Pregnancy Outcomes in Maternal Exposure to Guselkumab: Review of Cases Reported to the Company Global Safety Database

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Conflicts of Interest

UM: 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.

ML: Received research support from Celltrion, Lilly, Pfizer, and Takeda; and served as a consultant for AbbVie, Bristol Myers Squibb, Celltrion, Intercept, Johnson & Johnson, Lilly, Merck, Pfizer, Prometheus, Roivant, Sanofi, Spyre, Takeda, and Target RWE.

MJ: Received research grants for investigator-driven studies from Novo Nordisk Foundation and Takeda (grant no. NNF23OC0081717); has consulted for Ferring, Orion Pharma, and Takeda; has received speaker's fees from Eli Lilly, Ferring, MSD, Takeda, and Tillotts Pharma; and is on the advisory board of AbbVie, Eli Lilly, PharmaCosmos, and Tillotts Pharma.

CL, AG, MRB, and HL: Employees of Johnson & Johnson; may own stock/stock options in Johnson & Johnson.

LCC: Received grants/research support from AbbVie, Amgen, Celgene, Eli Lilly, Johnson & Johnson, Novartis, Pfizer, and UCB; worked as a paid consultant for AbbVie, Amgen, Bristol Myers Squibb, Celgene, Eli Lilly, Galapagos, Gilead, Johnson & Johnson, MoonLake, Novartis, Pfizer, and UCB; and has been paid as a speaker for AbbVie, Amgen, Biogen, Celgene, Eli Lilly, Galapagos, Gilead, GlaxoSmithKline, Johnson & Johnson, Medac, Novartis, Pfizer, and UCB.

JPG: Received grants from AbbVie, Biogen, Casen Fleet, Celgene/Bristol Myers Squibb, Chiesi, Dr. Falk Pharma, Faes Farma, Ferring, Gebro Pharma, Gilead/Galapagos/Alfasigma, Johnson & Johnson, Kern Pharma, Lilly, MSD, Mylan, Norgine, Italfarmaco, Otsuka Pharmaceutical, Pfizer, Roche, Sandoz, Takeda, Sanofi, Shire Pharmaceuticals, STADA, Teva, Tillotts Pharma, and Vifor Pharma.

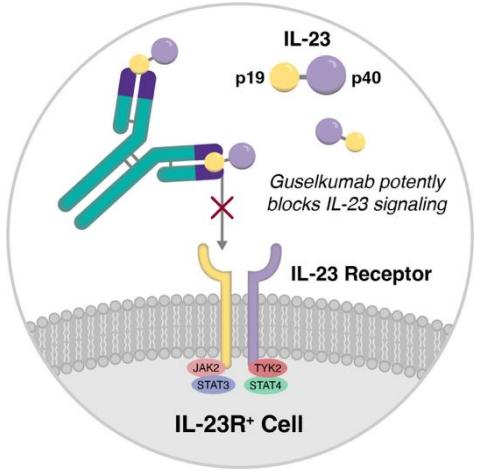
MC: Received grants from AbbVie, Biogen, Johnson & Johnson, Lilly, and Pfizer; has received fees from AbbVie, Faes, Johnson & Johnson, and Pfizer.

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)
- Data regarding the use of IL-23 inhibitors during pregnancy in women with psoriatic disease are limited

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, **IL**=interleukin, **PsA**=psoriatic arthritis, **PsO**=psoriasis, **UC**=ulcerative colitis.

Methods

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

Therapeutic indications were categorized as:

- Psoriatic disease
- IBD
- Other/not reported

Maternal GUS exposure occurred:

- Preconception only
- Any T1: during the 1st trimester with possible T2 or T3 exposure (excluding T1+T2+T3)
- T2+T3: after 1st trimester
- T3 only: 3rd trimester only
- T1+T2+T3: exposure during all 3 trimesters
- NR: not reported

