**Summer Training at**
**UCB Pharma India Pvt. Ltd.,**
**Mumbai**

# Perception Analysis and Market Positioning of Plegridy® (Peginterferon β-1a)

**By**
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**Under the guidance of**
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**MBA Pharmaceutical Management**
**2015-2017**


**The IIHMR University, Jaipur**
**2016**

INSTITUTE OF HEALTH
MANAGEMENT RESEARCH
(WHO Collaborating Centre for District Health System Based on Primary Health Care)

IIHMR UNIVERSITY

**TO WHOMSOEVER IT MAY CONCERN**

This is to certify that **Neha Bala,** student of MBA-Pharmaceutical Management from The IIHMR University, Jaipur has undergone Summer Training Project at UCB India Pvt. Ltd. from **14th April to 14th June, 2016.**

The candidate has successfully carried out the study designated to her during summer training and her approach to the study has been sincere, scientific and analytical. This training is in fulfillment of the course requirements.

I wish her success in all the future endeavors.

Col (Dr.) Ashok Kaushik
Dean, Academics and Student Affairs
The IIHMR University, Jaipur

13/06/2016

Mr. Abhishek Dadhich
Assistant Professor
The IIHMR University, Jaipur

June 30, 2016

**TO WHOMSOEVER IT MAY CONCERN**

This is to certify that Ms. Neha Bala was appointed as "Trainee" with our organisation for a summer internship project from April 14, 2016.

Neha successfully completed her project titled 'Perception Analysis and Market Positioning of Plegridy (Peginterferon beta-1a)' on June 14, 2016.

We wish her success in all her future endeavours.

With Best Regards,

**For UCB INDIA PRIVATE LIMITED**

**Sudip Chakraborty**
**Head - Neuro PVU & Commercial Operations**

**Grishma Patel**
**Talent Services Partner, India**

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CIN: U24239MH1959PTC011545

# Acknowledgement

The satisfaction and euphoria that accompany the successful completion of the project would be incomplete without the mention of the people who made it possible.

First of all, I express my sage sense of gratitude and indebtedness to our President, Dr. S.D.Gupta, and IIHMR University.

I would like to extend my sincere and heartfelt thanks to Mr. Sudip Chakraborty, Neurology PVU Head and Deep Bhandari, Business Unit Head-Multiple Sclerosis (MS), UCB India Pvt. Ltd. for providing me an opportunity to learn and develop professionally.

I would also like to express my deep sense of gratitude to my corporate mentor Mrs. Kanchan Waikole, Group Product Manager and my faculty mentor Mr. Abhishek Dadhich, Assistant Professor. I am greatly indebted to both of them for providing their valuable guidance at all stages of the study, their advice, constructive suggestions, positive and supportive attitude and continuous encouragement, without which it would not have been possible to complete the project.

To place on record, I owe a debt of gratitude to all my teachers for grooming me and my classmates for the inspiration needed to work with dedication and motivation throughout as an Intern at UCB India Pvt. Ltd.

I hope that I can build upon the experience and knowledge that I have gained and make a valuable contribution towards the industry in coming future.

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# ABBREVIATIONS

**UCB:** Union chimique belge

**MS:** Multiple Sclerosis

**RRMS:** Relapsing Remitting Multiple Sclerosis

**DMT:** Disease Modifying Therapy

**R&D:** Research and Development

**CNS:** Central Nervous System

**MRI:** Magnetic resonance imaging

**IgG:** Immunoglobulin G

**BBB:** Blood-brain barrier

**EDSS:** Expanded Disability Status Scale

# EXECUTIVE SUMMARY

The study aimed to analyze the perception and market positioning of Plegridy® (Peginterferon β-1a) among the Neurologists in metropolitan cities.

Semi-structured questionnaire was utilized for data collection from respondent i.e. 40 doctors comprising of Neurologists, from Mumbai and Delhi-NCR. Data was analyzed by compiling it & findings provided with doctor's opinion and a comprehensive review of the market situation to be used for framing and suggesting the market positioning strategy.

