

ID-1

[FEMARA[®]]
letrozole tablets

Oncologic Drugs Advisory Committee Meeting

**Bethesda, Maryland
December 13, 2000**

 **NOVARTIS**

ID-2

[FEMARA[®]]
letrozole tablets

Introduction

**Mathias Hukkelhoven, PhD
Vice President
Head, US Drug Regulatory Affairs
Novartis Pharmaceuticals Corporation**

 **NOVARTIS**

ID-3

Proposed Indication

Femara® (letrozole tablets) 2.5 mg is indicated as first-line hormonal therapy in postmenopausal women with advanced breast cancer.

 **NOVARTIS**

ID-4

Femara® Current Profile

- **Femara is a nonsteroidal aromatase inhibitor, blocking estrogen biosynthesis**
- **Approved as second-line breast cancer therapy since 1996 in over 75 countries worldwide (US = 1997)**
- **“Treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy”**

 **NOVARTIS**

ID-5

Post-Marketing Experience

- **More than 175,000 women worldwide have received Femara since market introduction**
 - **Few reported serious adverse events**
- **Well-tolerated**

 **NOVARTIS**

ID-6

Femara[®] Phase III Studies

Study 025

- **Pivotal study**
- **First-line therapy**

Study 024

- **Supportive study**
- **Preoperative setting**

 **NOVARTIS**

ID-7

Regulatory History

- **Agreements with FDA on June 17, 1997**
 - TTP as a primary endpoint
 - Single trial acceptable for registration



ID-8

New Clinical Profile

Data derived from the largest double-blind phase III randomized study in advanced breast cancer support the following clinical profile

- **Femara® at 2.5 mg once daily is more effective than tamoxifen in TTP, overall tumor response, clinical benefit, and TTF**
- **Femara is safe and well tolerated**
- **Femara is a potential new standard of care in first-line therapy of breast cancer**



ID-9

Agenda

Introduction Mathias Hukkelhoven, PhD
Current Clinical Practices Harold A. Harvey, MD
Pharmacology of Letrozole Ajay S. Bhatnagar, PhD
Clinical Data Margaret Dugan, MD
Questions and Answers



ID-10

Clinical Experts and Consultants

Principal Investigators

Study 025 Henning Mouridsen, MD
Study 024 Matthew Ellis, MB, PhD

Consultants

Statistics Lloyd Fisher, PhD

Independent DMC

Chairman Thomas Fleming, PhD

