

Antiviral Drugs Advisory Committee Meeting

April 24, 2007

New Drug Application (NDA) 022-128, maraviroc 150 and 300 milligram tablets, Pfizer, Inc., proposed for the treatment of antiretroviral-experienced patients with chemokine (c-c motif) receptor 5 (CCR5) – tropic human immunodeficiency virus (HIV).

ADDENDUM TO:

FDA/FCHR Collaborative Public Meeting on Long-Term Safety Concerns Associated with CCR5 Antagonist Development - Draft Report

PLEASE NOTE THAT THIS ATTACHMENT IS A DRAFT REPORT OF A SERIES OF MEETINGS THAT WERE CONVENED OVER THE PERIOD OF MAY 2005 THROUGH MAY 2006. THIS DOCUMENT IS CURRENTLY CIRCULATING AMONG MEETING PARTICIPANTS AND PLANNERS FOR COMMENTS AND EDITS. SOME OF THE DATA REFERENCED IN THE DOCUMENT MAY HAVE CHANGED OR BEEN UPDATED DURING THE ONGOING DEVELOPMENT OF CCR5 RECEPTOR ANTAGONISTS. THE DOCUMENT HAS BEEN INCLUDED IN THE BACKGROUND MATERIALS AS A REFERENCE TO PROVIDE THE COMMITTEE WITH A HISTORICAL BACKGROUND AND PERSPECTIVE OF PRIOR DISCUSSIONS AND CONCERNS REGARDING THE DEVELOPMENT OF THE CCR5 DRUG CLASS.