

Presentation Outline

TREAT

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Introduction

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Global Regulatory Affairs & Safety, Amgen Inc

Clinical Perspective

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Professor of Medicine, Associate Dean, Director,
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Benefit/Risk

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Global Development, Amgen Inc

Risk Management

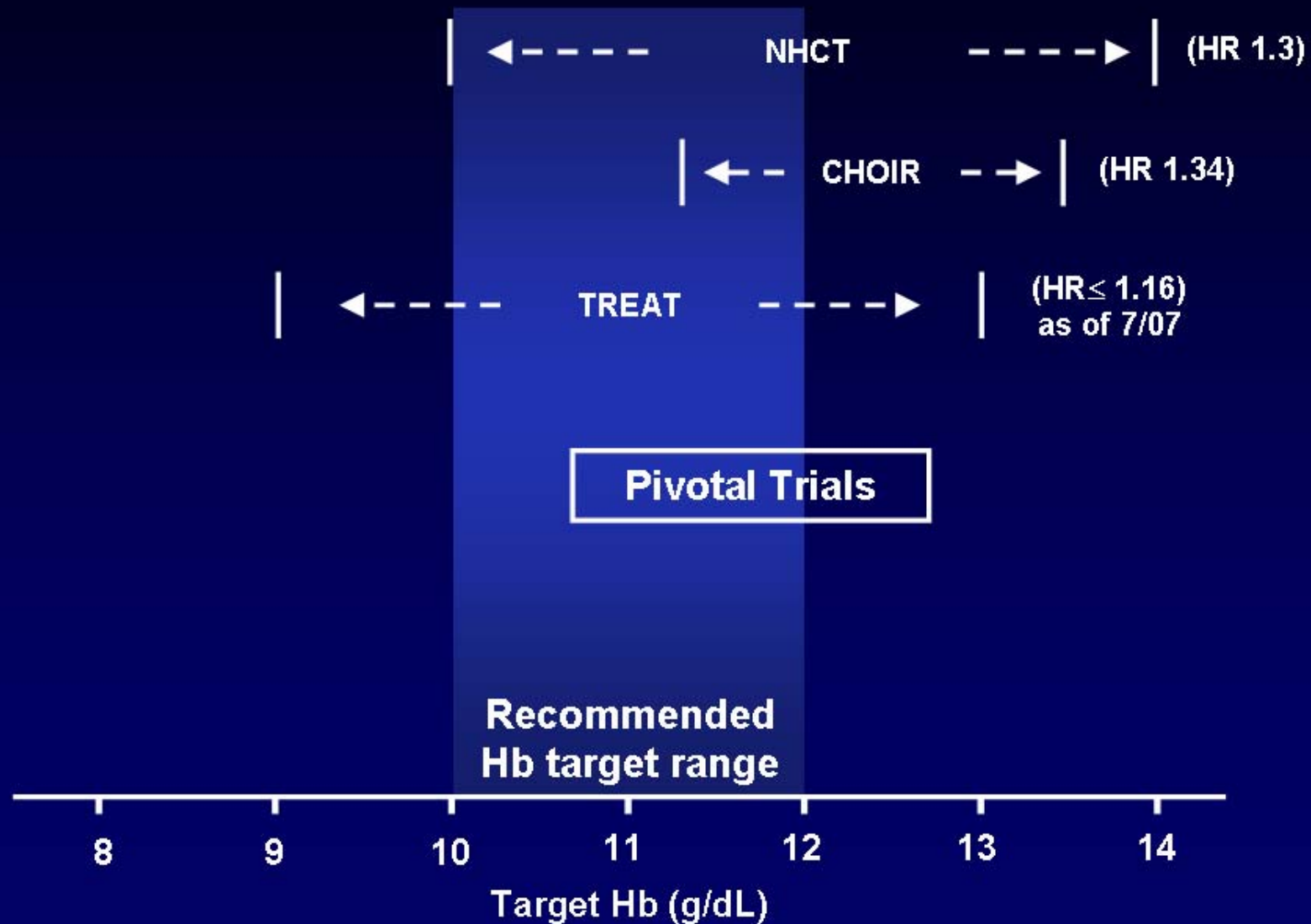
Paul Eisenberg, MD, MPH, FACC

Global Regulatory Affairs & Safety, Amgen Inc

Key Points

- **ESAs provide clear clinical benefits in CRF patients**
 - Transfusion avoidance
 - Improvements in anemia symptoms, physical function, and exercise capacity
- **Different risks are associated with targeting vs achieving specific Hb levels**
 - **Targeting** higher Hb (>13 g/dL) appears to confer risk
 - Patients who **achieve** Hb level >11 g/dL have less risk, however, this observation is complicated by factors such as underlying health status
 - Relationship of dose to risk is confounded
- **Rapid rise or decline in Hb (cycling) should be minimized**
- **Target Hb range of 10-12 g/dL is recommended as a prudent approach to risk management**
 - Managing risk through an achieved Hb ceiling of 12 g/dL is not consistent with results of RCTs

Summary Benefit and Risk of ESAs in Nephrology as Defined in RCTs



Sponsors Are Committed to Additional Risk Management on Key Issues

- **Hb target**
- **ESA responsiveness**
- **Hb cycling**