

Vontobel

Swiss Health Care Tour

Basel

November 8, 2010



Safe harbor

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Breaking news: success in EU Phase III study (1)

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	103	13 (12.7%)	0.0481 ^(a)
Placebo	89	4 (4.5%)	*Statistically significant vs placebo ^(a) Not powered to show stat. difference

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	72	12 (16.7%)	0.0483 ^(a)
Placebo	67	4 (5.9%)	*Statistically significant vs placebo ^(a) Not powered to show stat. difference

Treatment arm	Adverse events	mild	moderate	severe
Budesonide MMX 9 mg	55.5%	21.1%	25.0%	9.4%
Budesonide MMX 6 mg	62.5%	28.1%	29.7%	3.9%
Entocort	54.8%	23.8%	23.0%	7.9%
Placebo	44.2%	14.0%	24.8%	3.9%

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.

- **Trial design**

- 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 Entocort® EC 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
- Extension study on first 100-150 patients that go into remission (only has exploratory purposes for FDA)

Budesonide MMX®: going forward

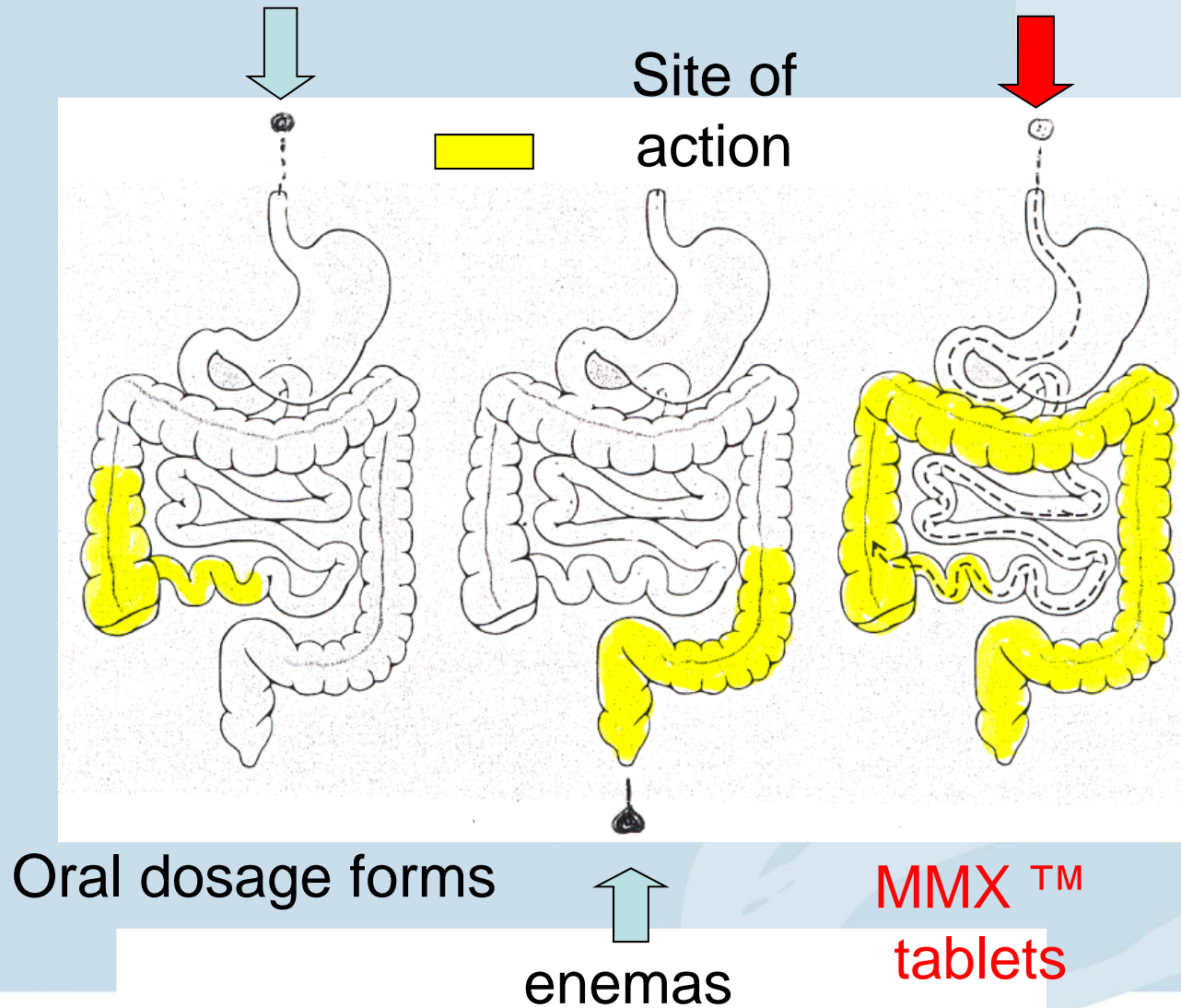
- **Projected filing**
 - EU H1 2011; USA H2 2011
- **Market entry**
 - A year later
- **Market**
 - In USA there is no steroid approved for mild to moderate UC
 - 2009 Entocort sales at \$ 237 m equal to Lialda® for a patient base 2/3 that of Lialda®
- **Projected peak sales**
 - USA \$150-250 million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