The project was carried out in 3 stages:

The first stage was to study about the Multiple Sclerosis, Disease Modifying Therapies used for its treatment, Market competitors and prepare a questionnaire followed by stage two which involves meeting with the Neurologists in various hospitals and clinics in Mumbai and Delhi-NCR region and conduct the survey. After the completion of the survey, the last stage followed which includes analyzing the data and getting a conclusion.

Following findings were observed after meeting with Neurologists, in two metropolitan cities:

- It was found that maximum numbers of patients of MS are on Avonex (43.2%).

- It was found that there are certain factors that influence the doctors to shift their patients on existing therapy of Interferon to the new drug are as follows:

    - Cost of the therapy
    - Failure of existing Disease Modifying Therapy.
    - Supportive clinical evidence

# COMPANY PROFILE

UCB (Union chimique belge) is a multinational biopharmaceutical company headquartered in Brussels, Belgium. A global biopharma focused on severe diseases in two therapeutic areas: neurology and immunology. Their operations are in approximately 40 countries, supported by more than 8,500 people. UCB had over € 3.88 billion global revenue in 2015. It is established in 1928, the successful transformation from a hybrid specialty chemical company into a patient-centric biopharma company. UCB is a company that focuses- on Meeting patients unmet needs and continuously advancing science. With more than 8,500 staff, UCB offers an exciting working environment where initiative can flourish and those with a 'can-do' attitude can thrive.

UCB is having many drugs in R&D pipeline like Vimpat®, Romosozumab**, Cimzia® and much more.

The UCB pipeline delivers:

- A promising portfolio targeting severe diseases and addressing unmet medical needs
- Focus on neurology and immunology diseases
- More convenient and effective treatments for patients and specialists.

UCB is connecting science in new ways, notably chemistry and biology, so that we can leverage the potential of these two disciplines, as well as illuminate the biological pathways involved in severe diseases.

# VISION

**Meeting patients' unmet needs:**

Working with physicians and healthcare professionals, UCB is engaging more with patients to better understand their clinical, economic, social and personal needs. What matters most is how they feel in their everyday life as they progress on their healthcare journey. UCB believes that patients inspire them to bring them the value through more cutting-edge science, more innovative drugs, and more practical solutions – so that they, and their careers, can get on with their lives.

**Continuously advancing science:**

There is no such thing as an "average patient". UCB don't want to do science for science's sake but are seeking to embed the real needs of specific patient populations in our science and innovation process. To achieve this UCB are leveraging scientific advances and skills in areas such as genetics, biomarkers and human biology. UCB wants to enhance their knowledge of the various expressions of a disease and the real life experience of patients so that ultimately their teams are able to deliver the right drug and the right care to the right patient.

# STRATEGY

UCB is a global biopharmaceutical company, with a focus on neurology and immunology. UCB is having a strong business with total revenue grew to €3.88 billion in 2015. With more than 8,500 people in all four corners of the globe, inspired by patients and driven by science.

Looking ahead, UCB has a solid platform for continuous growth through 2022 with our core products Cimzia®, Vimpat® and Neupro® and Keppra®, and is preparing the launches of next wave of potential medicines to help patients with epilepsy and osteoporosis. At the same time, UCB is excited about the progress in our early pipeline.

However, UCB recognizes that radical changes are taking place in the eco-system of care and that need to evolve accordingly.

The key element of UCB evolution is to focus on the delivery of increased patient value. There is no such thing as an "average patient". UCB want to use all the tools, channels and scientific advances at our disposal to develop a better understanding of the various expressions of a disease and embed the real needs of specific patient populations in our science and innovation process. Rather than starting researching any new drug with the science alone, UCB want to better connect patients with science and science with patients.

Better understanding the reality of patients living with neurological and immunological disorders will enable us to take a more holistic approach to care, ensuring that ultimately the right drug and the right care reaches the right patients in order for them to live the lives they choose.

# HISTORY

1920s – Creation of UCB and early innovations.

1930s – Expansion into industrial films and the U.S.

