

## **Expanding pharma operations**

Goldman Sachs Twenty-Fifth Annual Global Healthcare Conference Laguna Niguel, 8 June, 2004



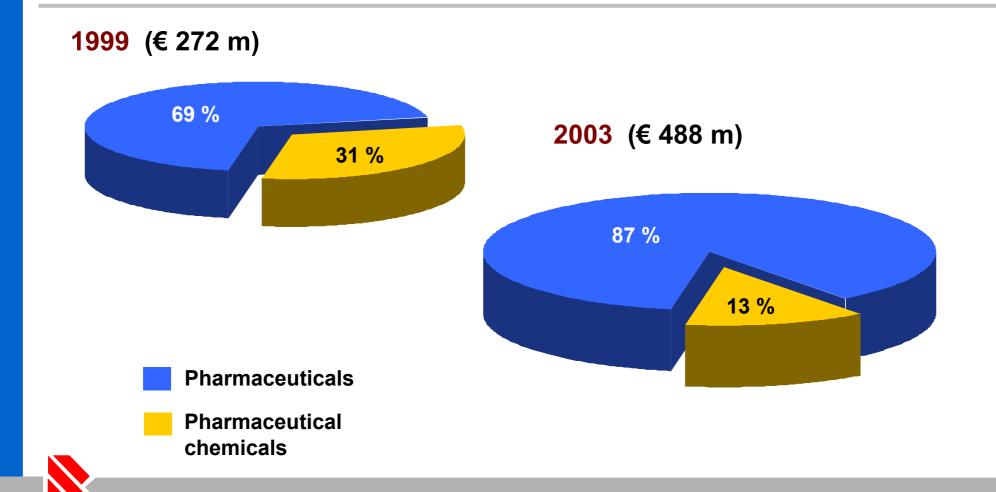
### **Company profile**

- A fully integrated pharmaceutical company listed on the Italian Stock Exchange since 1984
- Original research focused on cardiovascular and urological fields
- Direct operations in Italy, France and Spain covering a broad range of therapeutic areas
- Proprietary products sold worldwide through licensees
- Non-core activity: manufacturing and sales of pharmaceutical API's



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## **Composition of sales**

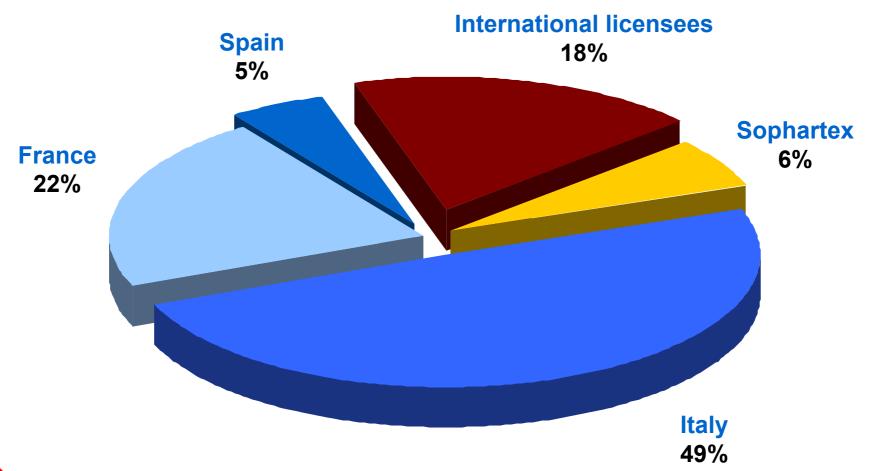


#### **CAGRs from 1999 to 2003**





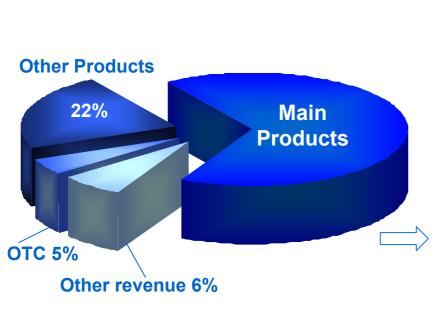
### Breakdown of first quarter 2004 pharmaceutical sales

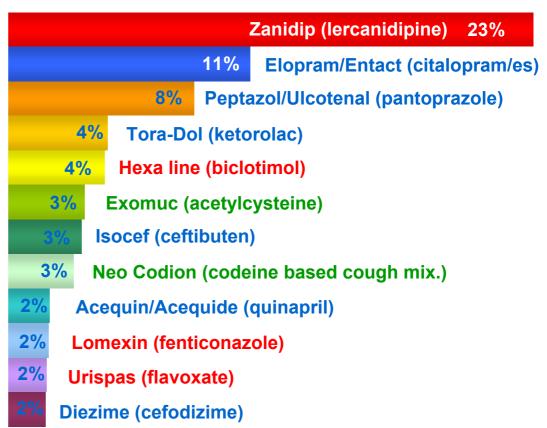




### **Main products**

Breakdown of 12 months pharmaceutical sales at March 2004 (€ 430 m)



