



*Results from EnteregTM Phase 3
Clinical Study 14CL308*

January 13, 2004





Forward-Looking Statements

This oral presentation and the questions and answers that follow contain forward-looking statements including but not limited to the following:

- Our plans to submit Entereg™ clinical studies 302, 306, 308 and 313 in an NDA
- Our NDA submission target date for Entereg™ late in the first half of 2004
- Our anticipated timing of completion and results of other clinical trials
- Our product development efforts
- Anticipated trial results and regulatory filing dates for our product candidates
- Analysis and interpretation of data by regulatory authorities
- Anticipated efforts of our collaborators
- Our estimates of market opportunity and commercial plans for Entereg™

Our forward-looking statements are subject to risks and uncertainties, known and unknown, that could cause actual results and developments to differ materially from those expressed or implied in such statements. You should review Adolor's SEC filings for further information about these and other relevant risks and uncertainties, available in its EDGAR database at <http://www.sec.gov> and from Adolor. Given the uncertainties affecting pharmaceutical companies in the development stage, you are cautioned not to place undue reliance on any such forward-looking statements, any of which may turn out to be wrong due to inaccurate assumptions, unknown risks, uncertainties or other factors. Adolor undertakes no obligation to publicly update or revise the statements made herein or the risk factors that may relate thereto.

Entereg™ for the Management of Postoperative Ileus



POI Phase 3 Program Summary

Study (Enrolled) (N= 2,146)	Primary Objective	Population (% MITT)
302 (N=451)	Efficacy	Large Bowel Resection (70%) Radical Hysterectomy (7%) Simple Hysterectomy (23%)
313 (N=510)	Efficacy	Bowel Resection (96%) Radical Hysterectomy (4%)
306 (N=519)	Safety	Simple Hysterectomy (100%)
308 (N=666)	Efficacy	Large/Small Bowel Resection (68%) Radical Hysterectomy (17.4%) Simple Hysterectomy (14.6%)



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Study Design

- Double-blind, placebo-controlled, randomized, multi-center
- Male or Female 18 years or older
- 666 subjects enrolled across 3 treatment groups
(Entereg™ 6 or 12 mg, or placebo)
- Large or Small Bowel Resection or Simple or Radical
Hysterectomy

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Study Design

- Subjects were to receive their first dose at least two hours prior to surgery, and then twice a day until Hospital Discharge or up to 7 days post-surgery
- Subjects were scheduled for postoperative pain management with intravenous Patient Controlled Analgesia with opioids
- Nasogastric tube to be removed at the end of surgery or by Postoperative Day 1 morning