1940s – Pharmaceutical support for the War effort

1950s – First therapeutic breakthroughs

1960s – Visionary research into biotechnology

1970s – Expansion of R&D and European network

1980s – The birth of a blockbuster (Zyrtec®)

1990s – Globalization and birth of second blockbuster (Keppra®)

2002 – Building resources for next leap forward

2004 – Transformation into a pure biopharma

2006 – First filing of biologic and a major acquisition

2008 – UCB shapes the organization for the future

2009 – Delivering through innovation

2010 - A year of strong delivery, Over 203 000 patients - almost doubled compared to 2009 - treated with UCB's new core products in over 27 countries across the globe.

2011 - Marked by execution and delivery of growth of the core medicines

2012 - "Crossover point", this 'crossover' is the inflection point which marks UCB's transformation into a patient-centric biopharmaceutical company

2013 - Start of a new era, Growth of core medicines in 2013 creates a strong foundation at the start of new era.

2014 - UCB confirms its position of strength with key assets delivering on growth promises

2015 - UCB is delivering on its growth promise

# INTRODUCTION

Multiple sclerosis (MS) is a potentially disabling disease of the brain and spinal cord (central nervous system). In MS, the immune system attacks the protective sheath (myelin) that covers nerve fibers and causes communication problems between brain and rest of the body and producing significant physical disability within 20-25 years in more than 30% of patients. Eventually, the disease can cause the nerves themselves to deteriorate or become permanently damaged. The hallmark of MS is symptomatic episodes that occur months or years apart and affect different anatomic locations.

Signs and symptoms of MS vary widely and depend on the amount of nerve damage and which nerves are affected. Some people with severe MS may lose the ability to walk independently or at all, while others may experience long periods of remission without any new symptoms.

There's no cure for multiple sclerosis. However, treatments can help speed recovery from attacks, modify the course of the disease and manage symptoms.

## Background

Multiple sclerosis (MS) is an immune-mediated inflammatory disease that attacks myelinated axons in the central nervous system (CNS), destroying the myelin and the axon in variable degrees. In most cases, the disease follows a relapsing-remitting pattern, with short-term episodes of neurologic deficits that resolve completely or almost completely. A minority of patients experience steadily progressive neurologic deterioration.

The cause of MS is not known, but it likely involves a combination of genetic susceptibility and a presumed nongenetic trigger (eg, viral infection, low vitamin D levels) that together result in a self-sustaining autoimmune disorder that leads to recurrent immune attacks on the CNS. Geographic variation in the incidence of MS supports the probability that environmental factors are involved in the etiology.

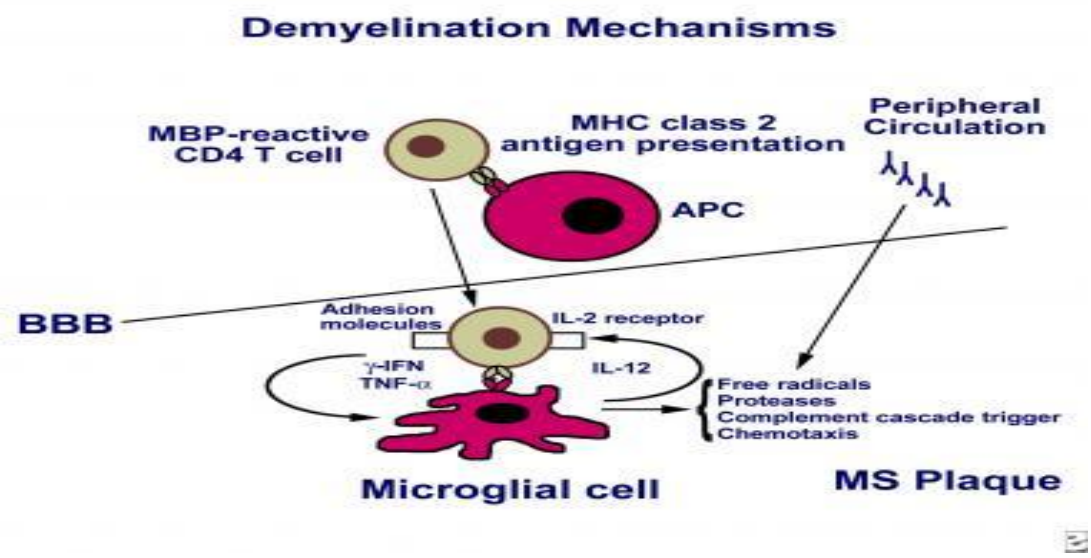
MS is diagnosed on the basis of clinical findings and supporting evidence from ancillary tests, such as magnetic resonance imaging (MRI) of the brain and cerebrospinal fluid examination. Traditionally, MS could not be diagnosed after only a single symptomatic episode, as diagnosis required the occurrence of repeat clinical attacks suggesting the appearance of lesions separated in time and space; however, recent guidelines allow diagnosis of MS even with a first clinical episode as long as ancillary tests support separation of lesions in time or space.

