

Budesonide

EU Phase III preliminary results

November 8, 2010



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Budesonide MMX®: Basis

- **Chemical entity budesonide**

- A non-halogenated glucocorticoid
- Greater topical anti-inflammatory activity with less systemic absorption than other glucocorticoids due to high first pass metabolism

- **Indication**

- Patients with Ulcerative Colitis of mild to moderate severity.

- **Design of Trials**

- Efficacy and safety of new oral Budesonide MMX® 9mg and 6mg, multicenter, randomized, double-blind, double-dummy comparative study versus placebo, with an additional reference arm evaluating Asacol® 2400 mg (in the USA) or 3 Entocort® EC 3 mg capsules (in EU).
- 2 X 440 patients; eligibility based on UCDAI 4-10. Remission set as UCDAI ≤ 1
 - Stool frequency score: 0
 - Rectal bleeding score: 0
 - Mucosal appearance score: 0
 - Physician rating score: max 1
- For USA only: Extension study on first 100-150 patients that go into remission (only has exploratory purposes for FDA)

Budesonide phase III clinical trials: end points

- **Primary end point**
 - Superiority versus placebo in attaining clinical remission (UCDAI ≤ 1) after 8 weeks treatment
- **Secondary end points**
 - Clinical improvement
 - Endoscopic improvement
- **Other end points**
 - Symptom resolution
 - Histologic healing
- **Safety set**
 - Adverse events
 - Vital signs
 - Clinical laboratory test results
 - Physical examination findings
 - Potential glucocorticoid effects

Preliminary Results of EU Phase III study

Efficacy: primary end point attained

Treatment arm	Number of patients ITT	Patients in remission	P-value
Budesonide MMX 9 mg	109	19 (17.4%)	0.0047*
Budesonide MMX 6 mg	109	9 (8.3%)	0.2876
Entocort EC 3 x 3 mg ^(a)	103	13 (12.6%)	0.0481**
Placebo	89	4 (4.5%)	

Treatment arm	Number of patients PP	Patients in remission	P-value
Budesonide MMX 9 mg	84	19 (22.6%)	0.0047*
Budesonide MMX 6 mg	73	8 (11.0%)	0.2922
Entocort EC 3 x 3 mg ^(a)	72	12 (16.7%)	0.0483**
Placebo	67	4 (6.0%)	

*Statistically significant vs placebo at 0.025

** Statistically significant vs placebo at 0.05

^(a)Not powered to show statistical difference between MMX arms and Entocort

Preliminary Results of EU Phase III study sensitivity analysis

Treatment arm	Number of patients	Patients in remission	P-value
Budesonide MMX 9 mg	127	19 (15.0%)	0.0022*
Budesonide MMX 6 mg	128	9 (7.0%)	0.2588
Entocort EC 3 x 3 mg ^(a)	126	13 (10.3%)	0.0429**
Placebo	130	5 (3.1%)	

* Statistically significant vs placebo at 0.025

** Statistically significant vs placebo at 0.05

^(a) Not powered to show statistical difference between MMX arms and Entocort EC

Preliminary Results of EU Phase III study Treatment – Emergent Adverse Events (TEAEs)

Treatment arm	TEAEs	Related	Mild	Moderate	Severe
Budesonide MMX 9 mg	55.5%	25.8%	21.1%	25.0%	9.4%
Budesonide MMX 6 mg	62.5%	21.9%	28.1%	29.7%	3.9%
Entocort EC 3 x 3 mg	54.8%	23.0%	23.8%	23.0%	7.9%
Placebo	44.2%	24.0%	14.0%	24.8%	3.9%

Preliminary Results of US Phase III study: Efficacy: primary end point attained

Treatment arm	Number of patients ITT	Patients in remission	P-value
Budesonide MMX 9 mg	123	22 (17.9%)	0.0143*
Budesonide MMX 6 mg	121	16 (13.2%)	0.1393
Asacol 2400 mg	124	15 (12.1%)	0.22 ^(a)
Placebo	121	9 (7.4%)	

Treatment arm	Number of patients PP	Patients in remission	P-value
Budesonide MMX 9 mg	69	20 (29.0%)	0.0027*
Budesonide MMX 6 mg	72	11 (15.3%)	0.2110
Asacol 2400 mg	73	10 (13.7%)	0.3144 ^(a)
Placebo	61	9 (8.2%)	