The Cosmo approach

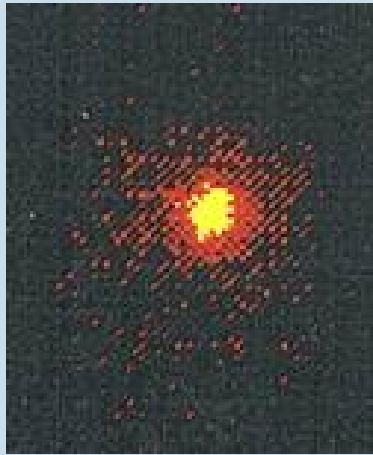
- **Use skills in complex manufacturing as starting point and USP**
 - Find applications for MMX technology
 - Focus on complex applications and new generics against total cost coverage and profit share
- **Focus on growth markets with little big pharma competition**
 - The IBD market is growing at >12% p.a.
 - Skin is an area of enormous interest to consumers but no new products
- **Product development strategy focused on improvements and re-indications**
 - Develop one new product per year
 - Far lower costs per project
 - Much higher success rates than with NCEs
- **Be entrepreneurial**
 - Cosmo has made a profit every year since the IPO
 - We seek to test proof of concept before incurring high cost
 - CEO and 44% shareholder has total compensation of EUR 220'000

IBD medications: sites of action

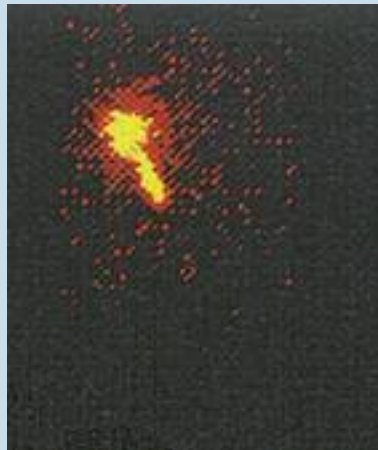
MMX™ tablets vs. other dosage forms



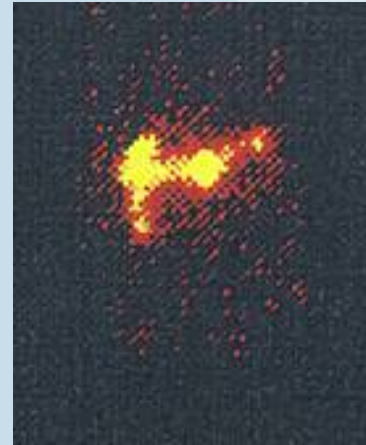
MMX: Proving extended release and persistence of radioactive traces released by MMX in gut



