

BIO 2009 – International convention

- **Topic** : *India : Insight Into Success Stories of Clinical Research.*
- **Venue** : *Georgia World Congress Center, Atlanta , Georgia, USA (May 18-21 ,2009)*
- *The following slides are an excerpt from the talk delivered by eminent leaders during BIO ATLANTA 2009.*



The Global Event
for Biotechnology

May 16 - 21, 2009, Monday - Thursday
Georgia World Congress Center
Atlanta, GA, USA



Heal, Fuel, Feed
The World.

India: Insight Into Success Stories of Clinical Research

Date: May 19, 2009
Time: 9:00 a.m.
Speaker: Dr. P.K. Tandon
Senior Vice President



Outline

Genzyme Corporation

Genzyme in India

Our Experience in CR in India

Summary

Our Global Corporation

- >11,000 employees worldwide
- Helping patients in 100 countries
- 17 manufacturing sites
- 9 genetic testing lab sites
- 17 major marketed products
- 2008 revenue of \$4.6 billion
- 85 locations in >40 countries
- Henri Termeer: Chairman, CEO



Genzyme in India

- **Compassionate Use products**
- **Commercial Products – Four Products in the Market**
- **Genzyme India Pvt Ltd established in 2008**
 - SAARC regional office
- **Plans**
 - Bring Genzyme portfolio to Indian Stakeholders and Invest in India through:
 - Products
 - Technology
 - Services
 - Knowledge
 - Clinical research/Data Management/Bio-Statistics and IT support
 - Planning to set up a regional hub as a part of Genzyme India

Our Address @Technopolis, Gurgaon

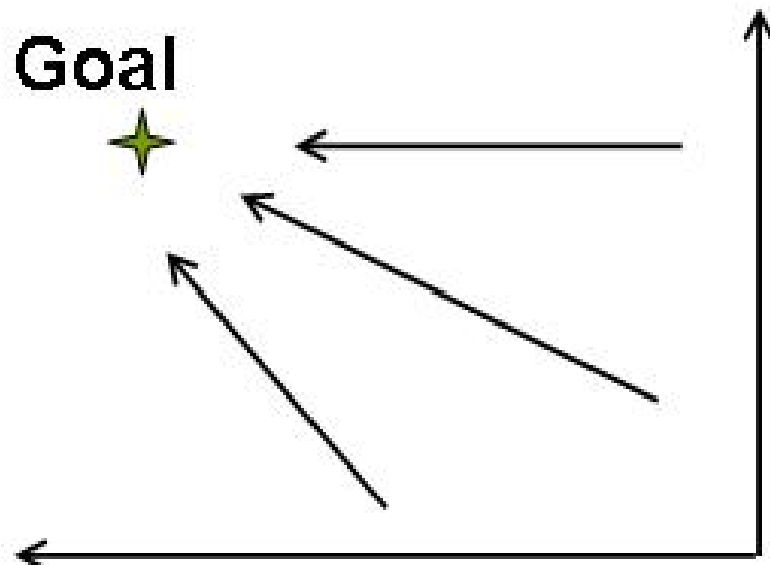


Genzyme India (Pvt) Ltd



Proposed Strategy for India

Value Creation, Value Capture, and Value Delivery



Selected Off-Shoring Activities

- ✓ Clinical Trials
- ✓ Clinical IT
- ✓ Biometrics and Bioinformatics
- ✓ Programming

- ✓ Alliances with Preclinical R&D Companies
- ✓ Clinical R&D
- ✓ Product Registration

Due Diligence (2005 - 2006)

1. **International and Indian CROs involved in clinical development and support.**

- To understand their capabilities and processes.