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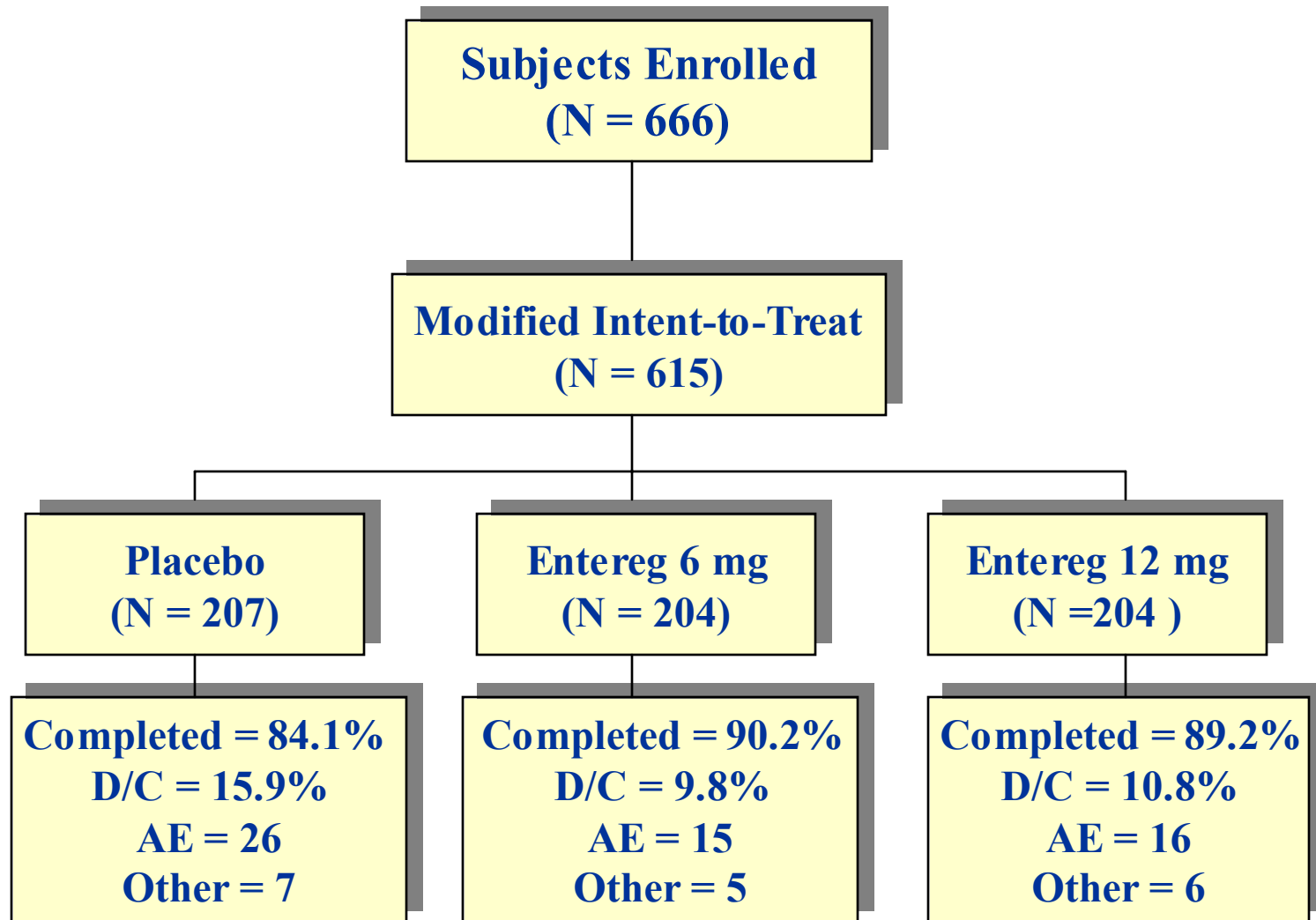
- **Primary Efficacy Endpoint**

- Time to recovery of gastrointestinal (G.I.) function (composite endpoint is upper AND lower G.I. recovery)
 - Time to upper G.I. Recovery: tolerating solid foods
 - Time to lower G.I. Recovery: flatus or bowel movement

- **Secondary Efficacy Endpoints**

1. Proportion of Responders
2. Time to be Ready for Discharge based solely on Recovery of G.I. Function
3. Time to First Flatus
4. Time to First Bowel Movement
5. Time to First Solid Food
6. Time to Hospital Discharge Order Written
7. Time to Tolerating Solid Food and First Bowel Movement

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Overall Demographics – MITT Population

	Placebo (N=207)	6 mg (N=204)	12 mg (N=204)	Overall (N=615)
Mean Age	56	56	58	57
Female (%)	65.7	61.8	64.2	63.9
Caucasian (%)	74.9	74.5	78.9	76.1



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Time to Recovery of GI Function – Primary Endpoint

6 mg dose vs. placebo

- Hazard ratio = 1.20 (P= 0.079)
- Approximately 8 hours earlier average time to recovery of GI function

12 mg dose vs. placebo

- Hazard ratio = 1.24 (P=0.038)¹
- Approximately 10 hours earlier average time to recovery of GI function

¹ Due to the multiple dose comparison to a single placebo group, a p-value less than 0.025 would be required to be considered statistically significant

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Time to Hospital Discharge Order Written

