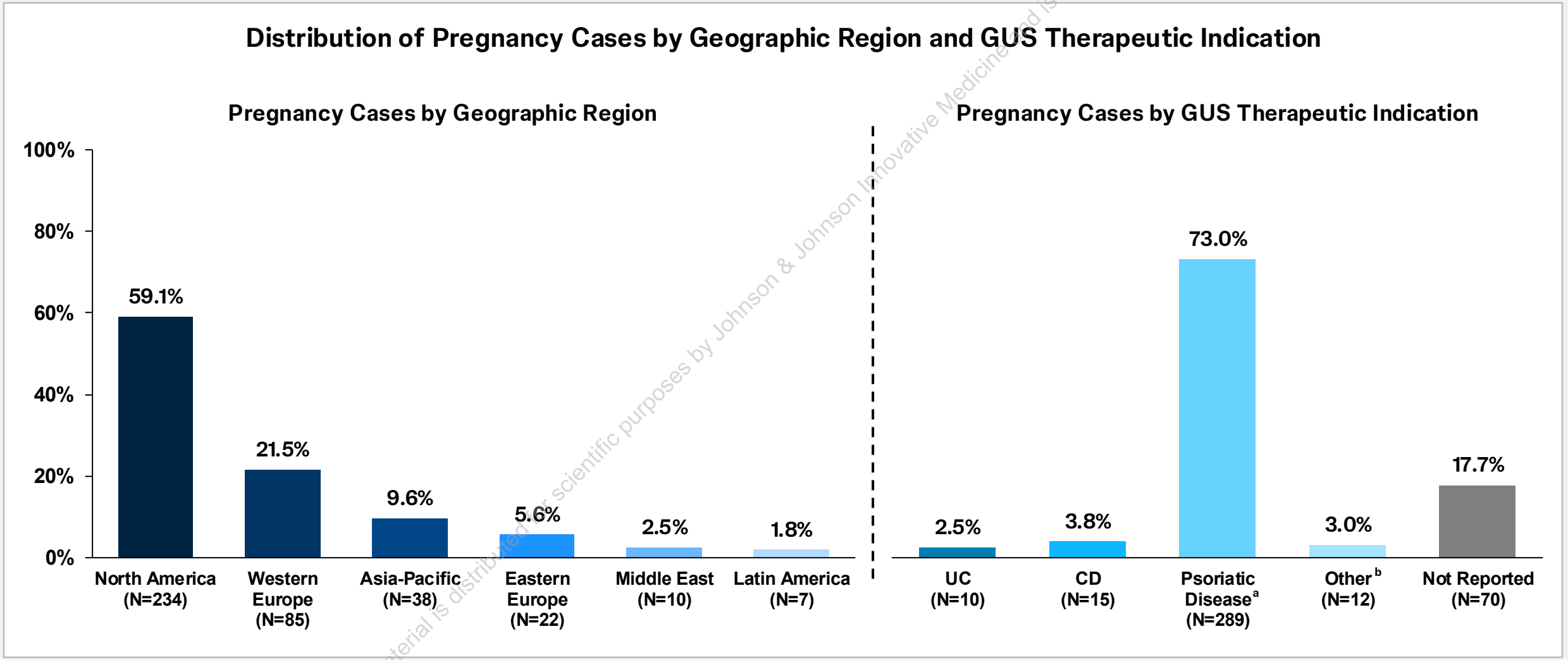
- Among cases with data reported, GUS exposure during the 1st trimester was most common



[a]Preconception only=within 3 months prior to conception. [b]Any T1 includes 105 events with exposure only during T1, 8 events with T1+T2, 18 events with T1+T2+T3, and 27 events with T1 and possible T2 and/or T3 exposure. **NR**=timing of exposure was not reported, **T1**=exposure during the 1st trimester and T2/NR, **T1**=exposure during the 1st trimester only, **T2+T3**=exposure after the first trimester, **T3**=exposure during the 3rd trimester only.