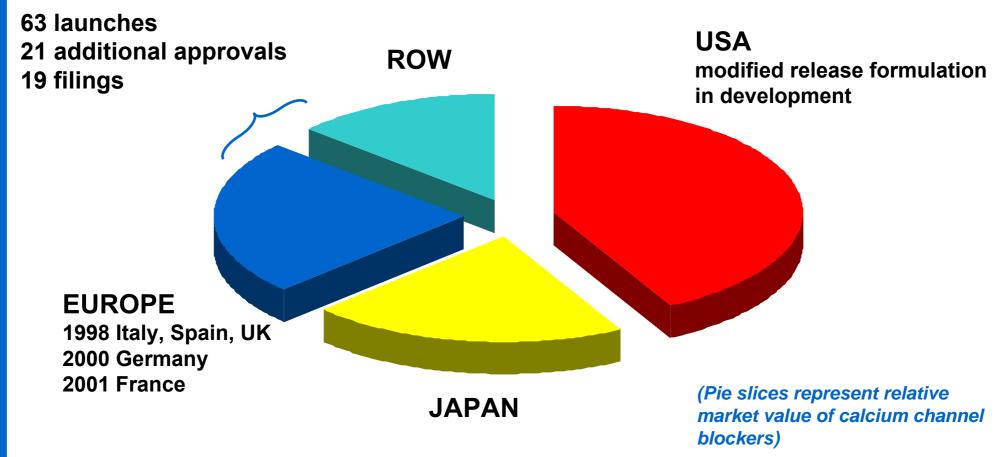




## ZANIDIP® (lercanidipine)

- Next generation calcium-channel blocker and first lipophilic DHP CCB to be filed with the FDA.
- Natural once a day. Potent, long-lasting vasodilatory activity.
   Highly vasoselective with gradual onset, smooth and uniform blood pressure lowering activity.
- Efficacy as best in class. Significantly improved tolerability over other DHP's.
- Hypertension market worth \$35 billion, CCB's about \$10 billion, of which around two thirds in U.S.A. and Japan.
- Leader is Norvasc<sup>®</sup> (amlodipine) with over one third market
   share

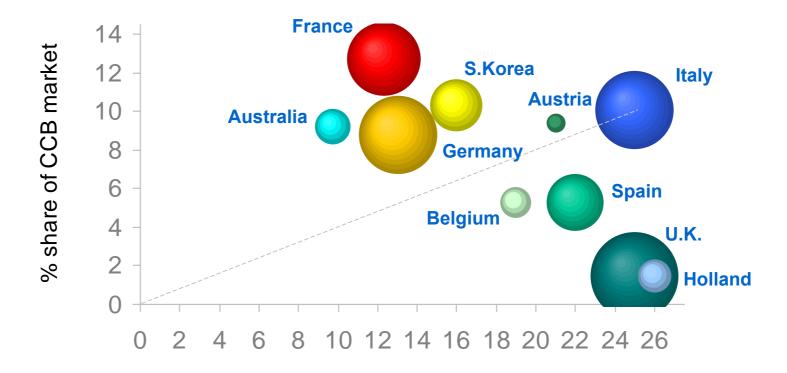
## Lercanidipine – Roll out status and plan





