

FDA Introductory Remarks

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FDA Summary Presentation

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Purpose of today's meeting

How did we get to this point?

Key regulatory interactions

Studies 301 and 302 – Design

The “futility” declaration

Studies 301 and 302 – Results

Understanding Study 301 and 302

Study 103 – Design

Study 103 – Results

Summary of efficacy

Substantial evidence of effectiveness



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