## Pathophysiology

Multiple sclerosis is an inflammatory, demyelinating disease of the CNS. In pathologic specimens, the demyelinating lesions of MS called plaques, appear as indurated areas—hence the term sclerosis. Examination of the demyelinating lesions in the spinal cord and brain of patients with MS shows myelin loss, destruction of oligodendrocytes, and reactive astrogliosis, often with relative sparing of the axon cylinder. In some MS patients, however, the axon is also aggressively destroyed.

The location of lesions in the CNS usually dictates the type of clinical deficit that results. As neural inflammation resolves in MS, some remyelination occurs, but some recovery of function that takes place in a patient could be due to nervous system plasticity. MS is also characterized by perivenular infiltration of lymphocytes and macrophages, as demonstrated in the image below. Infiltration of inflammatory cells occurs in the parenchyma of the brain, brainstem, optic nerves, and spinal cord.

The elevated immunoglobulin G (IgG) level in the cerebrospinal fluid, which can be demonstrated by an oligoclonal band pattern on electrophoresis, suggests an important humoral (ie, B-cell activation) component to MS. In fact, variable degrees of antibody-producing plasma cell infiltration have been demonstrated in MS lesions. The image below provides an overview of demyelination.




The mechanism of demyelination in multiple sclerosis may be activation of myelin-reactive T cells in the periphery, which then express adhesion molecules, allowing their entry through the blood-brain barrier (BBB). T cells are activated following antigen presentation by antigen-presenting cells such as macrophages and microglia, or B cells. Perivascular T cells can secrete proinflammatory cytokines, including interferon-gamma and tumor necrosis factor alpha. Antibodies against myelin also may be generated in the periphery or intrathecally. Ongoing inflammation leads to epitope spread and recruitment of other inflammatory cells (ie, bystander activation). The T cell receptor recognizes antigen in the context of human leukocyte antigen

molecule presentation and also requires a second event (ie, co-stimulatory signal via the B7-CD28 pathway, not shown) for T cell activation to occur. Activated microglia may release free radicals, nitric oxide, and proteases that may contribute to tissue damage.

## Etiology

**Genetic and molecular factors**: The concordance rate for MS among monozygotic twins is only 20-35%, suggesting that genetic factors have only a modest effect. The presence of predisposing non-Mendelian factors (ie, epigenetic modification in 1 twin), along with environmental effects, plays an important role. For first-degree family members (children or siblings) of people affected with MS, the risk of developing the disorder is sevenfold higher than in the general population, but familial excess lifetime risk is only 2.5–5%.

**Geography:** MS is more common in people who live farther from the equator, although exceptions exist. These exceptions include ethnic groups that are at low risk far from the equator such as the Samis, Amerindians, Canadian Hutterites, New Zealand Māori, and Canada's Inuit, as well as groups that have a relatively high risk close to the equator such as Sardinians, inland Sicilians, Palestinians and Parsis. The cause of this geographical pattern is not clear. While the north-south gradient of incidence is decreasing, as of 2010 it is still present.