6 mg dose vs. placebo

- Hazard ratio = 1.31 (P < 0.01)
- Approximately 14 hours earlier average time to hospital discharge order written

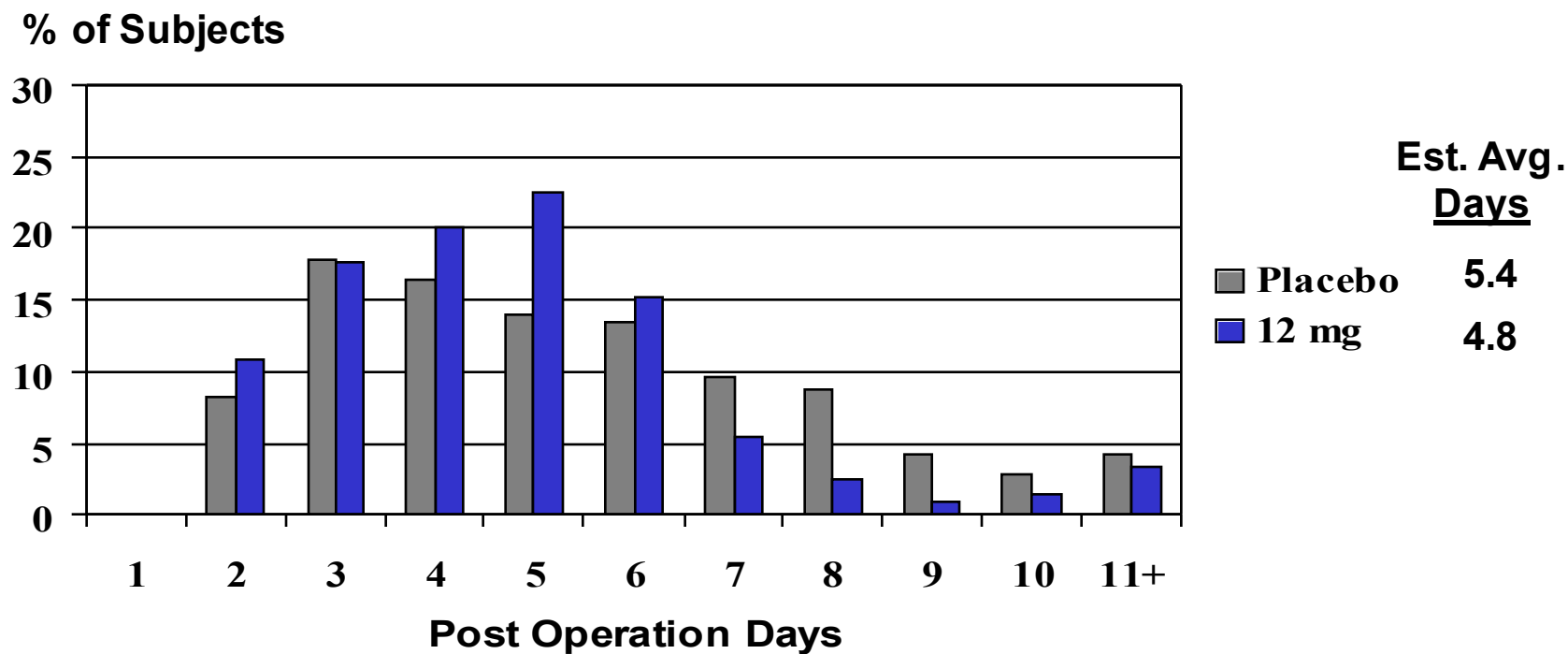
12 mg dose vs. placebo

- Hazard ratio = 1.28 (P < 0.05)
- Approximately 15 hours earlier average time to hospital discharge order written

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Additional Analysis: Hospital Discharge Order Written by Postoperative Day