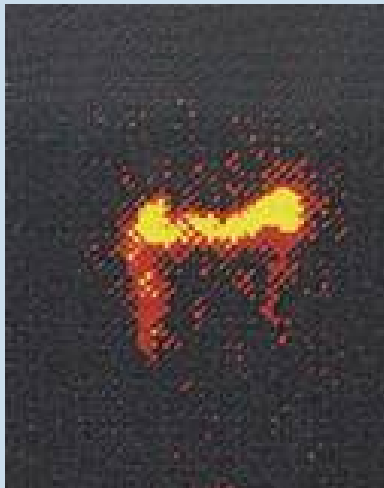
1h 30' duodenum



4h 30' ascending colon



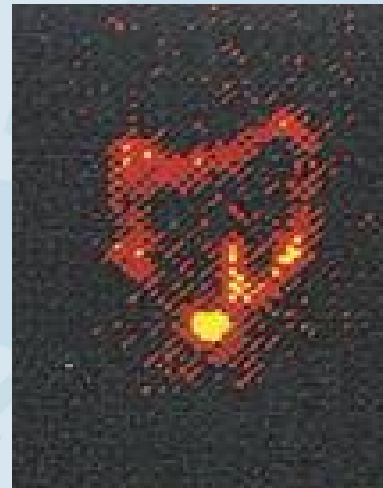
7h 30' transverse colon



10h transverse colon



16h descending colon



24h rectum

Cosmo's pipeline

Product and Indication	Drug type	Phase I	Phase II	Phase III	MA	Launch	Partner
Lialda ®/ Mezavant ®/Mesavancol® Mild to moderate Ulcerative Colitis	5-ASA				USA UK ITA		Shire/Giuliani
Zacol NMX® Intestinal Disorders (nutraceutical)	Dietary supplement				ITA	3 EASTERN EUROPEAN COUNTRIES	Dr. Falk
Budesonide MMX® Mild to moderate Ulcerative Colitis	Cortico-steroid					EU H1/12 USA H2/12	Ferring – Worldwide (excluding Japan & USA) Santarus - USA
Rifaximin SV MMX® Travellers' Diarrhoea - Clostridium Dificile	Antibiotic			H1/11 EU H2/11 USA			Dr. Falk – Europe & Australia (excluding Italy) Santarus - USA
			Dose ranging Q4/11				
LMW Heparin MMX® - Induction of remission in M2M UC - Maintenance treatment for UC of all severities	Biologic			H2/12 EU			
			H2/12				
CB-03-01 (NCE) Acne	Steroid ester, androgen antagonist						
CB-03-01 (NCE) Alopecia	Steroid ester, androgen antagonist						
CB-01-16 Opioid Induced Constipation	Opioids Antagonist		Q2/11				

The first product: Lialda®

- The Chemical entity mesalamine is an off-patent 5-ASA (amino salicylic acid)
- Indicated for Patients with Ulcerative Colitis of mild to moderate severity
- Market entry in March 2007. Analysts projections for 2010: \$ 323 m (Europe will come on-stream)
- Cosmo product pre tax income is projected to rise from ~ € 15 m to ~ € 27 m p.a. until end 2014 assuming 100% production:
 - From 2016 on they are projected to stabilize above € 13 m
 - Total development cost for Cosmo was € 1 m
- Competing products in 2009 were Asacol \$ 684 m; Pentasa \$236 m; Canasa \$ 95 m all with increased sales but decreasing TRX
 - Zydus filed ANDA for 1200 mg Mesalamine tablets in May 2010; Shire has filed law suit for patent infringement

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High galenic skills are crucial for future success

- To date FDA had required that generics need to prove bioequivalence for IBD drugs by conducting clinical trials
- New ruling by FDA to determine bioequivalence requirement of
 - in vitro dissolution tests and
 - comparative pharmacokinetic safety studies
- It is felt that clinical trials are more expensive but easier to conduct than in vitro tests
 - Demonstrating identical dissolution to our extended release MMX technology will be very challenging
- **Moving forward it will be increasingly important to have high galenic skills in developing products & life extensions of patents**

Rifamycin SV MMX®

- **Chemical entity rifamycin SV**
 - Off-patent, broad-spectrum antibiotic belonging to the ansamycin family, practically not absorbed when taken as a tablet
- **Market need**
 - Need for a non-absorbable antibiotic that does not sterilize bacteria in upper gut
 - Does not promote bacterial resistance
- **Competing products**
 - Xifaxan \$ 110 m in USA projected to grow to >\$ 2 billion including various other indications
 - Ciprofloxacin € 331 m
- **Partnerings**
 - In USA and EU
 - Not partnered in Latin America, Asia nor Africa

Rifamycin SV MMX®: Status and opportunities

• Status

- Positioned as new chemical entity in the USA
- Patient recruiting for phase III trials in the US ongoing and in the EU starting
 - Primary clinical endpoint: time to last unformed stool
 - EU trial is a single phase III trial on around 700 patients 400 mg b.i.d. X 72 hours non inferiority vs Ciprofloxacin 500 mg b.i.d
 - US trials are two consecutive phase III studies on 300 patients each 400 mg b.i.d. X 72 hours superiority vs. placebo

• Opportunities

- Highly effective against Clostridium Dificile Assoc Disease (CDAD)
- Probably very effective against Hepatic Encephalopathy
- Due to its anti-inflammatory properties, Rifamycin SV MMX®
 - Could also be used for IBD supportive therapies
 - Could be the drug of choice for the treatment of Diverticulitis, a chronic disease that affects more than 60% of people over the age of 60