## Signs and symptoms

Classic MS signs and symptoms are as follows:

- Sensory loss (ie, paresthesias): Usually an early complaint
- Spinal cord symptoms (motor): Muscle cramping secondary to spasticity
- Spinal cord symptoms (autonomic): Bladder, bowel, and sexual dysfunction
- Cerebellar symptoms: Charcot triad of dysarthria, ataxia, and tremor
- Optic neuritis, Heat intolerance, Depression, Euphoria.
- Trigeminal neuralgia: Bilateral facial weakness or trigeminal neuralgia
- Facial myokymia (irregular twitching of the facial muscles): May also be a presenting symptom
- Eye symptoms: Including diplopia on lateral gaze (33% of patients)
- Constitutional symptoms: Especially fatigue (70% of cases) and dizziness
- Pain: Occurs in 30-50% of patients at some point in their illness
- Subjective cognitive difficulties: With regard to attention span, concentration, memory, and judgment.
- Bipolar disorder or frank dementia: Maybe a late finding but is sometimes found at initial diagnosis.

## ABOUT THE PRODUCT

PLEGRIDY® is a subcutaneous injectable therapy for relapsing-remitting multiple sclerosis (RRMS), in which interferon beta-1a is pegylated to extend its half-life to permit a less frequent dosing schedule. Plegridy® is a member of the interferon class of treatments for MS. Plegridy® can only be obtained with a prescription and treatment should be started under the supervision of a doctor experienced in treating MS. Plegridy® is available as a solution for injection in pre-filled pens or pre-filled syringes that contain 63, 94 or 125 micrograms peginterferon beta-1a. Treatment should start with a dose of 63 micrograms, followed by a dose of 94 micrograms after two weeks, and then 125 micrograms every two weeks thereafter.

Plegridy® is the fifth therapy to be offered by Biogen Idec to people living with MS, expanding on a portfolio that addresses individual patient needs.

The safety and tolerability profile of Plegridy® observed was consistent with that of established MS interferon therapies. Plegridy® should be administered with caution to patients with previous depressive disorders, seizures, severe hepatic impairment and severe renal impairment. Cytopenias, including rare severe neutropenia and thrombocytopenia, have been observed in patients treated with Plegridy®. The following have been reported with interferon beta medicinal products including Plegridy® Elevations in hepatic enzymes, serious hypersensitivity reactions, and injection site reactions with subcutaneous administration, including injection site necrosis, and worsening of cardiac disease.

## CLINICAL RESULTS

The FDA approval of Plegridy® was based on a randomized, double-blind, and placebo-controlled, one-year study. The trial compared clinical and MRI outcomes at 48 weeks in patients who received Plegridy® 125 micrograms (n=512) or placebo (n=500) subcutaneously once every 14 days. All subjects had a baseline Expanded Disability Status Scale (EDSS) score from 0 to 5, had experienced at least 2 relapses within the previous three years, and had experienced at least 1 relapse in the previous year. None of the subjects had progressive MS. Neurological evaluations were scheduled at baseline, every 12 weeks, and at the time of a suspected relapse. Brain MRI evaluations were scheduled at baseline, week 24, and week 48. The primary outcome was the annualized relapse rate over 1 year. The annualized relapse rate was 0.26 in the Plegridy® arm and 0.40 in the placebo arm; relative reduction 36% (p=0.0007).

# OBJECTIVE & RATIONALE

## Objective of the Study

The main objective was to conduct this research is to understand the perception of Neurologist about Interferon beta-1a & develop the market positioning for new product launch i.e. PLEGRIDY®.

## Primary Objectives:

- To analyze the perception of Plegridy® among neurologists and its market positioning.
- To study and understand the concept and process of marketing research.
- To understand and get the concept of Marketing of Pharmaceutical products.

# RATIONALE

The project scope involves the study of the Disease Modifying Therapies (DMT's) used for Multiple Sclerosis (MS) treatment. Understand the rare disease i.e. Multiple Sclerosis and Interferon beta-1a class of drugs, their mechanism of action and clinical use & their place in therapy. The project scope also involves the finding of clinician preferences in current DMT's available with the marketing research and developing a market positioning for "Plegridy®" from the above collected data.

## Managerial Usefulness of the Study

This study helps to understand marketing research basic terminologies & different strategies for market positioning of pharmaceutical product.