Women living in North America and Western Europe comprised the majority of pregnancy cases

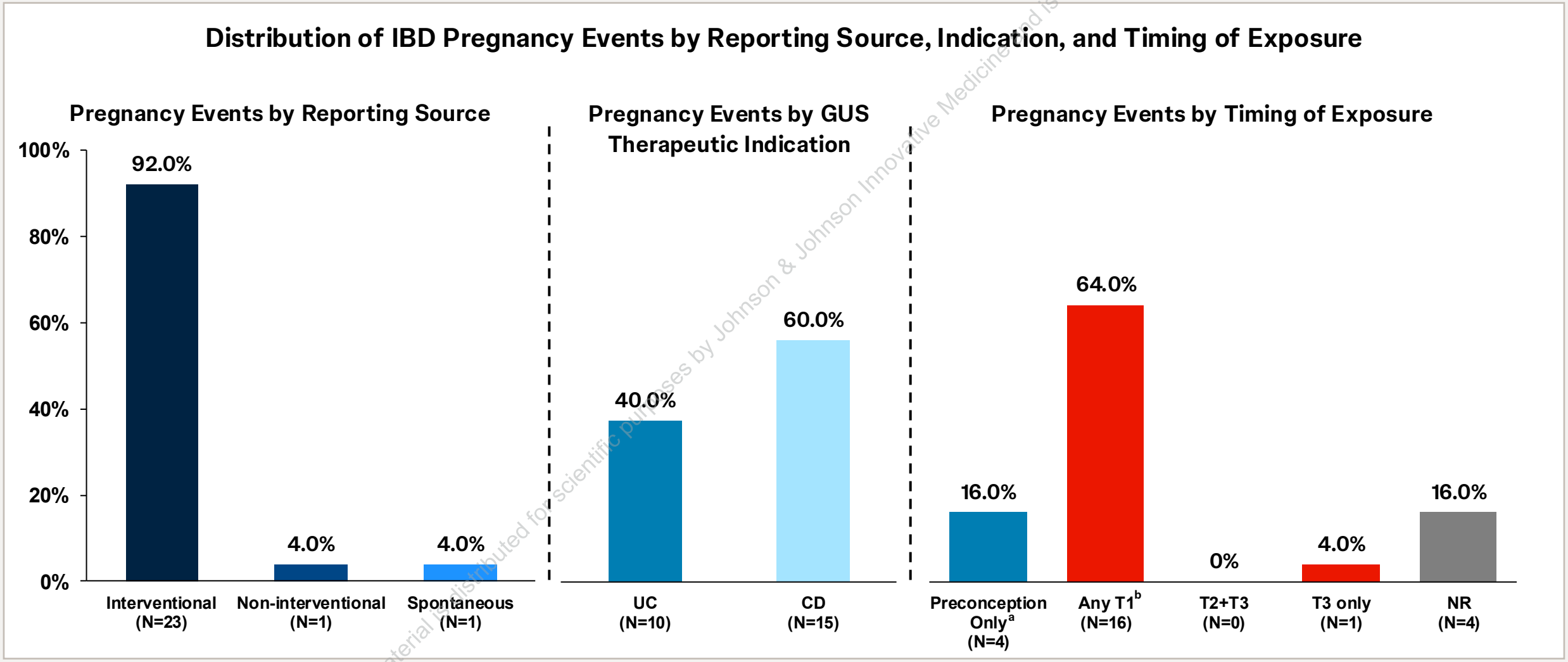
- Among cases with reported therapeutic indication, GUS was mostly used to treat psoriatic disease



[a]Includes cases reporting indications as PsO, PsA, and PsO + PsA. [b]Other indications included hidradenitis suppurativa, palmoplantar pustulosis, guttate PsO, pityriasis rubra pilaris, rheumatoid arthritis, and healthy individuals from Phase 1 studies.