LMW Heparin MMX®

- **Completed phase IIb clinical trials; demonstrated that LMW Heparin MMX®, when associated to 5-ASAs**
 - Endogenous substance: has no side effects
 - Stops bleeding and is substantially more effective than 5-ASAs
- **Presented LMW Heparin MMX® at DDW 2009 in Chicago**
 - Wide range of immunomodulating activity inhibiting pro inflammatory cytokines, Interferon γ , IL2, TNF α
- **Possible target indication expanded to maintenance of remission for UC patients of all severity**
- **FDA meeting for phase III preparation**
 - LMW Heparin presently not approved in the USA, i.e. it is a new chemical entity
 - Full preclinical tests required including carcinogenicity tests
- **EU partnering discussions and discussions for phase III trial design planned in Q4 2010**

CB-01-16: opioid antagonist MMX

- **Chemical entity:** *Naloxone*
- **Mechanism of action**
 - Naloxone is a powerful, off patent, opioid antagonist that displaces opioids from the cell receptor
- **MMX application**
 - MMX technology brings Naloxone to the colon only where it displaces the opioid from the MU receptor thus freeing peristaltic movements
- **Market size**
 - In the US there are 12 m persons that are chronic opioid users and more than 4.5 m persons that suffer from chronic opioid induced constipation
- **Status**
 - Phase I with dose escalation to start in Q1 2011
- **Market need; competition**
 - Currently no tablet is approved for use
 - NKTR 119 uses Naloxol and delivers this through pegylation technology. Was licensed to AZ. Is in phase II

The GI business plan: rapid change to high operating margins

GI in EUR m	2010 e	2011 proj	2012 proj	2013 proj	2014 proj	2015 proj
Revenues	30.0	44.1	48.7	100.8	118.5	150.1
Pre 2010 product revenues	28.1	30.9	38.8	47.7	40.5	32.1
COGS pre 2010 products	13.5	13.6	13.7	13.9	14.0	14.1
Net new product income	0	0	4.6	21.4	60.7	106.1
Milestones on new products	2.3	13.1	3.8	26.9	7.7	0
New product R&D	0.5	4.5	7.8	18.3	19.0	0
Net new generics income	0.1	0.1	1.5	4.9	9.6	12.0
SG&A	5.9	6.0	6.1	7.0	8.0	8.1
Continuing R&D	2.5	3.3	3.4	3.5	3.5	3.6
Pre tax operating income	8.1	16.7	17.6	58.2	73.9	124.3
Operating margin	27%	38%	36%	58%	62%	83%