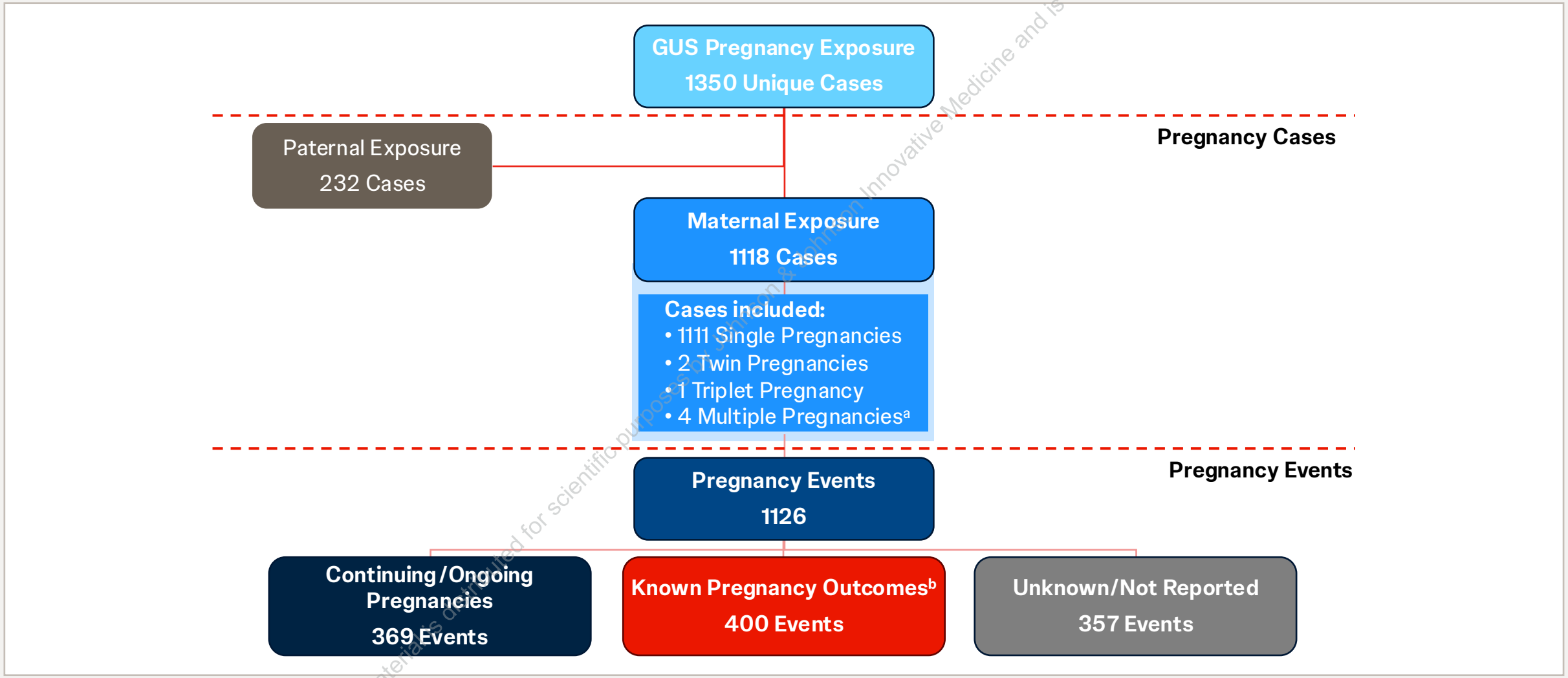
Pregnancy outcomes were classified as:

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

IBD=inflammatory bowel disease.