Most pregnancy events reporting indication of IBD were for CD treatment and from interventional studies

- The 1st trimester was most common time period for GUS exposure

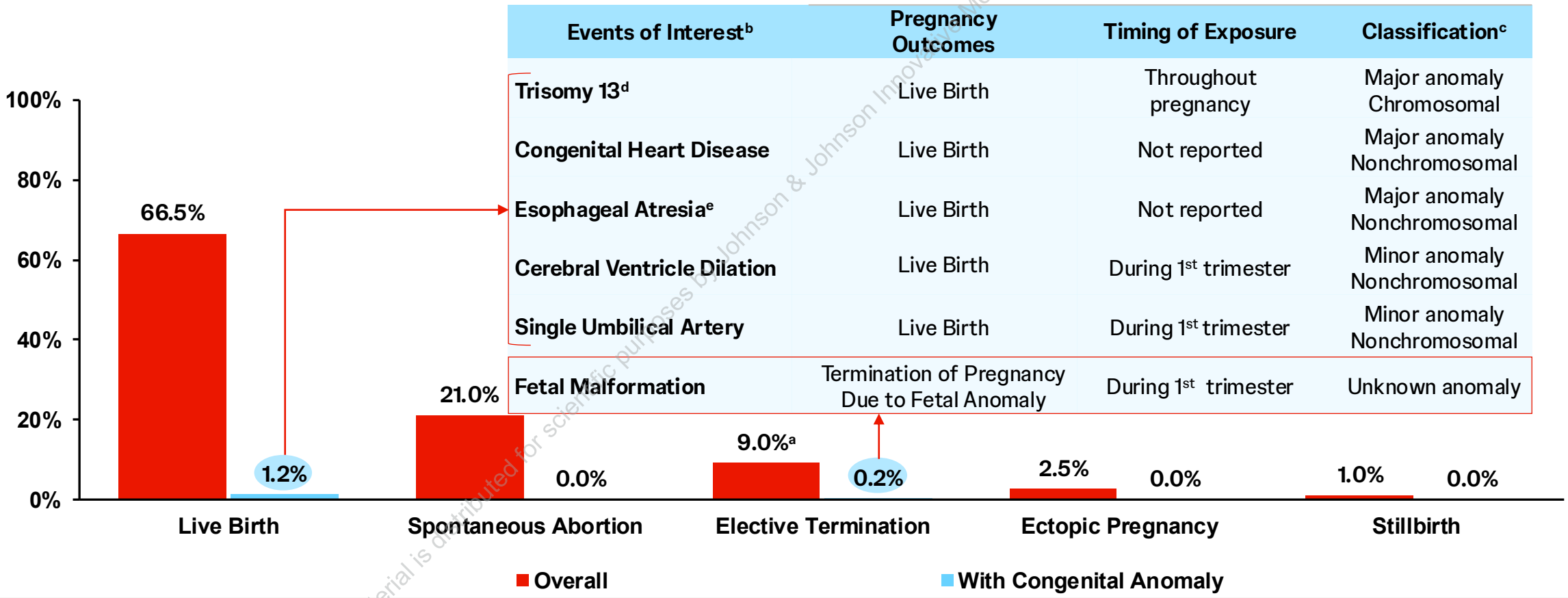


[a]Preconception only=within 3 months prior to conception. [b]Any T1 includes 14 events with exposure only during T1, 1 event with T1+T2+T3, and 1 event with T1 and possible T2 and/or T3 exposure. **NR**=timing of exposure was not reported, **T1**=exposure during the 1st trimester and T2/NR, **T1**=exposure during the 1st trimester only, **T2+T3**=exposure after the first trimester, **T3**=exposure during the 3rd trimester only.

66.5% (266/400) of pregnancy events with maternal exposure to GUS resulted in live birth

Of the 400 pregnancy events with known outcomes, 6 (1.5%) pregnancies were associated with congenital anomalies

- All pregnancy cases associated with congenital anomalies were reported retrospectively