# METHODOLOGY

## Sample Design:

Cross- sectional descriptive study

## Sampling:

Non probability convenience sampling

## Sample population:

Neurologist in two metropolitan cities

## Sample Size:

Total respondents: 40

Neurologists in Mumbai: 20

Neurologists in Delhi: 20

## Sample area:

Mumbai

Delhi-NCR

## Tool:

Semi-structured questionnaire was used to collect primary data

Microsoft Excel was used to carry out analysis

## Data Collection:

Primary- Through semi-structured questionnaire and meeting with respondents

Secondary- To understand study topic and objectives information from various sources like articles, journals, reference books, previous relevant studies was collected.

## Study duration:

Two (2) months

# FINDINGS

## 1. Total number neurologists examine MS patients in month:

As MS is a rare disease, it was essential to know the number of patients examined by a neurologist in a month.

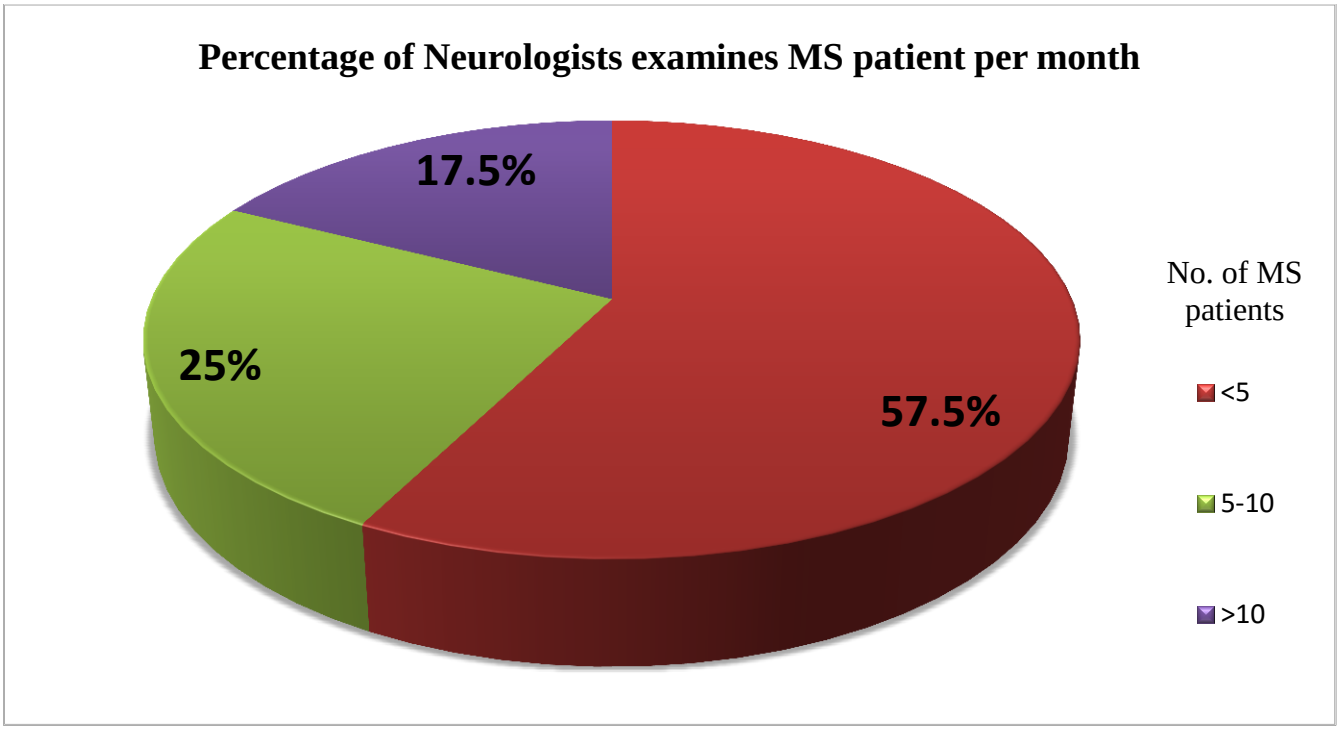



*Figure 1: Percentage of Neurologists examines MS patient in a month.*

## Interpretation:

- From the above chart, it is clear that 57.5% of neurologists examine less than 5 number of patients whereas 25% examine patients between 5-10 and 17.5% of neurologists examine more than 10 number of patients.