400 pregnancy events with known outcomes occurred among 396 women

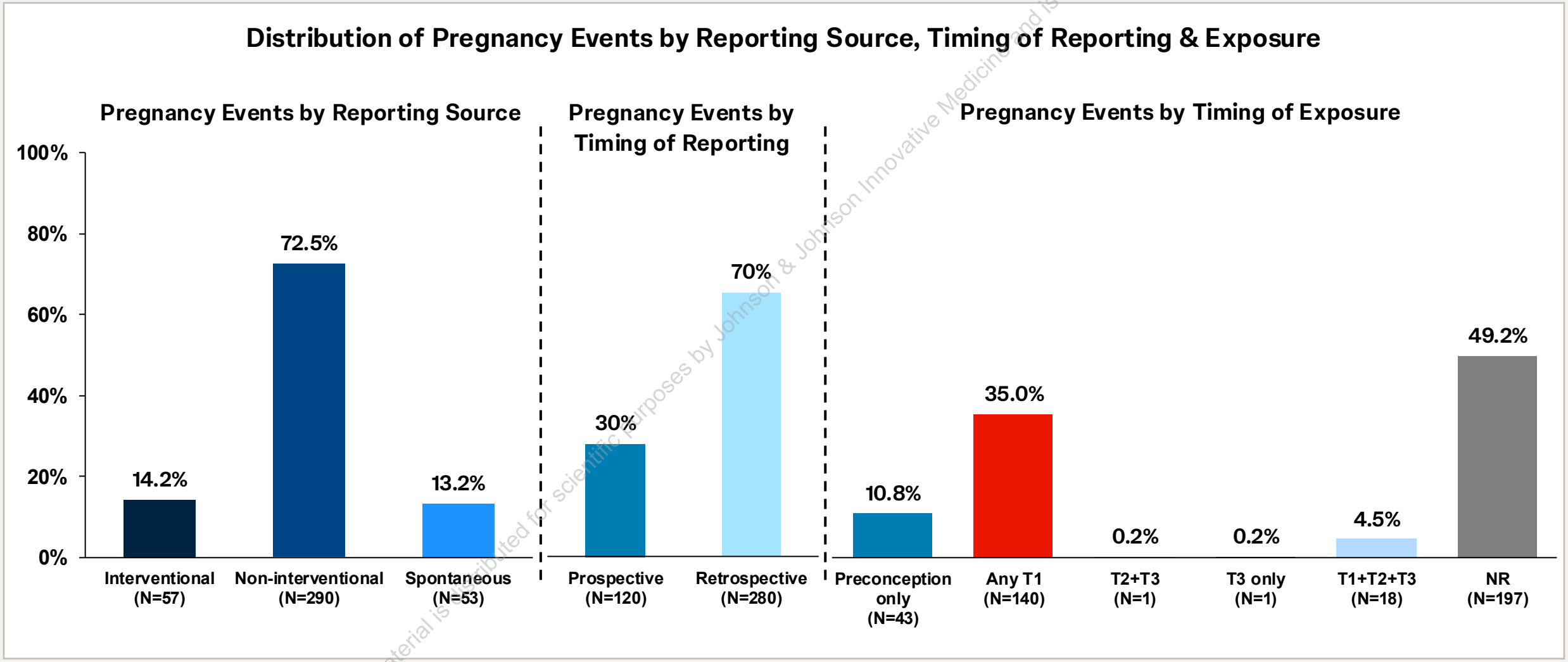
- Among the 67% of cases with age reported, mean maternal age was 32 years



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

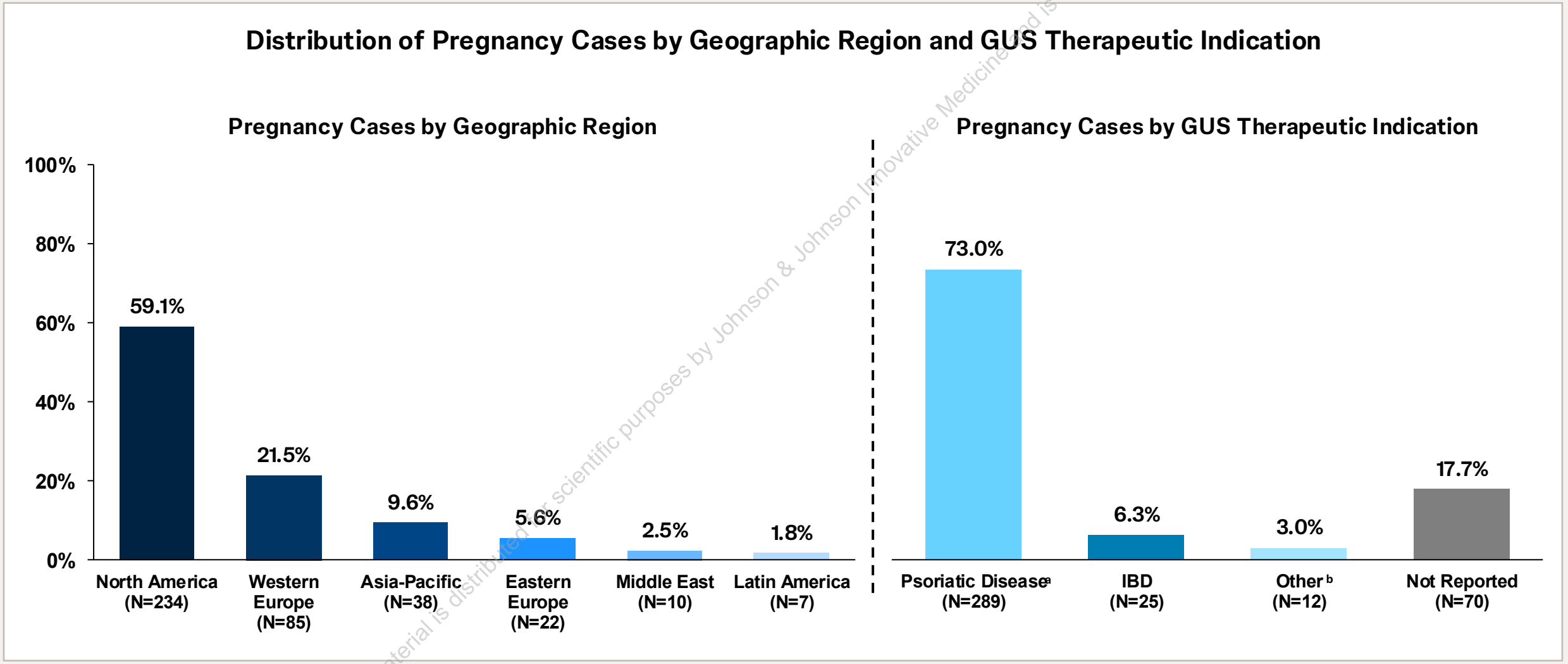
≥70% of pregnancy events were from non-interventional sources and were reported retrospectively