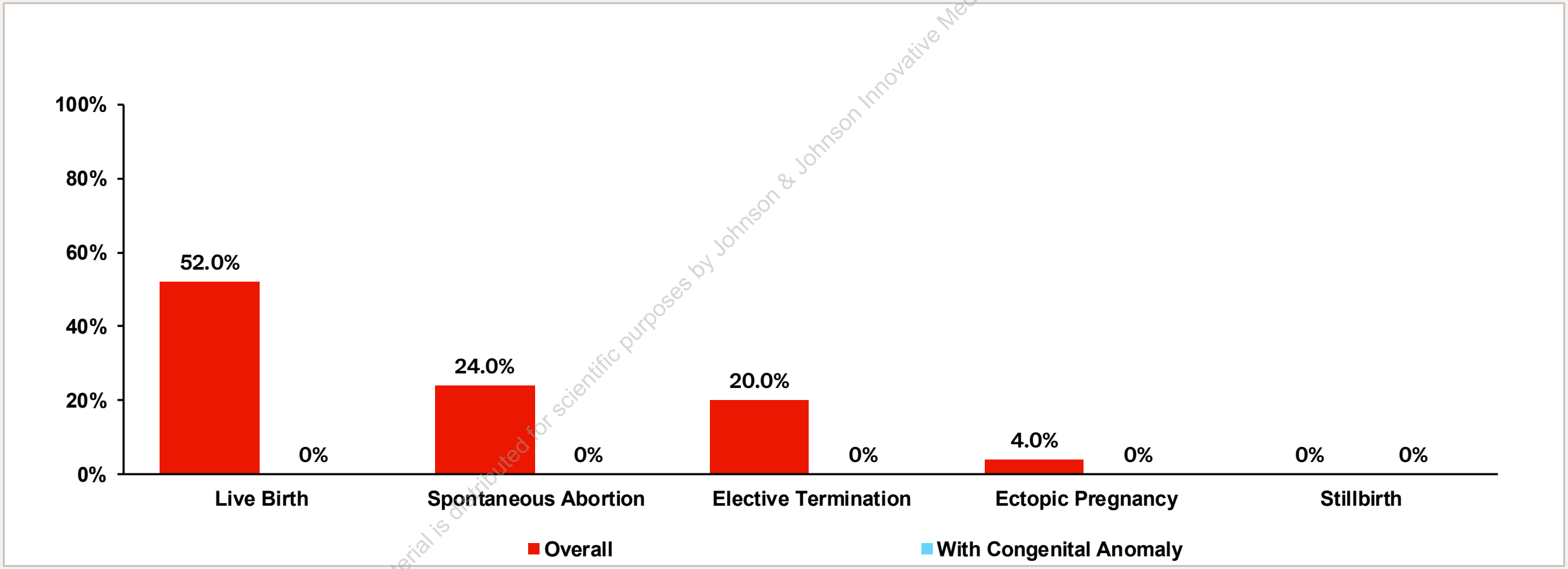


Events of Interest[b]	Pregnancy Outcomes	Timing of Exposure	Classification[c]
Trisomy 13[d]	Live Birth	Throughout pregnancy	Major anomaly Chromosomal
Congenital Heart Disease	Live Birth	Not reported	Major anomaly Nonchromosomal
Esophageal Atresia[e]	Live Birth	Not reported	Major anomaly Nonchromosomal
Cerebral Ventricle Dilation	Live Birth	During 1st trimester	Minor anomaly Nonchromosomal
Single Umbilical Artery	Live Birth	During 1st trimester	Minor anomaly Nonchromosomal
Fetal Malformation	Termination of Pregnancy Due to Fetal Anomaly	During 1st trimester	Unknown anomaly