- Hence, it is clear that majority of neurologists examine lesser number of MS patients therefore the population of the disease is less in number.

## 2. Total number of Neurologists examine Relapsing Remitting MS patients in a month :

After finding the number of MS patients, cases of RRMS was asked to the neurologists.

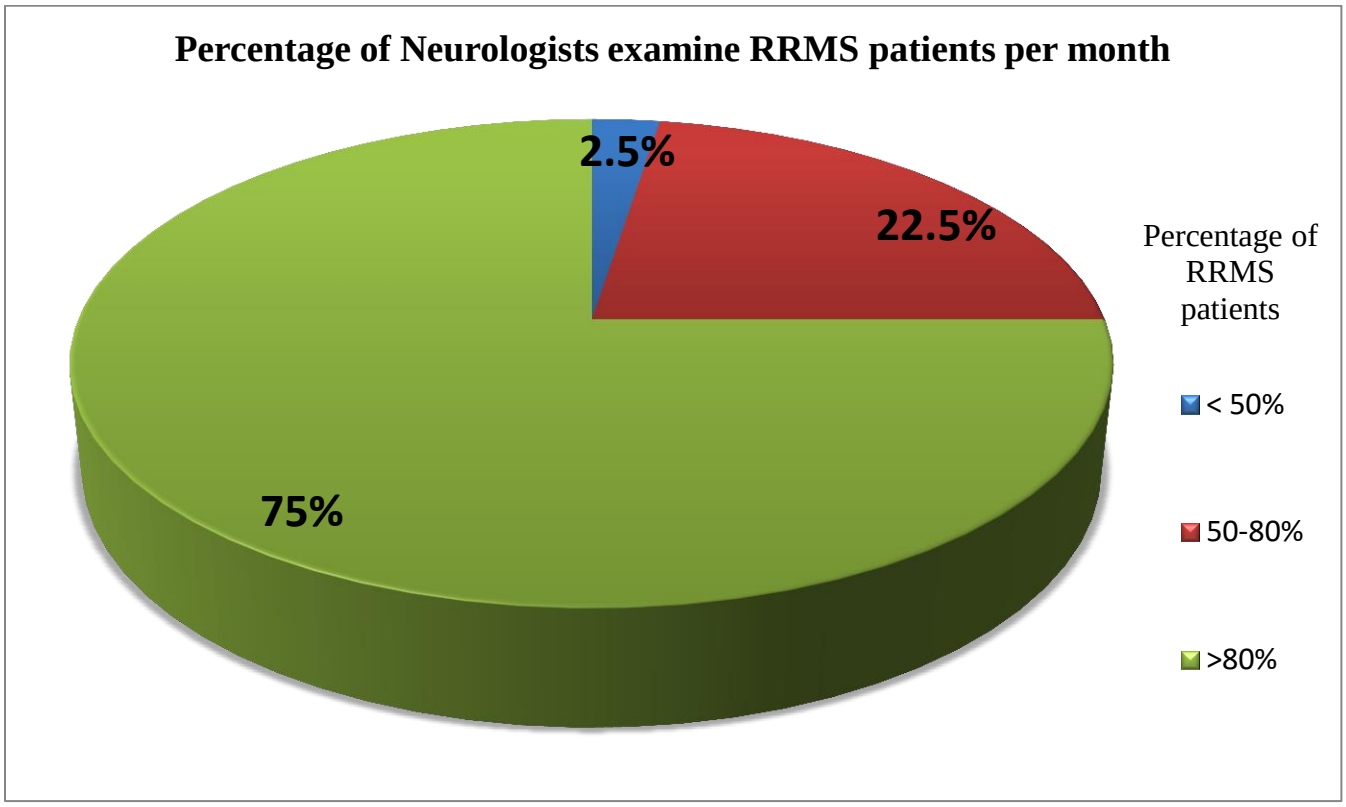



*Figure 2: Percentage of Neurologists examines RRMS patients per month.*

## Interpretation:

- From the above chart, it was found that 75% of neurologists examine more than 80% of RRMS patients whereas 22.5% examine 50-80% of RRMS patients and only 2.5% examine 2.5% RRMS patients.