2. **Leading Private/Public hospitals involved in Clinical Development.**

- To review their infrastructure, experience in conducting multinational clinical trials and medical expertise(s)

3. **Leading IT companies providing clinical IT solutions.**

- To evaluate capabilities of these companies for Data Management, Clinical Data Warehouse, Electronic Data Capture Integrations, CTMS

Proposed Model for India (Short Term)

Genzyme India to be the hub

- Senior staff managing a network of Indian CROs



Genzyme Corporation as the source

- Senior staff providing direction / support for Genzyme India



CROs with major Indian operations

- ✓ Biometrics and Bioinformatics
- ✓ Clinical Trials and Research
- ✓ Clinical IT Solutions

Clinical Development Activities: Clinical Trials

- **First Stand Alone Trial in India**

- ✓ Goal was to start in Q4 2007 to Q1 2008
- ✓ Objective: To determine if Enteric Coated (EC) Sevelamer has an effect on Lipid Profiles in hyper-cholesterolemic patients
- ✓ Target Sample Size = 120 patients
- ✓ Total Duration of the Study = 1 year
- ✓ Control groups = Cholestagel and No-Treatment/Diet

Why Manipal Acunova?

- ✓ Hospital Network: Only CRO with close Co-operation with Largest Private Hospital Network in India
- ✓ Experience: Diverse Experience in Phase I-IV studies
- ✓ Offerings: End to End Service (Trial related services under one roof)
- ✓ Systems: Established SOPs, ICH Guidelines, transparent procedures to map global compliance
- ✓ People: About 15% Human Capital worked in US/EU Pharmaceutical Companies
- ✓ Quality Focus: On time Quality Delivery with Open communication with Sponsors
- ✓ Technology: Validated and accredited Information Security Systems

Background and Rationale

Genzyme Bile Acid Sequestrants

Cholestagel / WelChol

- Marketed in US, out-licensed to Daiichi Sankyo
- Marketing Authorization in EU by Genzyme
- Active comparator for current trial

Renagel (sevelamer hydrochloride)

- Developed and marketed as phosphate binder

Enteric coated sevelamer hydrochloride

- Clinical development to take advantage of known bile acid sequestrant effect
- Enteric coating to potentially enhance efficacy
- New formulation of currently approved product: Renagel