CB-03-01: Anti-androgen for topical applications

- **Chemical name**

- *Cortexolone 17a-propionate*

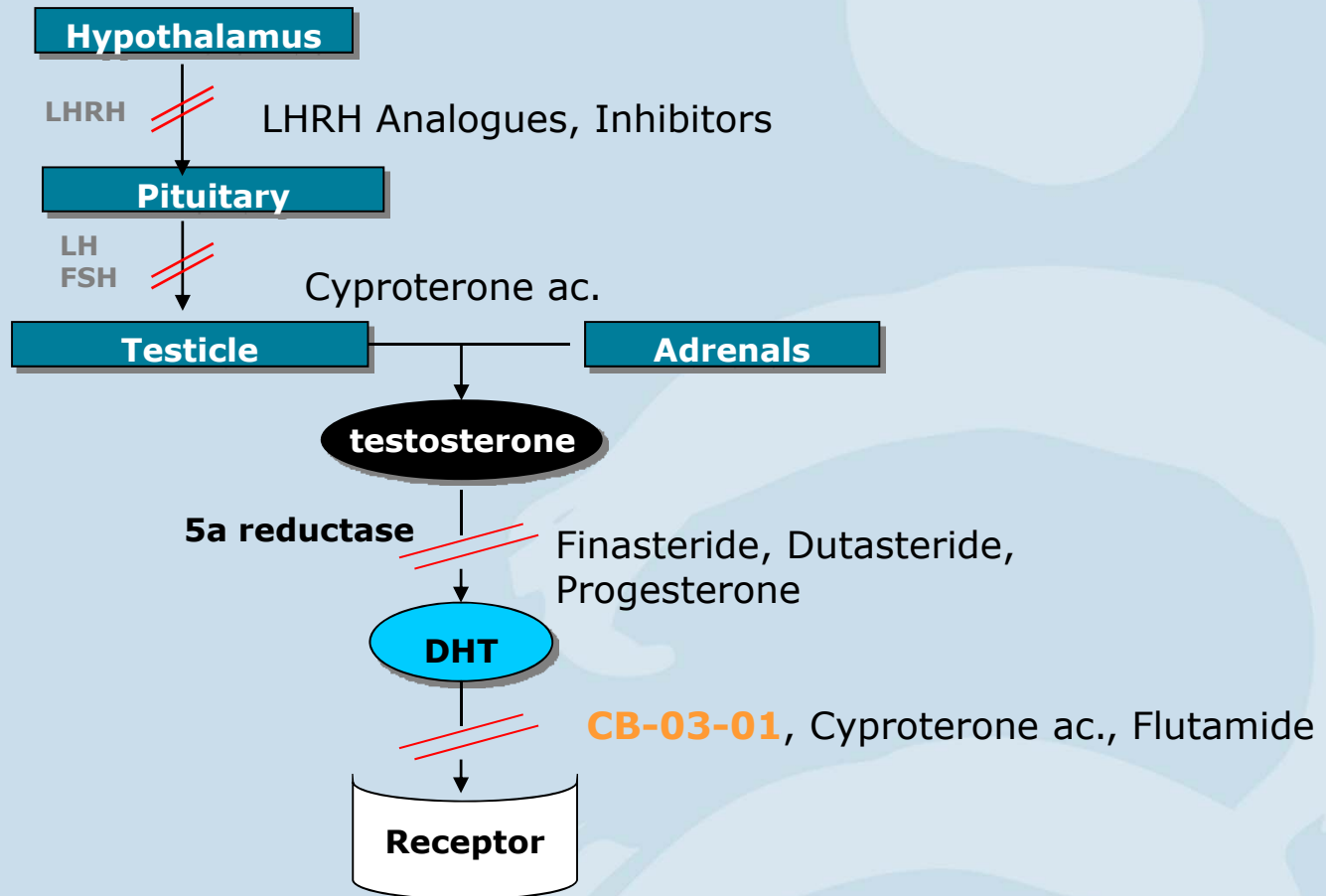
- **Therapeutic Area** *Antiandrogenic (ATC D11 AX)*

- New Chemical Entity (NCE) with antiandrogen properties, under development for topical treatment
- Anti-androgen without systemic effects
- Acts at the level on the skin androgen receptor only; blocking the binding or displacing of androgen hormones to the sebaceous gland and to the hair follicle; has moderate anti inflammatory activity similar to hydrocortisone

- **Medical need**

- A treatment for acne, seborrhea, alopecia and hirsutism that is effective by topical application
- A topical treatment that provides a reliable alternative to retinoids (poorly tolerated and presence of side-effects) and antibiotics/anti-infectives
- Is not a skin irritant
- Does not cause hormonal imbalance

