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Oncologic Drugs Advisory Committee Meeting Bethesda, Maryland December 13, 2000

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Introduction

Mathias Hukkelhoven, PhD

Vice President

Head, US Drug Regulatory Affairs

Novartis Pharmaceuticals Corporation

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Proposed Indication

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

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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"

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Post-Marketing Experience

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

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Femara® Phase III Studies

Study 025

- Pivotal study
- First-line therapy

Study 024

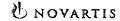
- Supportive study
- Preoperative setting

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Regulatory History

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



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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

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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

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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

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