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Study Endpoints

Time to:	MITT Population (12 mg dose)		
	HR	P-Value	Mean Diff (Hrs) ¹
Discharge Order	1.28	< 0.05	15.2
Ready for Discharge	1.29	< 0.05	11.8
First BM	1.49	< 0.01	16.1
First Solids	1. 19	NS	7.7
First Flatus	1.09	NS	4.1
Solids In, Solids Out	1.33	< 0.05	13.8
GI Recovery	1.24	NS	9.9

% Responders	Placebo	59.9 %
	12 mg	69.9 %

NS = not statistically significant
¹ As compared to placebo

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- Entereg™ was generally well tolerated
- Most frequent adverse events were :

Safety Population

	<u>Placebo</u>	<u>6 mg</u>	<u>12 mg</u>
	(N = 224)	(N = 220)	(N = 221)
Nausea	54.0%	47.7%	50.2%
Vomiting	25.0%	20.0%	20.8%
Pruritus	14.3%	10.5%	12.2%

Discontinuations for adverse events:

MITT	11.6%	6.8%	7.2%
<u>Other</u>	<u>1.3%</u>	<u>0.9%</u>	<u>0.5%</u>
Total	12.9%	7.7%	7.7 %

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Time to Recovery of GI Function – Primary Endpoint

Study	6 mg P-value	12 mg P-value
14CL302	<0.01	0.059
14CL313	<0.05	<0.01
14CL308	0.079	0.038

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Time to Discharge Order Written – Secondary Endpoint

Study	6 mg Mean Diff (hrs) ¹	12 mg Mean Diff (hrs) ¹
14CL302	14.1	7.5
14CL313	13.4	19.5
14CL308	14.3	15.2

¹ As compared to placebo

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Bowel Resection Patients

Study 308 and 313 Comparison (12mg dose)

Time to:	308 Bowel Resection Subgroup			313 MITT		
	HR	P-Value	Mean Diff (hours) ¹	HR	P-Value	Mean Diff (hours) ¹
Discharge Order	1.56	< 0.01	21.3	1.42	< 0.01	19.5
Ready for D/C	1.42	< 0.01	15.9	1.54	< 0.01	21.4
First BM	1.54	< 0.01	17.2	1.48	< 0.01	17.4
First Solids	1.29	NS	11.0	1.48	< 0.01	21.7
First Flatus	1.21	NS	6.8	1.29	NS	10.6
Solids In/Out	1.37	< 0.05	14.0	1.67	< 0.01	27.9
GI Recovery	1.32	NS	12.4	1.54	< 0.01	22.0

NS = not statistically significant

¹ As compared to placebo

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Treatment Emergent AE - Nausea

Study	Placebo	6 mg	12 mg
14CL302	67%	64%	57%
14CL313	64%	61%	55%
14CL308	54%	48%	50%

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Treatment Emergent AE - Vomiting

Study	Placebo	6 mg	12 mg
14CL302	32%	25%	15%
14CL313	26%	24%	20%
14CL308	25%	20%	21%

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Subjects Re-hospitalized Post Discharge (within 10-day Follow-up Period)

Study	Placebo	6 mg	12 mg
14CL302	8.5%	5.3%	2.7%
14CL313	7.9%	4.1%	4.0%
14CL308	6.7%	4.5%	4.5%

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NGT Insertion Post Surgery (MITT)

Study	Placebo	6 mg	12 mg
14CL302	6.9%	2.1%	7.2%
14CL313	14.8%	8.4%	4.8%
14CL308	8.2%	5.9%	5.9%



Entereg™ for the Management of Postoperative Ileus -- Phase 3 Program

Summary: Studies 14CL302, 14CL308, and 14CL313

- Compared to the placebo group:
 - Entereg™ achieved either a statistically significant difference or a positive trend in the primary endpoint, Time to GI Recovery, in all three studies for both the 6mg and 12mg doses compared to placebo
 - Entereg™ achieved either a statistically significant difference or a positive trend in the secondary endpoint, Hospital Discharge Order Written, in studies for both the 6mg and 12mg doses
- Entereg™ was generally well tolerated in 3 studies
- NDA submission targeted for late first half 2004