Endocrine control of androgen-dependent organs, and mechanism of action

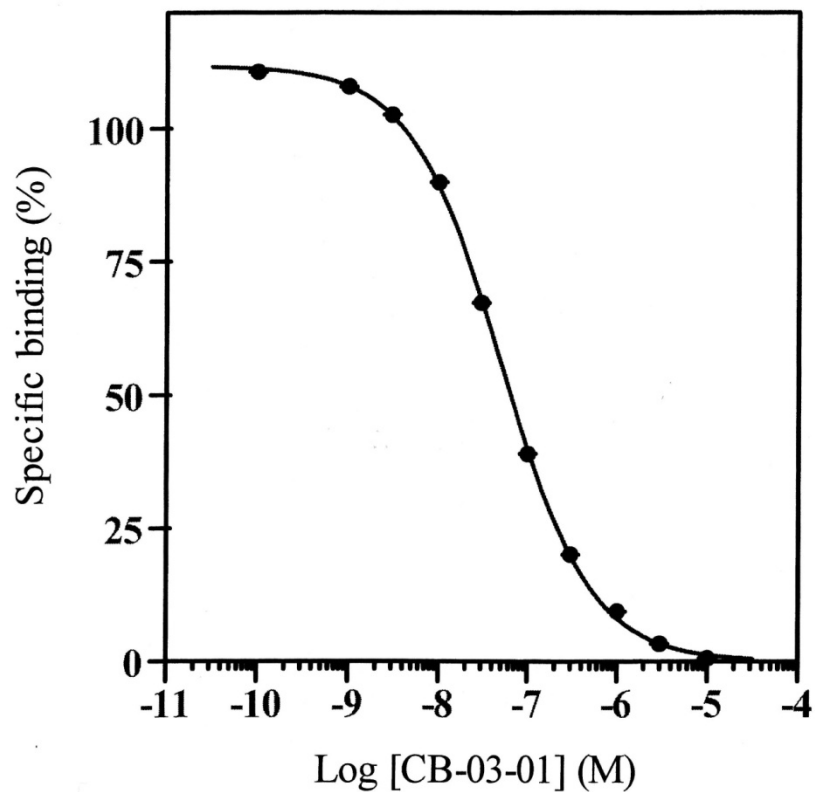


CB-03-01

Human androgen receptor binding

Competitive curve at the LNCaP human androgen receptor

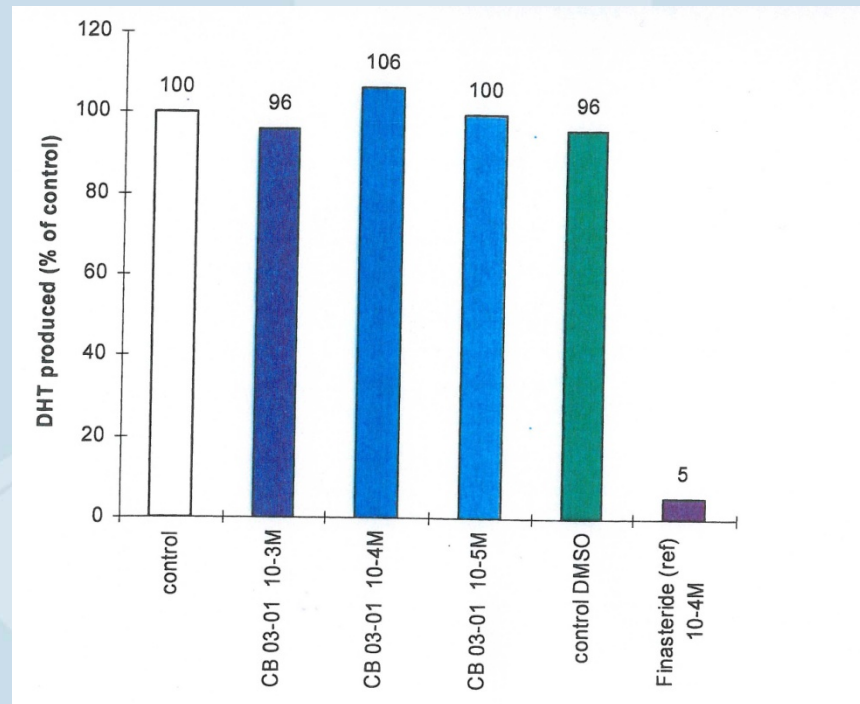
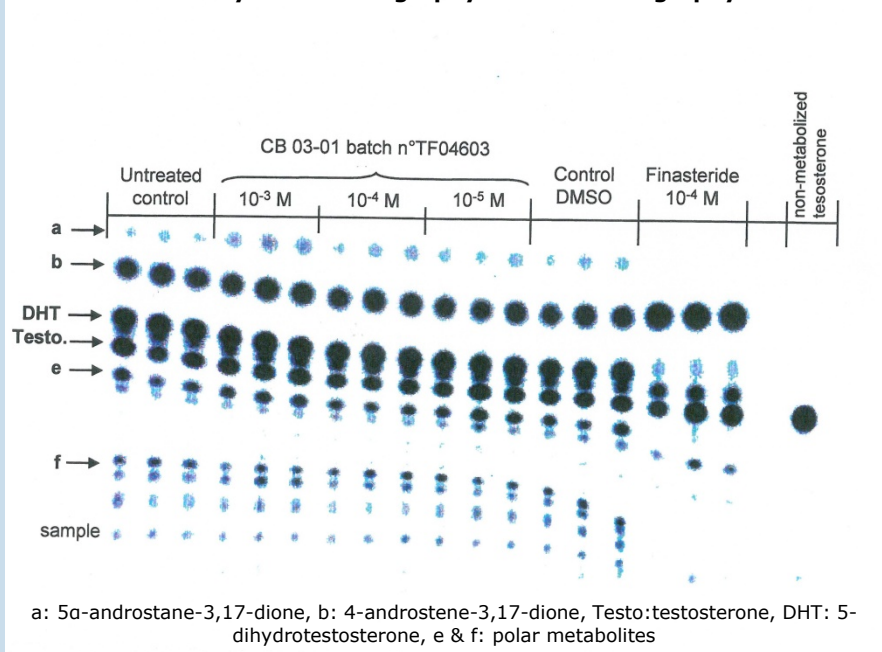
IC50 = 5.0E-08 M
nH = 0.9



