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

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Key Takeaways

- **These findings suggest no apparent impact of GUS on pregnancy outcomes; however, they should be interpreted cautiously given data limitations.**
- **Further studies are warranted to confirm these observations and to better characterize the safety profile of GUS exposure during pregnancy.**

The limitations of these findings include, but are not limited to, the lack of study control, a small sample size of pregnancies with known outcomes, and reported data with varying degrees of missing information.

Background

- The Global Consensus Consortium statement on the management of pregnancy in inflammatory bowel disease suggests women can continue treatment with interleukin (IL)-23 inhibitors throughout pregnancy[1]
- Guselkumab (GUS) is a dual-acting selective p19 subunit-targeted IL-23 inhibitor that blocks IL-23 signaling and binds to CD64, a receptor on immune cells that produce IL-23[2]
- GUS is approved to treat moderate-to-severe psoriasis (PsO), active psoriatic arthritis (PsA), and moderately to severely active ulcerative colitis (UC) and Crohn's disease (CD)[3]

Objective

- **In this analysis, we report data on pregnancy cases with known outcomes in women exposed to GUS during pregnancy**

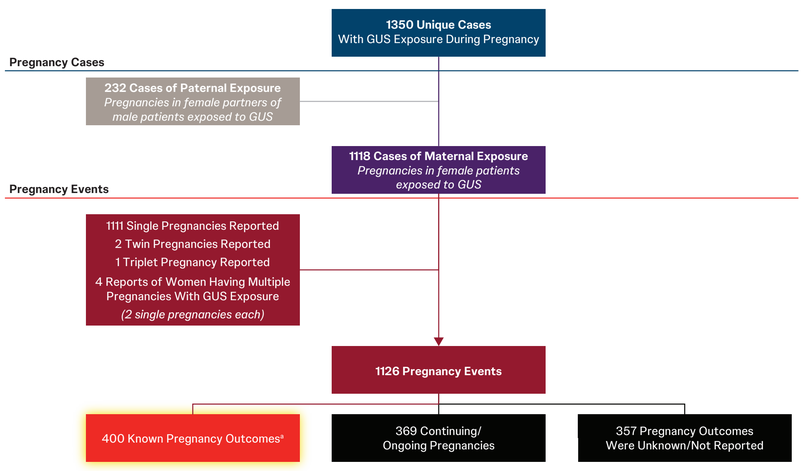
Methods

- **Pregnancy cases were reported to the Company Global Safety Database through 12 July 2025**
  - Cases with known outcomes were reported from clinical studies and spontaneous sources
- **Data were summarized descriptively for pregnancies reported prospectively and retrospectively**
- **GUS therapeutic indications in pregnancy cases were:**
  - Psoriatic disease
  - CD
  - UC
  - Other/not reported
- **Maternal GUS exposure was categorized as follows:**
  - Before conception (within 3 months prior to conception)
  - During the first trimester (T1)
  - After the first trimester only (T2, T3)
  - Throughout pregnancy
  - Not reported
- **Pregnancy outcomes were classified as:**
  - Live births with or without congenital anomalies
  - Spontaneous abortions
  - Elective terminations with or without fetal defects or unknown
  - Ectopic pregnancies
  - Stillbirths with or without fetal defects
  - Unspecified abortions with or without fetal defects or unknown

Results

Figure 1. A total of 400 pregnancy events with known outcomes occurred among 396 women

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



[a]*Includes 287 medically confirmed pregnancies and 109 medically unconfirmed pregnancies.*

