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## Pre-Determination Market Analysis of Gefilucar.

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### ABSTRACT

Pharmaceutical industry nowadays focuses more on branding a product apart from R&D, New chemical entity(NCE).Branding pharmaceutical products plays a key role for the opinion makers, as the constructed brand by the brand manager distinguishes the generic and branded drugs. Defining your brand is like self-discovering your own business. It all depends on how well a company brand their products and reaches the consumers(doctors). This paper is mainly focusing on new product launch of Gefitinib drug used for treating Lung Cancer. 83-88% cases are related to EGFR Mutation Positive treated with Gefitinib. GEFILUCAR is our brand which can withstand the competitors when compared to other brands as per market analysis. Results are discussed on market analysis of new product launch on lung cancer.

**Key words:** Branding, EGFR Mutation Positive, Lung Cancer, NSCLC, SCLC

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## INTRODUCTION

Oncology is among all medical branches because at any given time there are more than 450 active researchers. So things change quite fast, the most dynamic field of medicine is to enter into marketing. On this count it demands more responsibility for a brand manager to be equally dynamic. This paper is mainly focusing on new product launch of Gefitinib drug used for lung cancer. Gefilucar is the brand which is going to be launched as it is the most happening segment in Oncology.

The main objectives for the study before launching any new product into the market, they need to consider as follows:

- Pre-launch analysis
- Branding
- Packaging and development
- SWOT analysis
- Product launching planning
- Promotional input strategies
- Post marketing activities.

Cancer is a term used for diseases in which abnormal cells divide without control and are able to invade other tissues. Cancer cells can spread to other parts of the body through the blood and lymph systems. Some cancers do not form tumors. For example, leukemia is a cancer of the bone marrow and blood. Not all tumors are cancerous. Tumors can be classified as Benign and Malignant.

### **Benign tumors**

They are not cancerous. They can often be removed and in most cases, they do not spread to other parts of the body.

### **Malignant tumors**

They are cancerous. Cells in these tumors can invade nearby tissues and spread to other parts of the body. The spread of cancer from one part of the body to another is called metastasis.

Lung cancer is a disease characterized by uncontrolled cell growth in tissues of the lung. If left untreated, this growth can spread beyond the lung in a process called metastasis into nearby tissue and eventually into other parts of the body. Most cancers that start in lung, known as primary lung cancers, are carcinomas that derive from epithelial cells. The main types of lung cancer are small cell lung carcinoma (SCLC) also called "Oat Cell Cancer" and non-small cell lung carcinoma (NSCLC). The most common cause of lung cancer is long-term exposure to Tobacco Smoke [1]. Nonsmokers account for 15% of lung cancer cases, and these cases are often attributed to a combination of genetic factors, radon gas, asbestos and air pollution including secondhand smoke.

## Drug Profile

### Gefitinib

Trade name Iressa, marketed by AstraZeneca and Teva), is a drug used for lung cancers. Gefitinib is an EGFR inhibitor, like Erlotinib, which interrupts signaling through the epidermal growth factor receptor (EGFR) in target cells. Therefore, it is only effective in cancers with mutated and over active EGFR [2].

### Mechanism of action

Gefitinib is the first selective inhibitor of epidermal growth factor receptor's (EGFR)<sup>[2]</sup> tyrosine kinase domain. Thus gefitinib is an EGFR inhibitor. The target protein (EGFR) is a family of receptors which includes Her1(erb-B1), Her2(erb-B2), and Her 3(erb-B3). EGFR is over expressed in the cells of certain types of human carcinomas, for example in lung and breast cancers. This leads to an inappropriate activation of the anti-apoptotic Ras signaling cascade, eventually leading to uncontrolled cell proliferation. Research on gefitinib-sensitive NSCLC has shown that a mutation in the EGFR tyrosine kinase domain is responsible for activating anti-apoptotic pathways. These mutations tend to confer increased sensitivity to tyrosine kinase inhibitors such as Gefitinib and Erlotinib [3]. Of the types of non-small cell lung cancer histologies, adenocarcinoma is the type that most often harbors these mutations. These mutations are more commonly seen in Asian women, and non-smokers (who also tend to more often have adenocarcinoma). Gefitinib inhibits EGFR tyrosine kinase by binding to the adenosine triphosphate (ATP)-binding site of the enzyme. Thus the function of the EGFR tyrosine kinase in activating the anti-apoptotic Ras signal transduction cascade is inhibited, and malignant cells are inhibited.

### EGFR Diagnostic Test

EGFR mutations [4] test designed to predict which lung cancer patients may respond best to some therapies, including Gefitinib. This test examine the genetics of tumors removed for biopsy for mutations that make them susceptible to treatment.

