

***IN VIVO* GENOTOXICITY ASSAYS**

ANDREAS HARTMANN,¹ KRISTA L. DOBO,² AND HANS-JÖRG MARTUS¹

¹*Novartis Pharma AG, Basel, Switzerland*

²*Pfizer Global R&D, Groton, Connecticut*

Contents

- 1 Introduction
- 2 Standard *In Vivo* Test for Chromosomal Damage in Rodent Hematopoietic Cells
 - 2.1 *In Vivo* Micronucleus Assessment in Rodent Hematopoietic Tissue
 - 2.2 *In Vivo* Rodent Bone Marrow Chromosomal Aberration Assay
- 3 Supplemental *In Vivo* Genotoxicity Assays
 - 3.1 *In Vivo* Genotoxicity Tests for the Assessment of Primary DNA Lesions
 - 3.2 Unscheduled DNA Synthesis (UDS) Assay for the Detection of DNA Repair
 - 3.3 *In Vivo* Gene Mutation Assays
- 4 *In Vivo* Genotoxicity Tests for Investigating Germline Cells
- 5 Conclusion
- References

1 INTRODUCTION

The preclinical safety assessment of drug candidates includes conduct of assays intended to identify genotoxic hazards. Experience with genetic toxicology testing over the past several decades has demonstrated that no single assay is capable of detecting all genotoxic effects. Therefore, the potential for a chemical to cause genotoxicity is typically determined through a battery of tests conducted *in vitro* and *in vivo*. Genotoxicity tests are typically conducted early in the development of