Figure 4. Proportions of pregnancy cases reported by geographic region, N=396

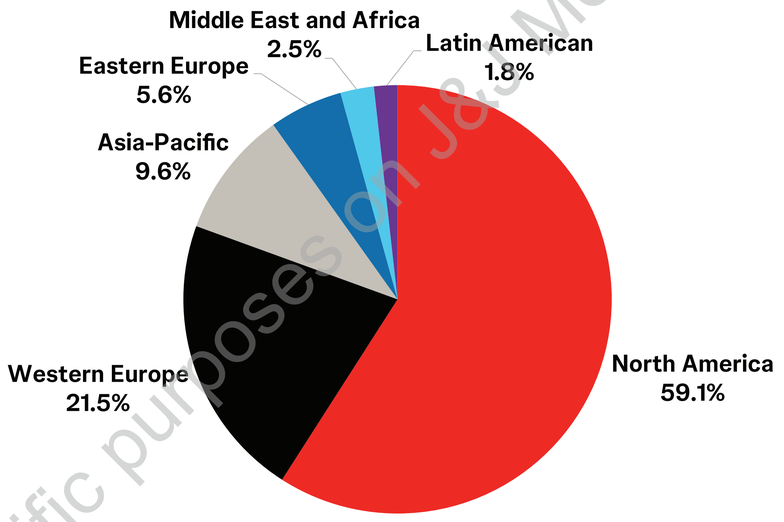
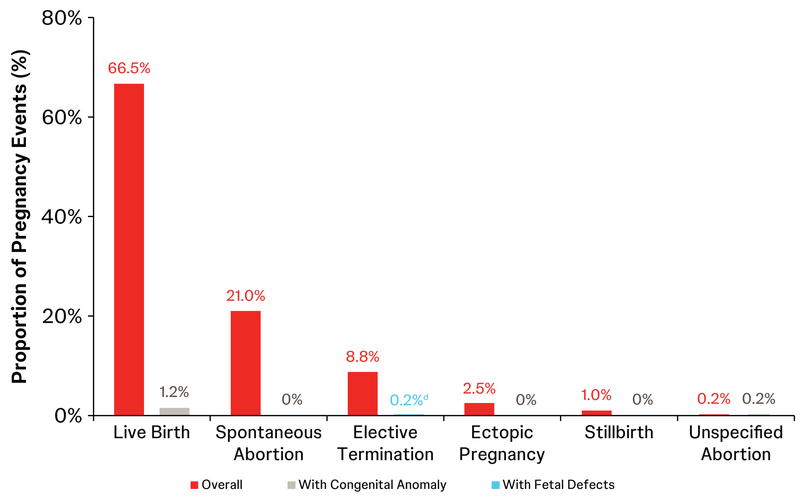


Figure 6. Proportions of Pregnancy Events by Outcome, N=400

- 66.5% of pregnancy events with maternal exposure to GUS resulted in live birth



[d]*One case reported baby adverse event of fetal disorder with no further information; conservatively, it was categorized as a fetal defect.*

Figure 2. Proportions of prospectively and retrospectively reported pregnancy events, N=400

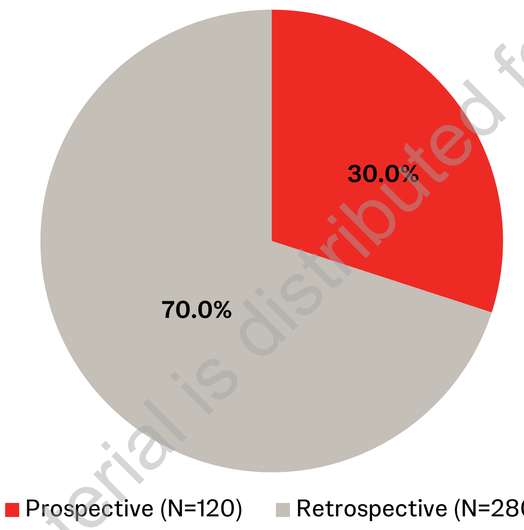


Table 1. Women exposed to GUS during pregnancy were treated for:

	Indication (N=396)	
	n-value	Percentage
Psoriatic Disease[b]	**289**	**73.0%**
Not Reported	**70**	**17.7%**
Inflammatory Bowel Disease	**25**	**6.3%**
CD	15	3.8%
UC	10	2.5%
Other[c]	**12**	**3.0%**

[b]*Includes cases reported as psoriasis, psoriatic arthritis, and psoriasis + psoriatic arthritis.* [c]*Other indications included hidradenitis suppurativa, palmoplantar pustulosis, guttate psoriasis, pityriasis rubra pilaris, rheumatoid arthritis, and healthy individuals from Phase 1 studies.*

Table 2. Congenital Anomalies by Pregnancy Outcome and Timing of Exposure

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

Events of Interest[e]	Number of Events	Pregnancy Outcomes	Timing of Maternal Exposure	Classification[f]
Trisomy 13[g]	1	Live Birth	Throughout pregnancy	Major anomaly Chromosomal
Congenital Heart Disease	1	Live Birth	Not reported	Major anomaly Nonchromosomal
Esophageal Atresia[h]	1	Live Birth	Not reported	Major anomaly Nonchromosomal
Cerebral Ventricle Dilation	1	Live Birth	During the first trimester	Minor anomaly Nonchromosomal
Single Umbilical Artery	1	Live Birth	During the first trimester	Minor anomaly Nonchromosomal
Fetal Malformation	1	Unspecified Abortion	During the first trimester	Termination of pregnancy due to fetal anomaly