### Causes of Cancer

- Alcohol
- Genetic Factors
- Environmental factors
- Sedentary Lifestyle Disorders
- Smoking

### Adverse effects

As Gefitinib is a selective chemotherapeutic agent, its tolerability profile is better than previous cytotoxic agents. Acne is reported very commonly. Other common adverse effects [5] ( $\geq 1\%$  of patients) include: diarrhoea, nausea, vomiting, anorexia, stomatitis, dehydration, skin reactions, paronychia, asymptomatic elevations of liver enzymes,

conjunctivitis, blepharitis. Infrequent adverse effects (0.1–1% of patients) include: interstitial lung disease, corneal erosion, aberrant eyelash and hair growth.

### Side Effects

Gefitinib may interact with other drugs or supplements, causing its level to either rise or lessen in your blood. If you are taking Rifampin, Phenytoin, Phenobarbital, Carbamezapine, Itraconazole, Ketoconazole, Nefazodone, Clarithromycin, Cimetidine, Ranitidine, Metoprolol, Ritonavir other drugs for Aids, you need to let your doctor know immediately. In addition, grapefruit or grapefruit juice may also change the level of this medication in your blood. Another side effect [5] are it can also affect your body's ability to form blood clots in order to stop bleeding, which may in turn double if you are taking any other medicine that can affect your ability to stop bleeding. Warn your doctor if you are taking aspirin, warfarin, clopidogrel, ticlopidine, or Vitamin E. This drug may cause diarrhoea and can lead to chemical imbalances in your body.

### Other Drug Interactions

CYP3A4 inducers [6,7] and H2-receptor antagonists decrease effectiveness of gefitinib. CYP3A4 inhibitors increase efficacy of gefitinib. Increased plasma concentrations of metoprolol when used with gefitinib.

### List of Contraindications:

Contraindicated in pregnancy .Category D: There is positive evidence of human foetal risk, but the benefits from use in pregnant women may be acceptable despite the risk (e.g., if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective).

## MATERIALS AND METHODS

Launching of new product requires an art as it can make the brand or break the product. A successful launch makes potential prescribers keen to try it, shorter product life cycles and rapid advances in technology. The methodology of new product launch for GEFILUCAR includes the following stages to be analyzed before launching of the product.

**Table 1: Performance evaluation review techniques (PERT): The time period taken before launching new product is as follows.**

Issues	Months before launch
Pre-launch analysis and clinical trials	24-36
Market analysis	Concurrent with clinical trials
Competitors analysis	24
Regulatory affairs	18-24
Fore costing budget	18-24
Promotion	06-12
Contingency planning	06-12
Field force training	00-01
Post launch market research	12 and onwards after launch



**A. Pre-launch analysis**

- Market analysis
- Disease understanding
- Present market potential
- Deciding for launch of molecule

**B. Branding**

- Brand search
- Brand name, logo, pinch line
- Trade mark applications
- Registrations

**C. Packaging and development**

- Brand font, colour etc.
- Type of packaging material
- Primary and secondary packaging
- Logistics

**D. WOT analysis**

- Analysis of strength, weakness, opportunities and threats for given molecule.
- Market forecasting

**E. Product launch planning**

- Date of launching
- Production planning
- Development and launch training for executives

**F. Promotional input strategies**

- Long term strategies
- Visual aids
- LBL
- Scientist literatures
- Other inputs

**G. Post Marketing Activity:**

- Post Marketing Surveillances (PMS)

**RESULTS AND DISCUSSION**

**Pre-launch analysis**

**Market analysis**

Scripting the total prescriptions, new prescriptions for competitors based on their brands and market shares because market script changes over period. Analyzing and comparing of brand or competitors total volume. Share of voice comparing brand with competitors. Behavioral and attribution research with in customer segment. Feedback from samples of sales representatives also provides a glimpse into regional activities.

**Competitor's analysis**

Prescription sales unit, share and their prices and their sales force structures. Promotional spend on their products. if in case any changes in product monographs. Patent expiry and potential generics entries and their line extension

### Analytical calculations

- Incidences of lung cancer 60,000 annually
- Roughly 80% accounts for NSCLC that is 60,000 of 80% =48,000
- Assuming 20% would be able to take medication so 20% of 48,000=9,600
- 9,600 cases for one year so over all for 5 years the number of patients will be 19200
- Out of 19200 cases 50% of cases will be EGFR mutation positive so that is 9,600 cases
- 9,600 cases are scope of EGFR mutation positive in which the patients can be treated with 3 types of medicines. They are Gefitinib, Erlotinib, and Cetuximab.

Gefitinib(83-88%)	Erlotinib(15-20%)	Cetuximab(7%)
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**Table 2: So out of 9,600 (83 to 88%)of patients will be treated with Gefitinib = 8450 cases.**

Trade Name	Manufacturer	Unit	Type	Quantity	Price
Chemogef	Neon Labs	250mg	Tablet	10 Tablets	Rs 4000/-
Chemofit	RPG Labs	250 mg	Tablet	10 Tablets	Rs 3500/-
Gefitinib	Natco Pharma	250 mg	Tablet	30 Tablets	Rs 10353/-
Gefonib	Miracalus Pharma	250 mg	Tablet	10 Tablets	Rs 3303/-
Geftib	Glenmark Pharmaceuticals	250 mg	Tablet	10 Tablets	Rs 9732.8/-
Geftilon	Celon Labs	250 mg	Tablet	10 Tablets	Rs 3330/-
Geftinat	Natco Pharma	250 mg	Tablet	30 Tablets	Rs 9750/-

So overall study about the competitors are based on their market share finally, decided to launch the molecule in the market.

