

## Erratum to the iPLEDGE Briefing Document

Joint Meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee and the  
Drug Safety and Risk Management Advisory Committee  
March 28-29, 2023

The erroneous text is followed by the correction in bold below.

- Page 29, Table 13, Year 16 Number of FRPs, Pregnancy rate, and Pregnant patients per 1000 FRPs with  $\geq 1$  RMA below:

Table 13: iPLEDGE Pregnancy Rate for PWCBP<sup>a</sup> With at Least 1 RMA (iPLEDGE Years 12-16)

	Year 12 (3/1/2017- 2/28/2018)	Year 13 (3/1/2018- 2/28/2019)	Year 14 (3/1/2019- 2/29/2020)	Year 15 (3/1/2020- 2/28/2021)	Year 16 (3/1/2021- 12/10/2021)
Number of FRPs	199,031	214,984	232,762	257,876	285,622
Number of iPLEDGE Pregnancies during the reporting year	185	193	174	168	184
Pregnancy rate, %	0.09	0.09	0.07	0.07	0.06
Pregnant patients per 1000 FRPs with $\geq 1$ RMA	0.9/1000	0.9/1000	0.7/1000	0.7/1000	0.6/1000

Abbreviations: FRP=females of reproductive potential; PWCBP=Patients who can become pregnant; RMA=Risk Management Authorization.

<sup>a</sup> Patients were categorized as females of reproductive potential.

Source: FINAL iPLEDGE Year Fourteen Annual Report, Table 16; iPLEDGE Year 16 Bridge Report, Table 16.

Corrected to read as:

Table 13: iPLEDGE Pregnancy Rate for PWCBP<sup>a</sup> With at Least 1 RMA (iPLEDGE Years 12-16)

	Year 12 (3/1/2017- 2/28/2018)	Year 13 (3/1/2018- 2/28/2019)	Year 14 (3/1/2019- 2/29/2020)	Year 15 (3/1/2020- 2/28/2021)	Year 16 (3/1/2021- 12/10/2021)
Number of FRPs	199,031	214,984	232,762	257,876	<b>246,084</b>
Number of iPLEDGE Pregnancies during the reporting year	185	193	174	168	184
Pregnancy rate, %	0.09	0.09	0.07	0.07	<b>0.07</b>
Pregnant patients per 1000 FRPs with $\geq 1$ RMA	0.9/1000	0.9/1000	0.7/1000	0.7/1000	<b>0.7/1000</b>

Abbreviations: FRP=females of reproductive potential; PWCBP=Patients who can become pregnant; RMA=Risk Management Authorization.

<sup>a</sup> Patients were categorized as females of reproductive potential.

Source: FINAL iPLEDGE Year Fourteen Annual Report, Table 16; iPLEDGE Year 16 Bridge Report, Table 16;

**UBC Data on file.**