Errata to FDA Briefing Document
GI Drugs Advisory Committee Meeting

March 8, 2018

sNDA203214, supplement 18
Tofacitinib

Proposed for the treatment of adult patients with moderately to severely active ulcerative colitis who have demonstrated an inadequate response, loss of response, or intolerance to corticosteroids, azathioprine, 6-mercaptopurine, or tumor necrosis factor inhibitor therapy.

DISCLAIMER:

The attached package contains background information prepared by the Food and Drug Administration (FDA) for the panel members of the advisory committee. The FDA background package often contains assessments and/or conclusions and recommendations written by individual FDA reviewers. Such conclusions and recommendations do not necessarily represent the final position of the individual reviewers, nor do they necessarily represent the final position of the Review Division or Office. We have brought the application for tofacitinib proposed for the treatment of moderate to severe ulcerative colitis to this Advisory Committee in order to gain the Committee's insights and opinions, and the background package may not include all issues relevant to the final regulatory recommendation and instead is intended to focus on issues identified by the Agency for discussion by the advisory committee. The FDA will not issue a final determination on the issues at hand until input from the advisory committee process has been considered and all reviews have been finalized. The final determination may be affected by issues not discussed at the advisory committee meeting.

This document contains errata to the original FDA Briefing Document issued for the Advisory Committee meeting held March 8, 2018.

The erroneous text is identified by a strikethrough, with correction following in bold, unless otherwise specified.

1. Page 9 (Executive Summary)

~~There were no deaths in the induction trials~~ and the rates of serious adverse events (SAEs) were low and comparable between placebo and tofacitinib.

The Agency notes that one of the five deaths which occurred during the tofacitinib development program did occur during induction (please see description on page 65 of the FDA briefing document).