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



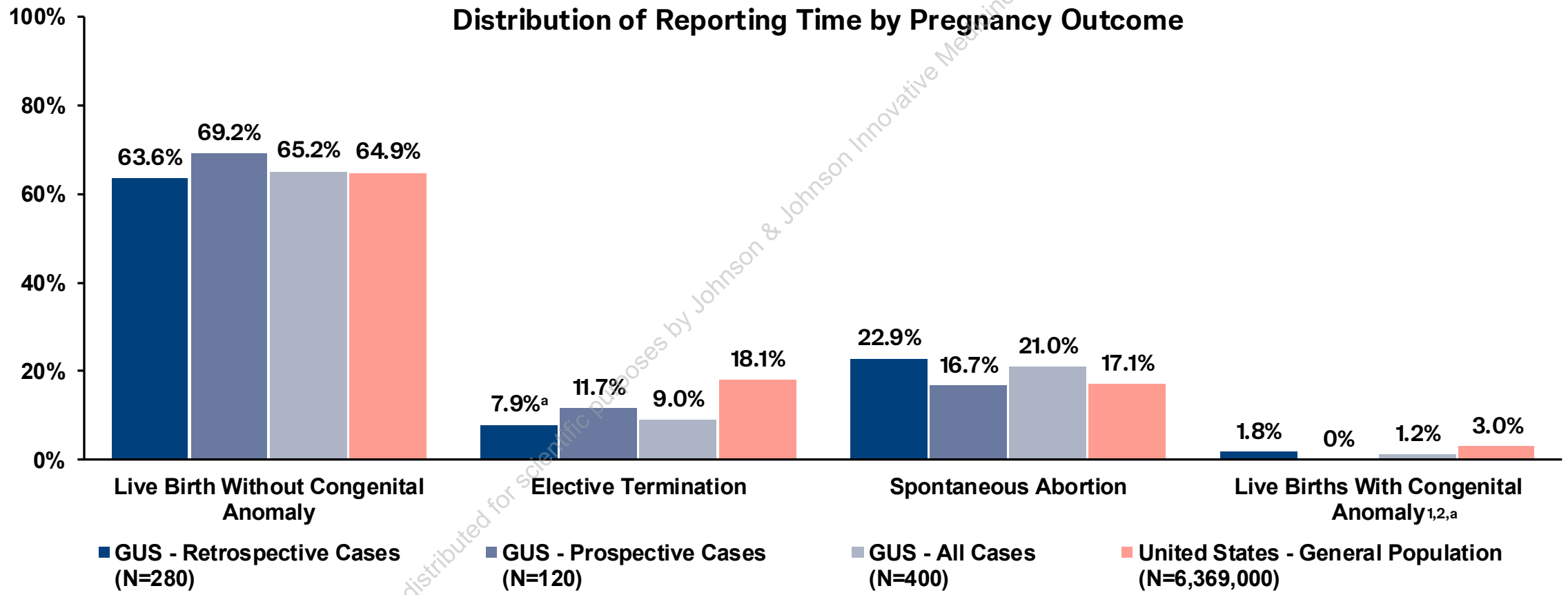
Preconception only=within 3 months prior to conception. **Any T1** includes 105 events with exposure only during T1, 8 events with T1+T2 exposure, and 27 events with T1 and possible T2 or T3 exposure (excluding T1+T2+T3). **T2+T3**=exposure after the 1st trimester. **T3 only**=exposure during the 3rd trimester only. **T1+T2+T3**=exposure during all 3 trimesters. **NR**=timing of exposure was not reported.