*Statistically significant vs placebo

^(a)Not powered to show statistical difference

Preliminary Results of US Phase III study Treatment – Emergent Adverse Events (TEAEs)

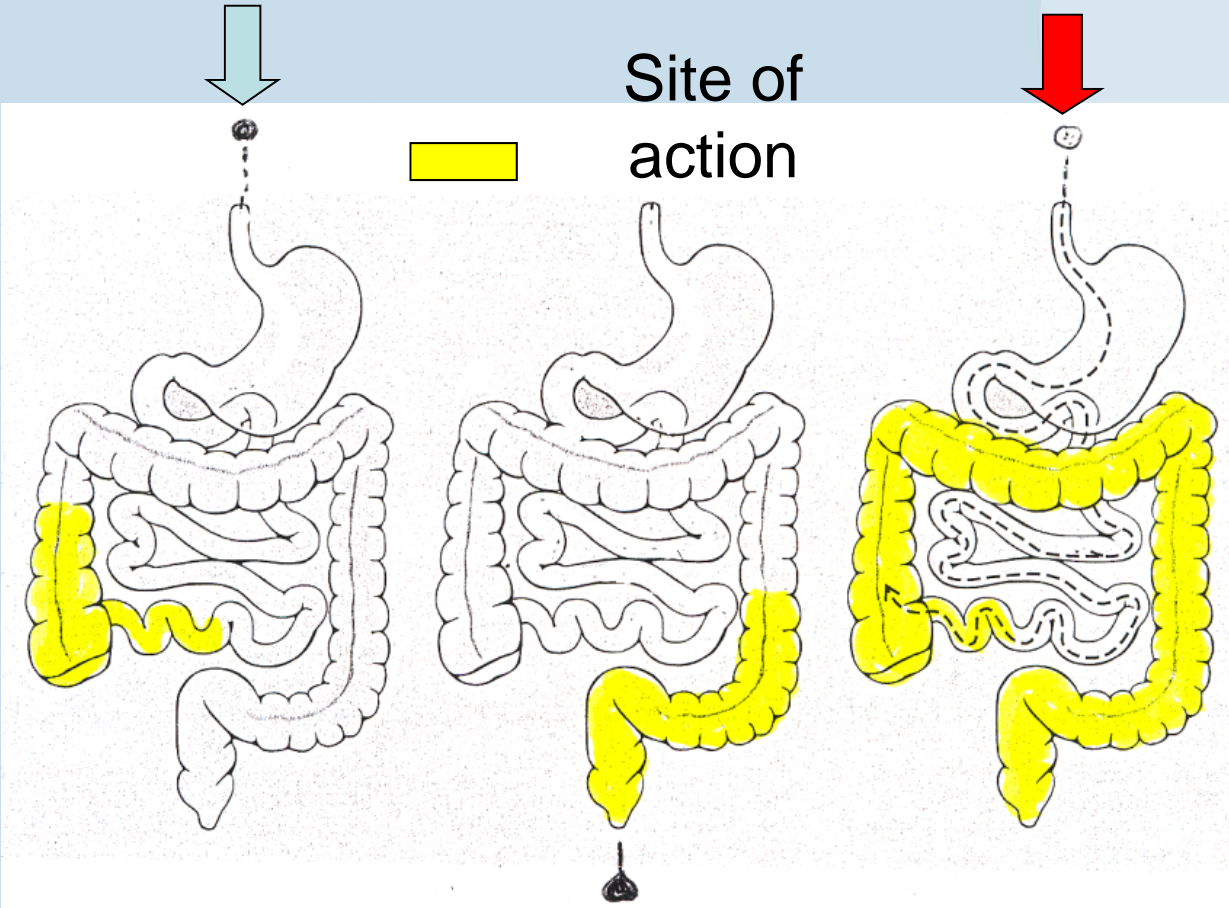
Treatment arm	TEAEs	Related	Mild	Moderate	Severe
Budesonide MMX 9 mg	57.5%	28.3%	23.6%	27.6%	6.3%
Budesonide MMX 6 mg	58.7%	27.8%	26.2%	23.0%	9.5%
Asacol 2400 mg	63.0%	24.4%	30.7%	27.6%	4.7%
Placebo	62.0%	26.4%	24.0%	26.4%	11.6%