[e]*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.* [f]*Major and chromosomal congenital anomalies per EUROCAT classification are reported unless otherwise specified.* [g]*Pre-term delivery at less than 37 weeks; baby died due to Trisomy 13.* [h]*Baby adverse event of tracheomalacia was reported.*

Figure 3. Proportions of pregnancy events by reporting source, N=400

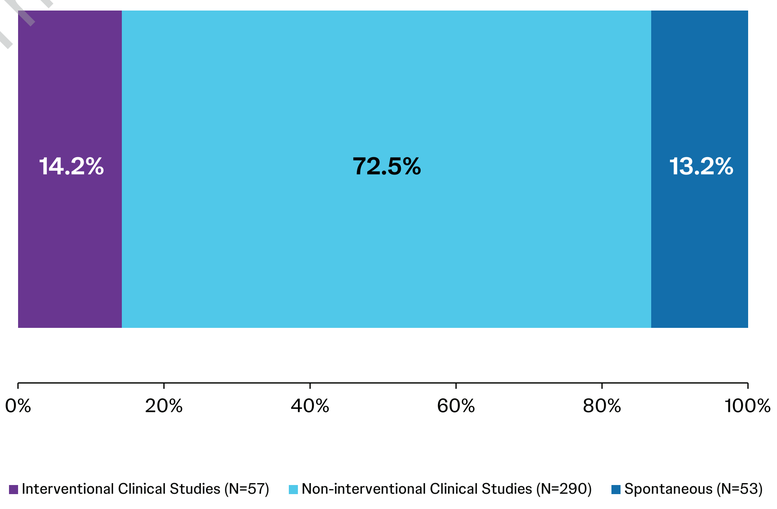


Figure 5. Proportions of pregnancy cases reported by timing of exposure, N=400

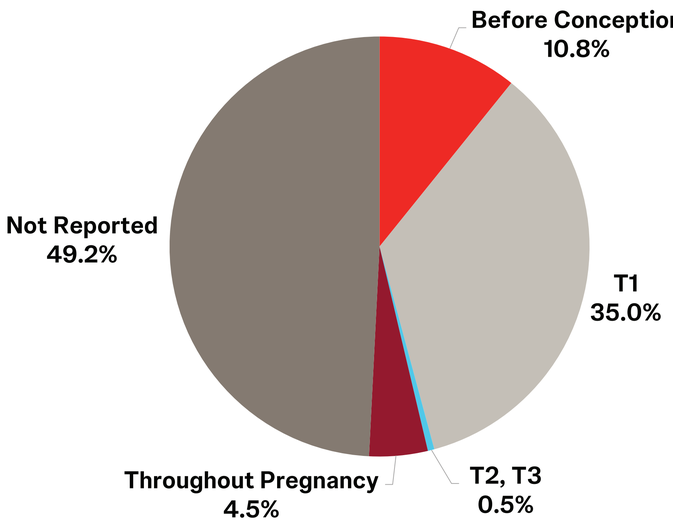
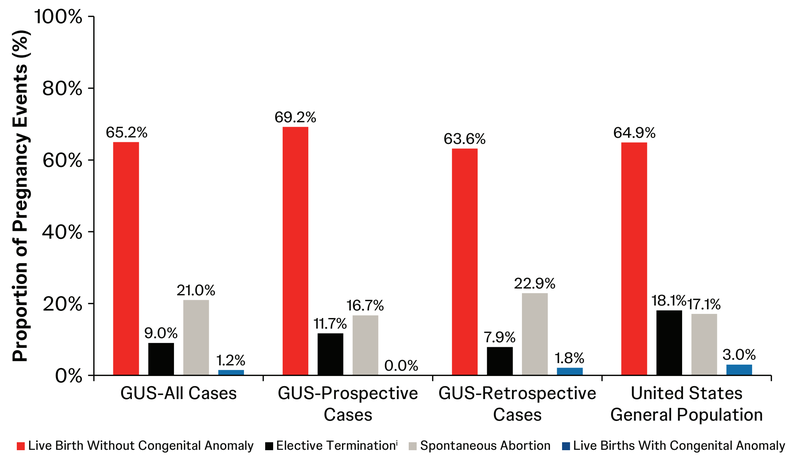


Figure 7. Rates of Pregnancy Outcomes With Maternal Exposure vs United States General Population[4,5]

- Rates of pregnancy outcomes in women exposed to GUS were consistent with those of the general US population



[i]*Included cases reporting unspecified abortions.*

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