Women living in North America and Western Europe, and those with PsD, comprised the majority of pregnancy cases



[a]Cases reporting indications as PsO, PsA, and PsO + PsA, including 67% with PsO only and 6% with PsA +/- PsO. [b]Other indications include hidradenitis suppurativa, palmoplantar pustulosis, guttate PsO, pityriasis rubra pilaris, rheumatoid arthritis, and healthy individuals from Phase 1 studies. **PsD**=psoriatic disease.

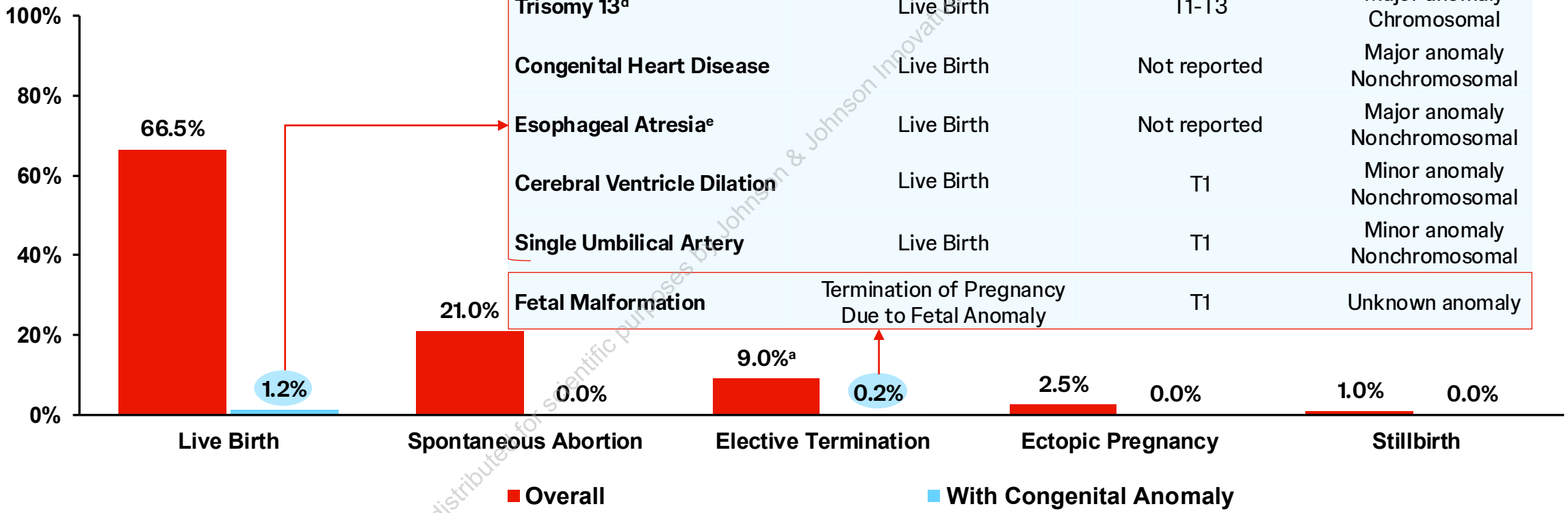
Pregnancy outcomes with maternal GUS exposure were consistent with the US general population



[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.

Among 400 pregnancy events with known outcomes, 6 (1.5%) 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	T1-T3	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	T1	Minor anomaly Nonchromosomal
Single Umbilical Artery	Live Birth	T1	Minor anomaly Nonchromosomal
Fetal Malformation	Termination of Pregnancy Due to Fetal Anomaly	T1	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.

Key Takeaways

- **Findings among women with immune-mediated inflammatory disorders, most commonly PsD, suggest no apparent impact of GUS on pregnancy outcomes**
- **Rates of live births, elective terminations, spontaneous abortions, and congenital anomalies were consistent with the US population**
- **Additional studies are warranted to confirm these observations and further characterize the safety profile of GUS exposure during pregnancy**

Results should be interpreted cautiously given data limitations:

- **Small sample size of pregnancies with known outcomes**
- **Data were reported with varying degrees of missing information**
- **Findings are GUS-specific and not generalizable to other IL-23 inhibitors**