### Branding

Brand plan serves as reference to execute a brand strategy, a well-constructed brand plan will be of great value requiring the brand manager to analyze the market potential, define objectives and strategies, lays down financial budgets and minor progress.

We analyzed exciting brand names and coined some new brand names like Gefilac, Pulmonib, Egfrib, Nslac, Geficar, Gefilucar, Gefican. After the brand search legal registration of one brand name from trade mark organization. Our brand management team finally registered our brand name for Gefitinib molecule as Gefilucar.

### Packaging and Development

Our brand font and colour are brown with pink which is representing cancer affected lungs from brown to pink type. Technical packaging is available

## SWOT Analysis

SWOT these are usually set up in a quadrant. Strength and weakness are qualities and attributes that are intrinsic to the brand. These are facts and are usually in comparison to competitors. Opportunities and threats are extrinsic factors to the brand and are possibilities of future by extrinsic we referring to the market or competitors.

- *Strengths:* Oncology is “MOST HAPPENING” segment. The number of incidences and scope is very high Gefitinib market scope and turnover is high ,based on this the company will be expected to get breakeven point within 5 yrs.
- *Weakness:* In EGFR mutation positive patients can be treated with other medicines like Erlotinib, and Cetuximab so only 85% of possible cases. In 85% we have very well established and high reputation companies like competitors so the company need to face more pressure and competition in market.
- *Opportunities:* The opportunities of Gefitinib in market are high scope because of incidences. The disease expansion also very high because carcinogens like smoking, asbestos poisoning and pollution etc.
- *Threats :* Gefitinib is an Oncological product so the shifting of one brand to another brand is very less case is possible in oncology so this is the only threat possible. After SWOT analysis the market for casting will be finalized.
- *Market forecasting:* Market share less than 5% in starting 6 months,8% of market share in 1 year ,10-12% of market share in 2years,15 to 20% market share in 3 years positively is estimated.

## Product launch planning

Date of launching before 2months it should be decided. Production planning within given 2 months, production of drugs will be done. Development and training for executives is done by training on presentation of launch and awareness about the product for inner organization and depth training conducted for medical executives who will interact with doctors.

## Promotional input strategies

Long term strategies are:

- Conducting CME for doctors forum (opinion makers)
- Conducting free EGFR TEST
- Providing supportive and rehabilitation therapies
- Awareness program on Lung cancer and seminars on Anti -Tobacco
- Conducting events on "SAY NO TO TOBACCO"
- Visual Aids Presentations of opinion makers
- LBL (leaf before literature)

- Scientist literatures

### Preparing of literature and sales aids

Pharmaceutical advertising of prescription products are generally in four forms:

- Detailing
- Gifting drug samples to the opinion makers.
- Participating in congress of various medical associations like (APICON, NEUROCON, DERMACON)
- Sponsoring Medical Awareness Campaigns, Seminars.

Detailing how ever continues to be very important method or sending messages across to the medical professionals. For this reason your messages while preparing literature and other sales aids is very important. It should be delivered by the medical representatives precisely, with impact and clarity.

### Post-Launch activities

Post launch activities includes post marketing surveillances (PMS), especially if you are introducing the product for the first time in India. PMS will help you understand the efficacy of the drug in actual clinical practice.

Another important post launch activity is extensive field work to gauge your strategies, its implementation levels, to know the response to the sales promotion materials and even your common strategy.

Market Research will help you to get first hand information on how the competitors are reaching and what are their counter strategies and by forecasting many post launch activities will emerge.

**Table 3: Promotional Budget Planning.**

PROMOTIONAL TYPE	Rs	Percentage %
ADVERTISING	105000	2.9%
LITERATURE	50000	1.2%
MAILING	60000	1.3%
REHABILITATION CENTER	70000	1.4%
EXHIBITION	200000	0.3%
SYMPOSIUM	500000	1.2%
SPONSORSHIP	500000	1.2%
VIDEOS	10000	0.2%
SAMPLES	100000	0.2%
GIFTS	60000	1.3%
OTHERS	5000	1.2%
TOTAL	5010000	13% (approx)





## CONCLUSION

Brand management is description about knowing your brand or a product and its uses and its movement in the market. GEFILUCAR is the brand which will have the competitive effect in the molecule when compared to other brands in market as per analysis undergone in the existing market, I hereby conclude that the data and analysis of the patients affected by lung cancer and their Cost Factor, SWOT Analysis, Environmental Conditions and Promotional Budget Planning to launch GEFILUCAR with a marginal cost and safety factors which could reach the patients with minimal effects. Final goal is to achieve the reach of GEFILUCAR in each and every lung cancer patients in India.

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