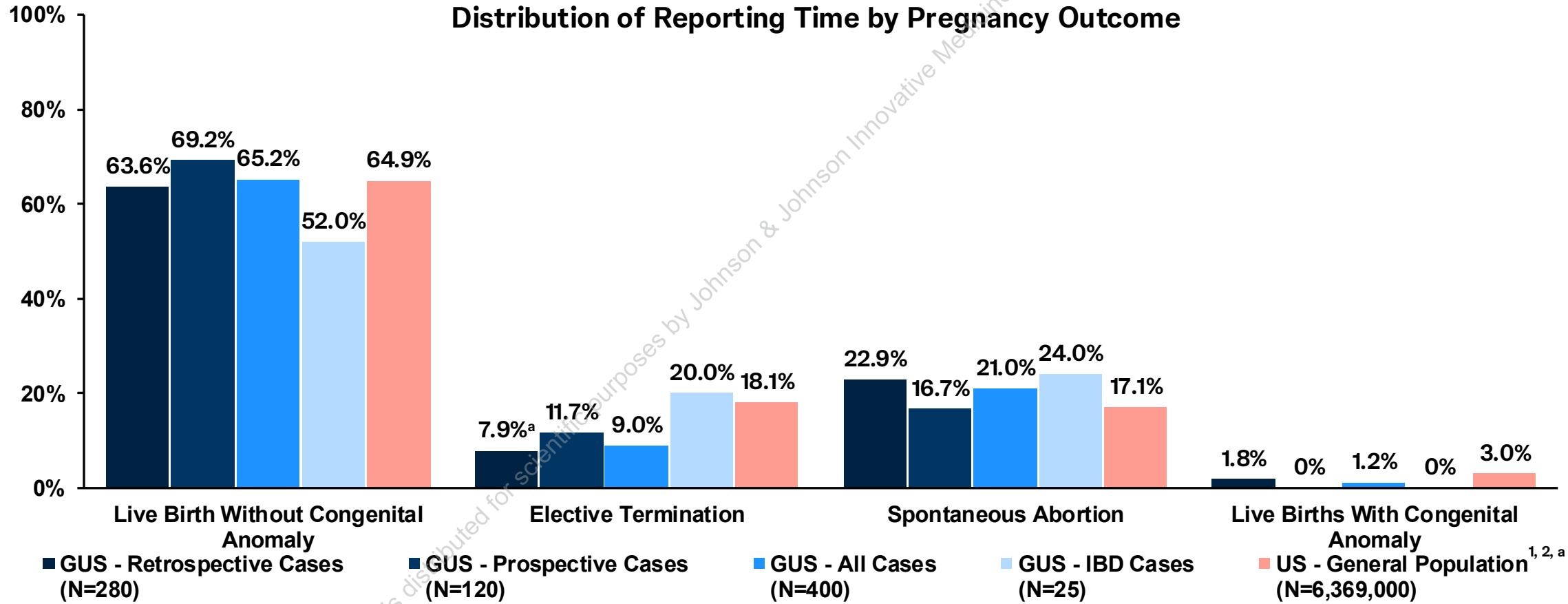
[a]One case reported baby adverse event of fetal disorder with no further information; conservatively, it was categorized as a fetal defect. [b]Medical Dictionary for Regulatory Activities (MedDRA, version 28.0) was used to identify adverse events based on the System Organ Class of congenital, familial, or genetic disorders, which is sub-search of the Standardized MedDRA Query of pregnancy and neonatal topics. [c]Major and chromosomal congenital anomalies per EUROCAT classification are reported unless otherwise specified. [d]Pre-term delivery at less than 37 weeks; baby died due to Trisomy 13. [e]Baby adverse event of tracheomalacia was reported.

52.0% (13/25) of IBD pregnancy events with maternal exposure to GUS resulted in live birth

Of the 25 pregnancy events with IBD indication, no pregnancies were associated with congenital anomalies



Pregnancy outcomes with maternal exposure were consistent with the US general population



[1]Curtin SC, et al. *Pregnancy Rates for U.S. Women Continue to Drop*. Centers for Disease Control and Prevention, U.S. Dept of Health and Human Services; 2013:1-7. [2]About Birth Defects. U.S. Centers for Disease Control and Prevention. February 25, 2025.

[a]Congenital anomalies affect 1 in every 33 babies in the United States.

Key Takeaways

- **The findings of this study suggest no apparent impact of GUS on pregnancy outcomes**
- **Live births, elective terminations, spontaneous abortions, and congenital anomalies were consistent with the US population**
- **More studies are warranted to confirm these observations and to further characterize the safety profile of GUS exposure during pregnancy**

Results should be interpreted cautiously given data limitations:

- **Lack of study control**
- **Small sample size of pregnancies with known outcomes**
- **Data were reported with varying degrees of missing information**

ACKNOWLEDGEMENTS

- Under the direction of the authors and in accordance with Good Publication Practices, Alyssa Cortina of Johnson & Johnson provided writing and editorial assistance
- This work was supported by Johnson & Johnson

Scan the QR code
The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way.