Table of Contents

Administrative history of the BLA	Section 1- p 1-3
Executive Summary	Section 2-p 4-6
Background information on NHL	Section 3 p 7-11
Recent Regulatory Approvals	Section 3 p 11-12
Description of the Product	Section 4 p 14
Dosing Regimen	Section 4 p14 –21
Overview of Clinical Studies	Section 5 p 22
Study RIT-II-004	Section 5 p 22-46
• Protocol synopsis	Section 5 p 22
• Patient Enrollment &Disposition	Section 5 p 30
• Efficacy Results	Section 5 p 36
• Safety Results	Section 5 p 42
Study CP 97-012	Section 6 p 47-62
• Protocol synopsis	Section 6 p 47
• Patient Enrollment &Disposition	Section 6 p 51
• Efficacy Results	Section 6 p 55
• Safety Results	Section 6 p 58
Study RIT-II-002	Section 7 p 63-78
Study RIT-II-000	Section 7 p 79-88
Study RIT-II-001	Section 7 p 88-92
Analyses of Transformed NHL Subset	Section 8 p 93
Long-term Responder Subset	Section 9 p 100
Integrated Summary of Safety	Section 10 p 110
Biodistribution and Dosimetry	Section 11 p 131
Appendix 1- Communications with sponsor	Section 12 p 163
Appendix 2- Bioresearch Monitoring	Section 13 p 170
Appendix 3- Financial Disclosure	Section 14 p 174