Study Design

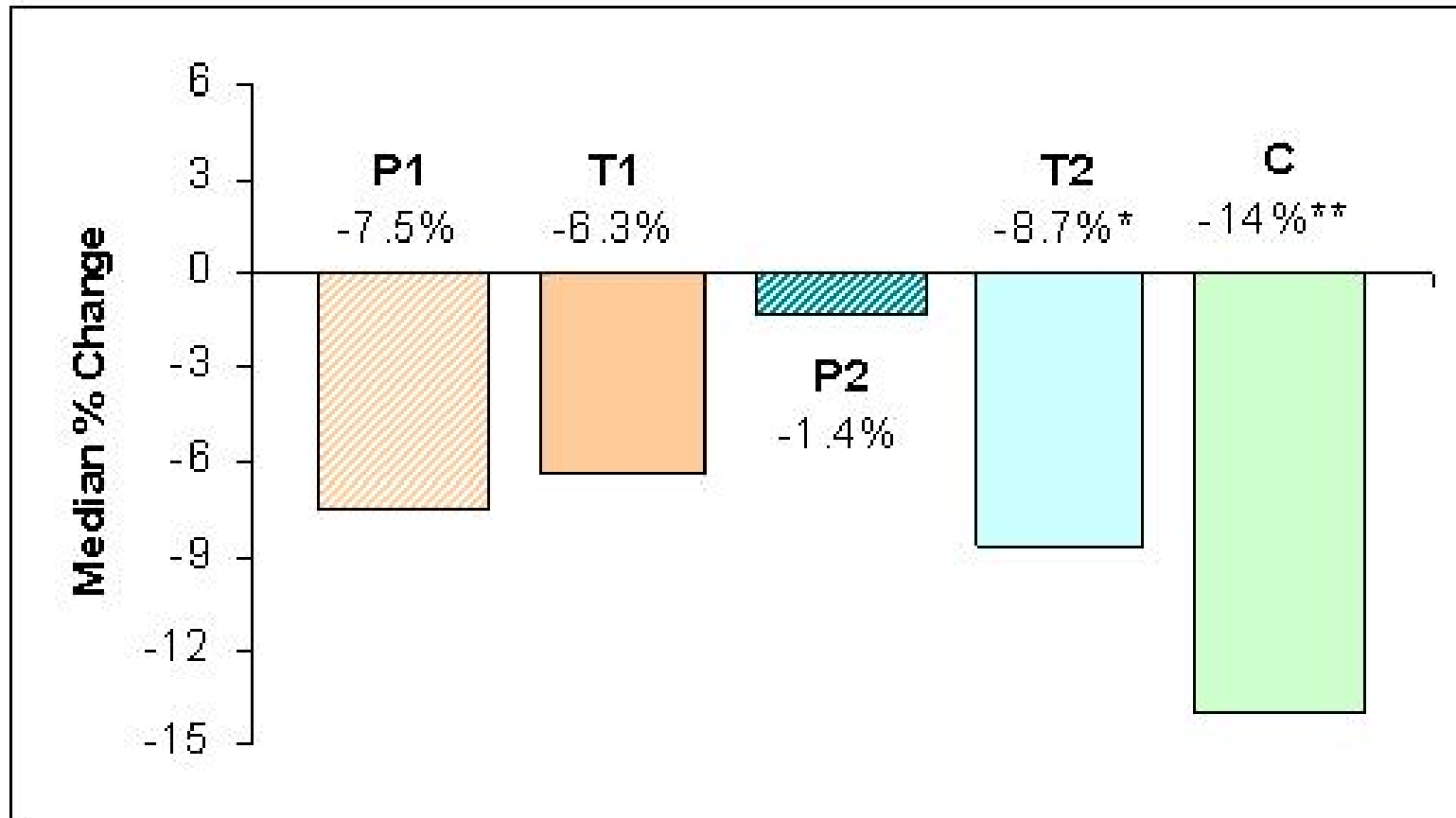
- **Prospective, randomized, single blind, active and placebo-controlled, parallel-group, multi-center study**
- **Investigational Study Treatment**
 - Enteric Coated Sevelamer (ECS) tablets for oral administration (2 dosing regimens)
- **Comparator Study Treatment**
 - Colesevelam (Cholestagel) tablets for oral administration
- **Placebo Study Treatment**
 - Placebo tablets for oral administration
- **Trial Size**
 - 120 patients randomized into 5 groups: 2:1:2:2:1
 - 6-8 sites

Investigators and Study Sites

Site No./Principal Investigators	Study Centers	Enrolled
1. Dr. (Prof) T. V. Devarajan	Apollo First Med Hospital, Chennai	n=20
2. Dr. (Prof) H. B. Chandalia	Diabetes Endocrine Nutrition Management & Research Center, Mumbai	n=19
3. Dr. P. H. Chauhan	P.D. Hinduja Hospital, Mumbai	n=20
4. Dr. Bipin Kumar Sethi	CARE Hospital, Hyderabad	n=19
5. Dr. Subhash Kumar Wangnoo	Indraprastha Apollo, New Delhi	n=10
6. Dr. Mala Dharmalingam	M. S. Ramaiah Hospital, Bangalore	n=14
7. Dr. V. Kumaravel	Associates of Clinical Endocrinology Education & Research, Chennai	n=10
8. Dr. S. R. Aravind	DIACON Hospital, Bangalore	n=8
		n=120

LDL - C

Percentage Change from Baseline at Week 6



Summary

- First Proof of Concept GCP trial in India was successful
- First investigator site was initiated on January 14, 2008 and the final study report received on January 30, 2009 (Total duration of about 1 year)
- Manipal Acunova completed this 120 patient trial within budget and the timelines
- Minimal but constant oversight was needed to maintain the momentum and the timelines
- Infrastructure (Personnel and Genzyme India Office) is in place to expand the clinical development in India