### Lercanidipine as a % of all calcium channel blockers

#### **Bubble size represents \$ market value of CCB's**



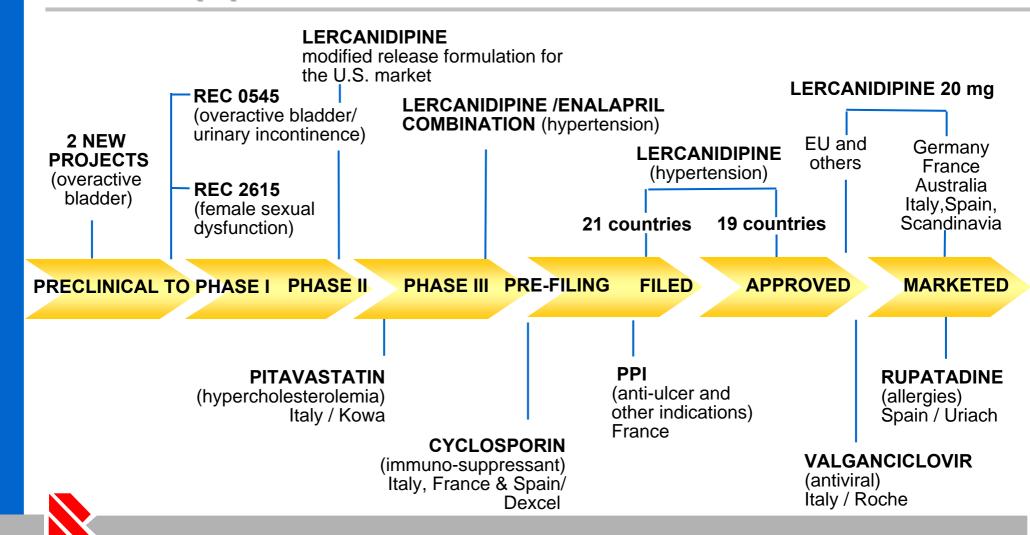
Quarters from launch

Source: IMS data - 1Q 2004



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### **Product pipeline**



## Filling the pipeline: Ongoing R&D - lercanidipine

- 20mg strength approved in Europe and other countries.
   Launched in Germany, France and Australia in 2003, Italy,
   Spain and Scandinavia in 1Q 2004, roll-out continues
- Modified release formulation under development with Forest Labs for the U.S. market
- Agreement with LifeCycle Pharma for the development of a modified release formulation for the European and other markets
- Patent life in extension, two new patent applications published



## Filling the pipeline: Ongoing R&D - lercanidipine

- Lercanidipine-enalapril fixed combination:
  - New aggressive targets for blood pressure control
  - Combination of drugs needed for most patients
  - Patient compliance
  - Fixed combinations will play a significant role in the future hypertension market
  - Phase III nearing completion, filing in EU expected at end 2004



- Micturition disorders affect over 70 million people in the major pharmaceutical markets
- Only 20% are diagnosed and not all receive or are able to tolerate the current pharmacological therapies
- Drug spending for these conditions is still limited
- Anticholinergic agents are the most commonly used drugs for the treatment of urinary incontinence
- They are effective but have many side effects



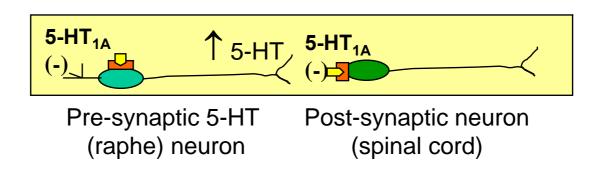
- Recordati has long standing research expertise in the urogenital field
- Research activity has moved towards the study of the central nervous system mechanisms that control the bladder's function
- Potent antagonists of the  $\alpha_1$ -adrenergic receptors, which are highly selective for the lower urogenital tract, were pioneered by Recordati
- A new target for novel drugs was identified, the 5-HT<sub>1A</sub> serotoninergic receptor and leads to other targets are being optimized



- Rec 0545 is an antagonist of the 5-HT<sub>1A</sub> receptor and is currently entering the proof of concept clinical program
- This molecule acts through an innovative mechanism and could present an improved tolerability profile over the anticholinergics
- Sales of drugs for urge incontinence are estimated to reach \$ 1.6 billion in 2008
- Anticholinergics (antimuscarinics) will still be the leading class



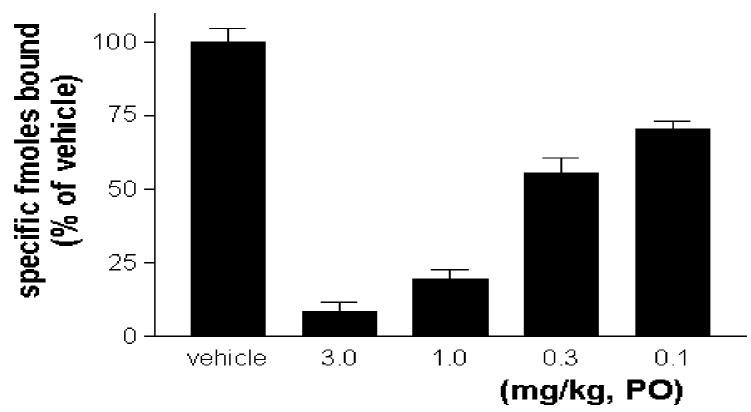
## **Mechanistic Rationale for 5-HT<sub>1A</sub> Antagonists in Inhibiting LUT Function and Treating OAB**



- Somatodendritic (NRM) 5-HT<sub>1A</sub> antagonism increases 5-HT release in the spinal cord
- 5-HT is inhibitory to lower urinary tract function. It inhibits elimination and promotes storage (dampens afferent input and/or descending efferent drive)
- Unlike antimuscarinics, 5-HT<sub>1A</sub> antagonists increase capacity without directly affecting bladder contractility