Budesonide MMX®: going forward

- **Projected filing**
 - MAA in EU in H1 2011; NDA for USA H2 2011
- **Market entry**
 - A year later
- **Market**
 - In USA there is no steroid approved for mild to moderate UC
 - 2009 Entocort sales at \$ 237 m equal to Lialda® for a patient base 2/3 that of Lialda®
- **Projected peak sales**
 - USA \$150-250 million
 - targeted at the ~30% of patients that do not react to 5 ASA's
 - After assessing safety data the entire 5 ASA market could be targeted
 - RoW EUR 100 million
- **Licensing revenue**
 - USA: licensed to Santarus; 12-14% royalties; plus ~10% COGS for US
 - RoW: 25-33% total return
 - Japan: unpartnered

IBD medications: sites of action

MMX™ tablets vs. other dosage forms

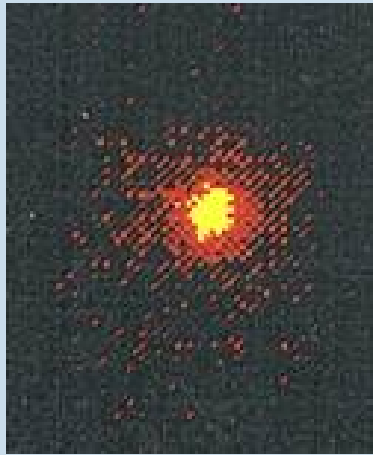


Oral dosage forms

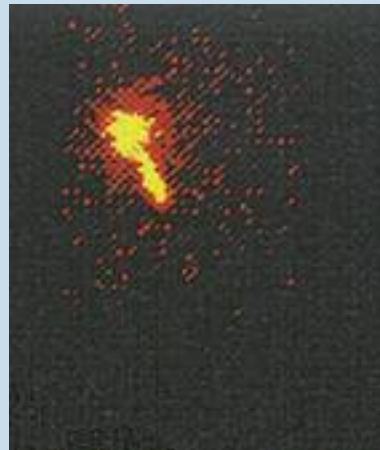
↑
enemas

MMX™
tablets

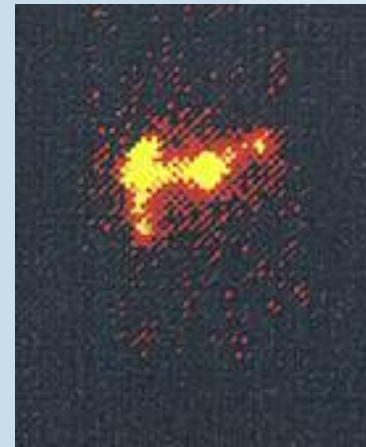
MMX: Proving extended release and persistence of radioactive traces released by MMX in gut



1h 30' duodenum



4h 30' ascending colon



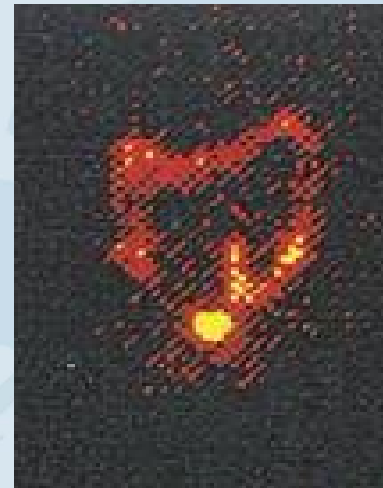
7h 30' transverse colon



10h transverse colon



16h descending colon



24h rectum

Outlook for 2010: Recurring Revenue growth, continued profitability, pipeline expansion

- Revenues projected at around € 30.5 million (+10%)
 - Analysts project Lialda® sales to increase to \$ 323 m ie by 36%. Royalties and manufacturing income are expected to increase accordingly.
 - Contract Drug Manufacturing revenue should increase by > 10%
 - License fees of \$ 3 million for Budesonide included
- Stable COGS ratio
- Positive EBITDA, PAT and no cash consumption
- Cash position maintained; no external financing required

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