FDA Clinical Review of

BLA 98-0369

Herceptin[®] Trastuzumab (rhuMAb HER2)

Date of Submission: May 4, 1998 Date of Approval: September 25, 1998

Sponsor: Genentech, Inc.

Food and Drug Administration Center for Biologics Evaluation and Research

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Portions of the reviews of the statistical, product and pharmacology/toxicology sections have been included in the clinical review in order to improve the logical flow of the content and provide the reader with a comprehensive overview of the subject.

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Table of Contents

| Тор | ic | Page |
|-------|--|------|
| 1.0 | Background of the Product | 06 |
| 2.0 | Sponsor's Proposed Indication | 09 |
| 3.0 | Clinical Pharmacology Review | 10 |
| 4.0 | Methodology of the Clinical Review | 14 |
| 5.0 | Clinical Trial H0649g-Phase 2 | 18 |
| | 5.1 Title H0649g | 18 |
| | 5.2 Study Design and Conduct H0649g | 18 |
| | 5.3 Results - Efficacy H0649g | 21 |
| | 5.4 Results - Safety H0649g | 27 |
| 6.0 | Clinical Trial H0648g-Phase 3 | 31 |
| | 6.1 Title H0648g | 31 |
| | 6.2 Title H0659g | 31 |
| | 6.3 Study Design and Conduct H0648g | 31 |
| | 6.4 Study H0659g | 36 |
| | 6.5 Methodology of Data Review H0648g | 37 |
| - | 6.6 Results - Efficacy H0648g | 37 |
| | 6.7 Results - Safety H0648g | 60 |
| 7.0 | Relationship Between Level of HER2/neu Protein | |
| | Overexpression and Clinical Benefit | 73 |
| 8.0 | Overall Efficacy for all Phase 2 and 3 studies | 77 |
| 9.0 | Reviewer's Conclusions | 79 |
| 10.0 | Appendix A: Patient Summaries | 83 |
| 11.0 | Appendix B: Pharmacology/Toxicology | 92 |
| 12.0 | Appendix C: Abbreviations | 96 |
| 13.0 | Appendix D: Definitions | 98 |
| 14.0 | Appendix E: Questions for the Oncologic Drugs Advisory | |
| | Committee Meeting September 2, 1998 | 100 |
| 15.0 | Final FDA Clinical Reviewer Recommendation | 105 |
| Figu | re | Page |
| Figur | e 1. Kaplan-Meier Estimates Survival H0649g | 27 |
| Figur | re 2. Time to Progression, All Patients H0648g | 50 |
| Figur | re 3. Time to Progression, AC Patients H0648g | 51 |
| Figur | re 4. Time to Progression, Taxol Patients H0648g | 52 |
| Figur | re 5. Survival Plot, All Patients H0648g | 56 |
| Figur | re 6. Survival Plot, AC Patients H0648g | 57 |
| Figur | e 7. Survival Plot, Taxol Patients H0648g | 58 |
| Figur | e 8. Summary of Cardiotoxicity Events | |
| | H0648g and H0649g | 69 |
| Figur | e 9. Kaplan-Meier Estimates of Cardiac Toxicities | |
| | by Cumulative AC Dose | 71 |

. . .

DOCKET

| Figure | | Page |
|------------|--|------|
| Figure 10. | Kaplan-Meier Estimates of Cardiac Toxicities (3/4) | 1 |
| | by Cumulative AC Dose | 71 |
| Figure 11. | Time to Progression 2+ Patients H0648g and | |
| | H0649g | 75 |
| Figure 12. | Time to Progression 3+ Patients H0648g and | |
| | H0649g | 76 |
| | | |

| Table | | Page |
|-----------|---|-------|
| Table 1. | Selection Criteria H0649g | 19 |
| Table 2. | Reasons for Discontinuation of Therapy H0649g | 22 |
| Table 3. | Demographics H0649g | 24 |
| Table 4. | Primary Endpoint H0649g - FDA derived data set | 26 |
| Table 5. | Secondary Endpoint H0649g - Sponsor derived | |
| | data set | 26 |
| Table 6. | Adverse Events H0649g | 28-30 |
| Table 7. | Comparison of original and final protocol H0648g | 33 |
| Table 8. | Demographics H0648g | 39 |
| Table 9. | - Sites of metastatic Disease H0648g - FDA analysis | 40 |
| Table 10. | Concomitant therapy by study arm H0648g | 45 |
| Table 11. | Cumulative dose for anthracyclines and | |
| | paclitaxel H0648g | 45 |
| Table 12. | Patients who stopped therapy prior to completing | |
| | 6 cycles of chemotherapy H0648g | 46 |
| Table 13. | Patients who completed chemotherapy and | |
| | then stopped Herceptin H0648g | 46 |
| Table 14. | Reasons for stopping therapy H0648g | 47 |
| Table 15. | Time to Progression - Sponsor derived data set | |
| | H0648g | 49 |
| Table 16. | Time to Progression - FDA derived data set | |
| | H0648g | 49 |
| Table 17. | Response rate and duration of response - Sponsor | |
| | derived data set H0648g | 54 |
| Table 18. | Response rate and duration of response - FDA | |
| | derived data set H0648g | 54 |
| Table 19. | Time to Treatment Failure - Sponsor derived | |
| | data set H0648g | 55 |
| Table 20. | Survival H0648g | 55 |
| Table 21. | Responding patients relative to IHC score of | |
| | protein over-expression | 60 |
| Table 22. | Proportion of patients who had tumor response: | |
| | 2+ vs 3+ | 60 |

Clinical Review

. ...

| Table 23. | Adverse events H0648g - Listing as percent of | |
|-----------|---|-------|
| | those enrolled and treated | 61-62 |
| Table 24. | Adverse events H0648g - Listing by number of | |
| | moderate and severe events | 63-64 |
| Table 25. | Selected toxicity events - FDA derived data | |
| | set H0648g | 65 |
| Table 26. | Profile/demographics of patients who developed | |
| | cardiotoxicity H0648g | 68 |
| Table 27. | Incidence of cardiotoxicity class I-IV by | |
| | cumulative dose range H0648g | 70 |
| Table 28. | Incidence of cardiotoxicity class III-IV by | |
| | cumulative dose range H0648g | 70 |
| Table 29. | Percent of patients testing 2+ or 3+ by IHC | |
| | H0648g and H0649g | 73 |
| Table 30. | Response rate by IHC score H0648g and H0649g | 74 |
| Table 31. | Median time to progression of 2+ vs 3+ patients | |
| | enrolled on H0648g | 74 |
| Table 32. | Efficacy results for all Herceptin studies | |
| | submitted to the BLA | 78 |
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