CB-03-01

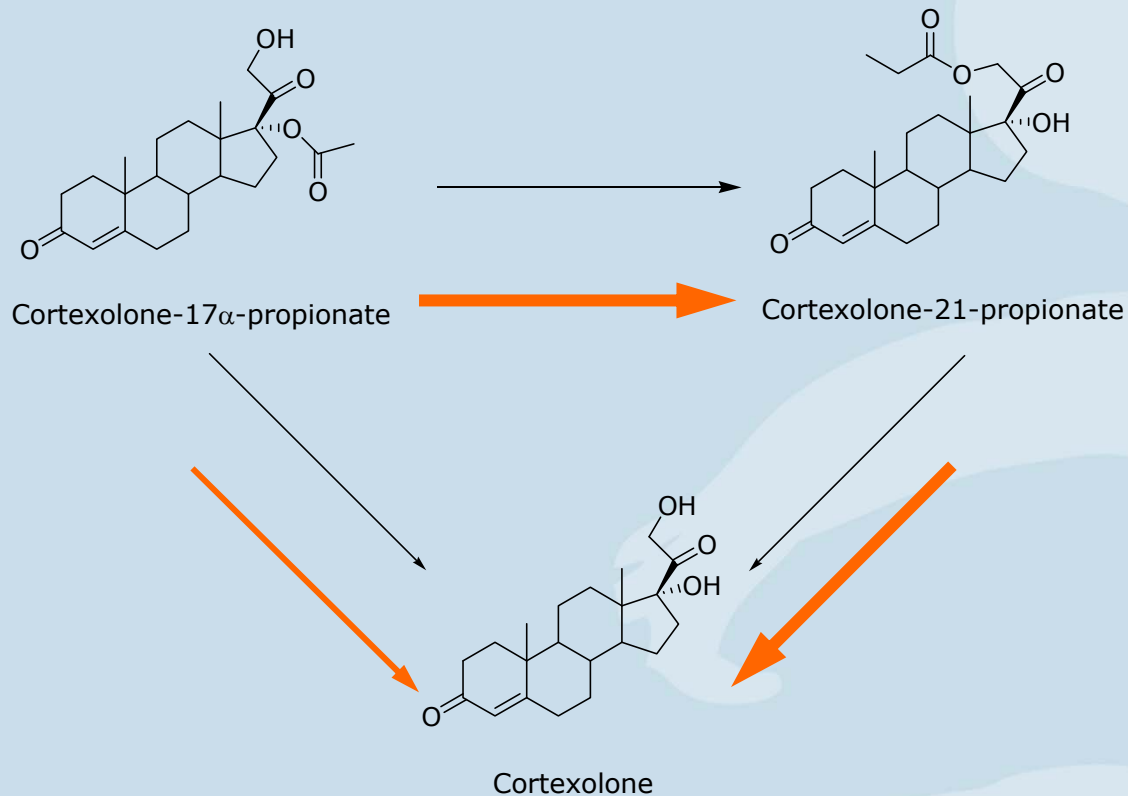
Effect on testosterone metabolism in human skin

[¹⁴C]-testosterone and metabolites after transepidermal diffusion (24h)
Thin layer chromatography and autoradiography



Unlike finasteride, CB-03-01 does not inhibit skin 5 α -reductase, and does not influence skin metabolism of testosterone to DHT

CB-03-01: a very simple and linear metabolic pathway



- The final compound is cortisolone, whose safety profile is well known
- The aim is to achieve high local activity together with systemic safety thanks to the in vivo hydrolysis pattern

CB-03-01 1% cream

Phase II Acne Study Clinical Results - Summary

Efficacy of CB-03-01 1% cream in acne vulgaris

Parameter	Placebo cream (n=14)	Retin-A 0.05% cream (n=30)	CB-03-01 1% cream (n=28)
Total Lesion Count (TLC)			
- % reduction vs. baseline, at weeks 8	37.1	52.5	65.7 ^(a)
- median time (days) to reach improvement 50%	58	57	43
Inflammatory Lesion Count (ILC)			
- % reduction vs. baseline, at weeks 8	38.9	50.7	67.2 ^(b)
- median time (days) to reach improvement 50%	58	44	36
Acne Severity Index (ASI)			
- % reduction vs. baseline, at weeks 8	39.5	53.0	68.3 ^(c)
- median time (days) to reach improvement 50%	57	44	42
Investigator Global Assessment (IGA)			
- % of success at weeks 8	7.1	11.5	22.2

