In this US cohort, the use of bictegravir during pregnancy appears to be common. Findings do not suggest early safety signals for adverse birth outcomes with bictegravir use in pregnancy.

### BACKGROUND
- **Bictegravir (BIC),** co-formulated in a tablet with tenofovir alafenamide and emtricitabine, is being increasingly prescribed to pregnant persons with HIV (PWH)
- Limited birth outcome data have been reported in PWH who have taken BIC

### METHODS
- **Study Population**
  - PWH 18-45 years of age enrolled in at least one PHACS-affiliated protocol:
    - SMART
    - AMP Up
    - AMP Up Life
    - HOPE
- Received BIC for at least 7 days during pregnancy
- Completed follow-up through delivery

### Statistical Methods
- Prevalence with Clopper-Pearson 95% CIs was calculated among infants exposed to BIC
  - For anomalies, only exposure to BIC in the first trimester was considered
- Maternal CD4 count and HIV viral load (VL) nearest and prior to delivery were reported (if available)

### RESULTS

#### Summary of demographic characteristics:
- Median PWH age at delivery was 29.7 years (IQR: 26.1, 33.9)
- 71% of PWH reported their race/ethnicity as Black or African American
- 52% had annual household income <$20,000
- All US census regions were represented
- HIV disease status nearest to delivery:
  - 82% had maternal VL <50 copies/mL
  - 95% had maternal VL <200 copies/mL

#### Timing of BIC use:
- 50% of PWH initiated BIC prior to conception
- 99 infants (69%) were exposed to BIC in the first trimester

#### Birth outcomes:
- Summarized in Table 2
- No neonatal deaths or perinatal HIV transmissions were reported

### Table 2: Birth Outcomes of Infants Exposed to ≥ 7 Days of Bictegravir during Gestation

<table>
<thead>
<tr>
<th>Infant Outcome</th>
<th>Pre-Conception Initiation (N=144)</th>
<th>Post-Conception Initiation (N=147)</th>
<th>Total (N=291)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preterm birth</td>
<td>37.0% (39/107)</td>
<td>38.4% (41/107)</td>
<td>37.9% (80/214)</td>
</tr>
<tr>
<td>Small for gestational age</td>
<td>19.7% (15/75)</td>
<td>20.4% (15/74)</td>
<td>19.9% (30/155)</td>
</tr>
<tr>
<td>Preterm birth</td>
<td>19.7% (15/76)</td>
<td>20.4% (15/74)</td>
<td>20.0% (30/150)</td>
</tr>
<tr>
<td>Small for gestational age</td>
<td>19.7% (15/76)</td>
<td>20.4% (15/74)</td>
<td>19.7% (30/150)</td>
</tr>
<tr>
<td>Congenital anomalies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Birth weight Z-Score</td>
<td>N=76</td>
<td>N=77</td>
<td>N=153</td>
</tr>
<tr>
<td>Birth length Z-Score</td>
<td>N=76</td>
<td>N=77</td>
<td>N=153</td>
</tr>
<tr>
<td>Any major congenital anomaly</td>
<td>N=76</td>
<td>N=77</td>
<td>N=153</td>
</tr>
</tbody>
</table>

### REFERENCES

### CONTACT INFORMATION

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