ERRATA TO THE BRIEFING DOCUMENT GASTROINTESTINAL DRUGS ADVISORY COMMITTEE (GIDAC) FOR ADVISORY COMMITTEE MEETING MARCH 8, 2018

SNDA 203214/SUPPLEMENT-018

APPLICANT: PFIZER INC.

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ADVISORY COMMITTEE BRIEFING MATERIALS

AVAILABLE FOR PUBLIC RELEASE

1. INTRODUCTION

The following errors have been identified in the Pfizer briefing document prepared for tofacitinib ulcerative colitis advisory committee. These identified errors do not carry through to other sections of the briefing materials and do not affect the overall safety conclusions as stated in the briefing document. The errors are identified by a ~~strikethrough~~ with corrections identified in **bold** text below.

2. IDENTIFIED ERROR

2.1. Error 1: Page 88 Section 7.2.2.2.3.2 Clinical Characteristics of NMSC in UC

In the Overall Cohort, NMSC was reported in ~~13~~ **15** subjects. Among a total of 31 NMSC event terms, 27 were AEs. The remaining 4 NMSC event terms corresponded to biopsies or excisions performed for NMSC AEs. Most NMSC AEs (19 events, 70.4%) were mild in severity, 3 (11.1%) of the NMSC AEs were considered SAEs, and most (22 events, 81.5%) had resolved by 29 September 2017. None of these NMSC AEs resulted in discontinuation of tofacitinib. Among the 15 subjects who reported NMSC, 12 (80%) were in the PD 10 mg BID group. These included 9 subjects who reported basal cell carcinoma (BCC), 9 subjects who reported squamous cell carcinoma (SCC), and 3 subjects who reported both BCC and SCC. Of the 9 subjects who reported SCC, most had prior history of NMSC, all had prior exposure to AZA/6-MP, and most had prior exposure to TNF inhibitors.

2.2. Error 2: Page 96 Section 7.2.2.3 Clinical Laboratory Evaluations (3rd Bullet)

At the end of 52 weeks of post-induction therapy, mean decreases in ALC in tofacitinib treated subjects were larger than that in the placebo group, although mean ALC at the end of 52 weeks of additional treatment remained within the normal range. In the Overall Cohort, ~~11.0%~~ **11.1%** of subjects had ALC $<1.0 \times 10^9$/L prior to exposure to tofacitinib (ie, at baseline), and the proportion of subjects with post-baseline confirmed ALC $<1.0 \times 10^9$/L was **19.3%** ~~16.4%~~. Only ~~0.7%~~ **0.9%** of subjects met the criteria of discontinuation related to decreased ALC.

2.3. Error 3: Page 101 Section 7.2.4 Deaths (Following Table 23)

The mortality rate including all cases in the Tofacitinib All group of the Overall Cohort was ~~**0.10**~~ **0.24/100 PY** and was similar to those reported for the RA (0.25/100 PY), PsA (0.08/100 PY), and PsO (0.18/100 PY) programs (all exposure; Table 12; Table 229a.2.1) and for UC patients in external observational data from literature review (0.48 to 1.17/100 PY).