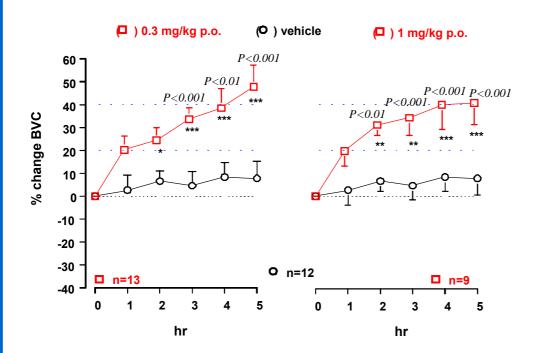


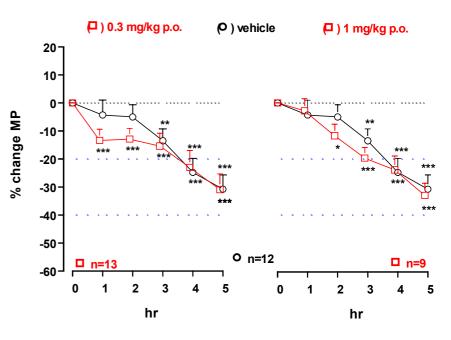
## Rec 0545 Potently Inhibits [3H]OH-DPAT Binding to 5-HT<sub>1A</sub> Receptors in Rat Hippocampus *Ex Vivo*





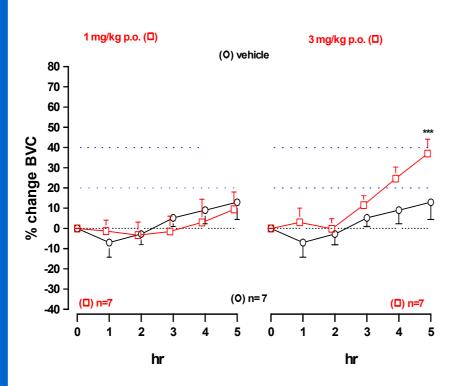
## Rec 0545/2: Cystometry in conscious rats

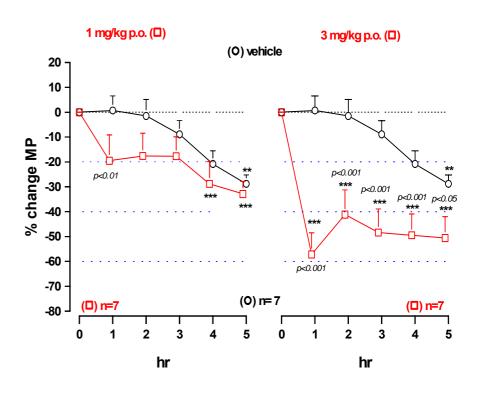






## Oxybutynin: Cystometry in conscious rats







### Summary: Rec 0545

- Rec 0545 is endowed with a potent and selective antagonistic effect at 5-HT<sub>1A</sub> receptor
- Shows remarkable activity in increasing bladder volume capacity (or time between micturitions) without blunting bladder contractility (differently from antimuscarinics)
- A completely new approach for controlling overactive bladder



- Two other potential biological targets for new drugs for the treatment of micturition disorders have been identified and new candidates are being synthesized for further development
- Rec 2615 is another new active compound identified by Recordati. It is in development for the treatment of female sexual dysfunction, and is approaching the clinical phase



## Operational highlights first quarter 2004

- Pharmaceutical sales up 5.8%
- Lercanidipine sales up 36.9%
- Net income up 28.4%
- 20mg strength of lercanidipine launched in a total of nine markets to date
- First steps taken to reorganize the pharmaceutical chemical business, EBIT at break even
- A new project for the development of a modified release version of lercanidipine in place



## Plan 2004 - 2007 Assumptions

- Current geography
- Excluding Sophartex sold in April 2004
- Excluding any sales of lercanidipine in either Japan or the U.S.
- Excluding acquisitions in other EU markets



## Plan 2004 – 2007

(million euro)	2004	2007	CAGR
SALES	475	550	5.0%
EBIT	85	106	7.5%
NET INCOME	50	66	10%



## **Company strategy**

- Confirm commitment to research and development in the urological and cardiovascular fields
- Acquire new product licenses

Expand geographical presence in Europe



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All mentions and descriptions of Recordati products are intended solely as information on the general nature of the company's activities and are not intended to indicate the advisability of administering any product in any particular instance.

Recordati, established in 1926, is a European pharmaceutical group, listed on the Italian Stock Exchange (Reuters RECI.MI, Bloomberg REC IM, ISIN IT 0003074447), dedicated to the research, development, manufacturing and marketing of pharmaceuticals and pharmaceutical chemicals, with headquarters in Milan, Italy and operating subsidiaries in France, Ireland, Portugal, Spain, Switzerland and the United States.

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