^(a) statistically significant vs. Placebo (<0.001) and vs. comparator (<0.05)

^(b) statistically significant vs. Placebo (<0.05)

^(c) statistically significant vs. Placebo (<0.01)

CB-03-01 in Androgenetic Alopecia (AGA) AN OVERVIEW FROM AN AMBULATORY EXPERIENCE (I)

RESULTS OF CLINICAL DATA:

Parameter	CB-03-01 1%			CB-03-01 5%			Cyproterone ac. 1%			17 α -estradiol 1%		
	Basal	T1	T2	Basal	T1	T2	Basal	T1	T2	Basal	T1	T2
Hair diameter (mm)	0.41	0.73	0.88	0.66	0.74	0.91	0.51	0.61	0.74	0.53	0.65	0.73
Pull test (score)	3	1	1	3	1	1	3	2	2	3	1	1
Wash test (hairs n°)	181	123	64	193	117	65	178	132	72	196	136	71
Follicular density (n° / cm ²)	71	89	109	73	88	111	70	82	96	74	84	98
Sebometric evaluation (qualitative)	high	medium	low	high	medium	low	high	medium	low	high	high	high
Subjects improved (%)	---	76	85	---	79	85	---	59	66	---	61	69

T1= one week after treatment completion; T2= four weeks after treatment completion

OVERALL:

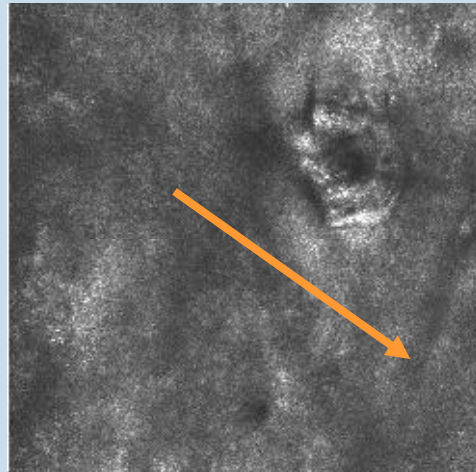
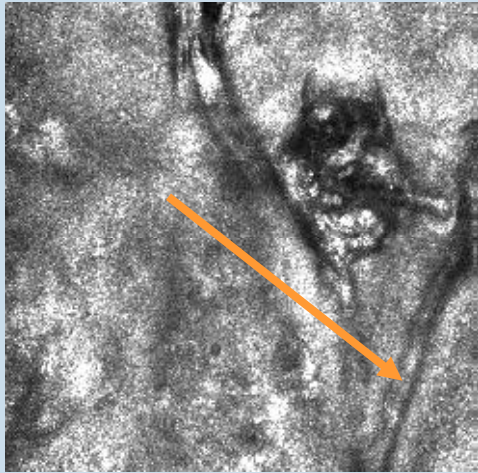
CB-03-01 at both concentrations 1% and 5% consistently increased hair diameter, follicular density and overall improvement more than Cyproterone acetate 1% and 17 α -estradiol 1%

CB-03-01 was also more active than comparators in improving pull test, wash test and sebometric evaluation

No evident difference of activity detected between the two concentrations of CB-03-01

No local or systemic effects were reported following the administration of the tested items

CB-03-01 in Androgenetic Alopecia (AGA) AN OVERVIEW FROM AN AMBULATORY EXPERIENCE (II)



Reduction of vessel diameter of peribulbar capillaries and a decrease of the number of inflammatory cells was noted after treatment with CB-03-01



- From left to right:
- reduction of dimension of sebaceous gland
 - improvement of the follicular units inside the ostium (5 hair follicles)
 - reduction of inflammatory and fibrotic evidence around the ostium

CB 03-01: Market opportunity in alopecia

Market potential

- It is presumed that around 40% of men between 20 and 65 suffer hair loss and up to 40% of these try to do something about it
 - **Around 20% of these are willing to use drugs ie around 3% of all men**
- Up to 50% of all women after menopause suffer hair loss and up to 60% of these try to do something about it
 - **Around 33% of these are willing to use drugs , ie around 10% of all women >50**

FDA approved drugs

- No topical anti androgen approved
- Propecia; an alpha 5 reductase inhibitor, taken as a tablet, had revenues of \$ 429 m (2008)
- Minoxidil/Regaine/Rogaine are vasodilators and are off patent

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 € 2 million budgeted; no assumptions for CB-03-01 licensing agreement(s)
- Stable COGS ratio
- Positive EBITDA, PAT and no cash consumption
- Cash position maintained; no external financing required

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