- Therefore, it is clear that majority of neurologists are going over maximum number of RRMS patients.

### 3. Total number of patients on DMT's:

Neurologists were asked that what number of patients the put on Disease Modifying Therapies.

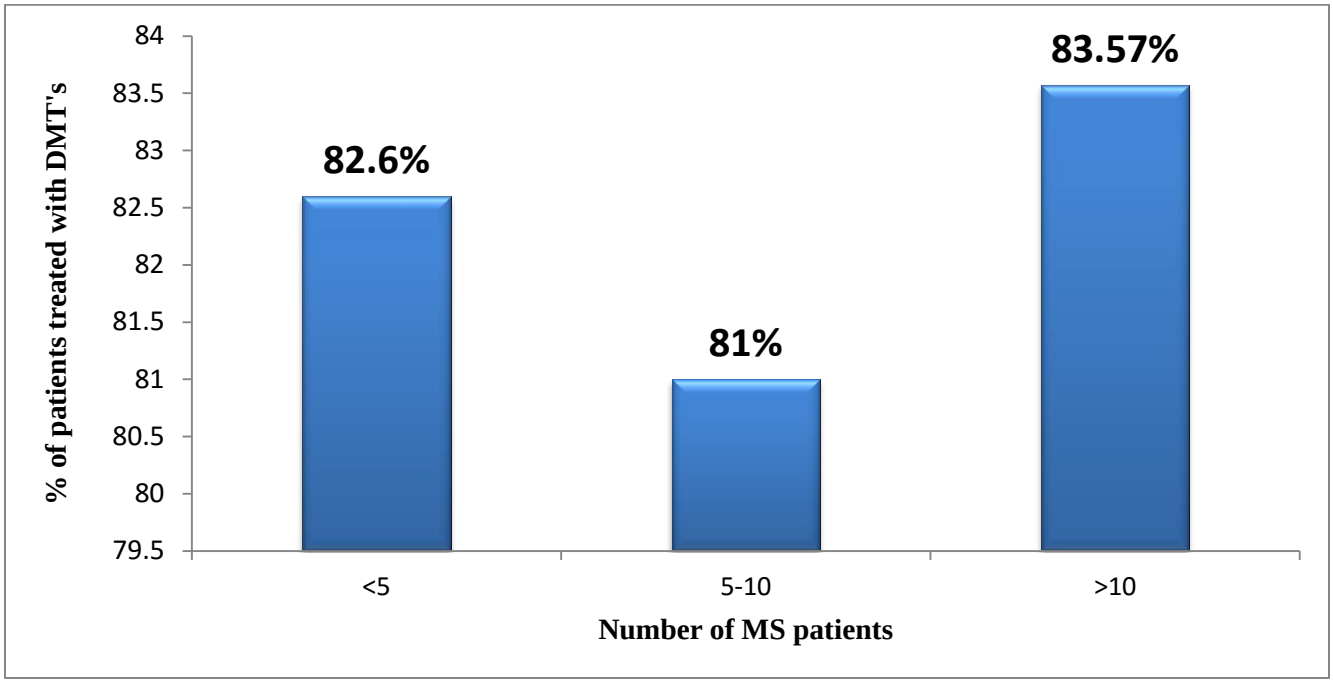



*Figure 3: Percentage of MS patients treated with DMT's.*

## Interpretation:

- From the above chat it is clear that neurologists who examine less than 5 numbers of patients and more than 10 numbers of patients put 82.6% and 83.57% of them on DMT's respectively, whereas neurologists who examine patients between 5 to10 put 81% of them on DMT's.

- Hence, majority of neurologists are treating MS patients with DMT's.

## 4. Most preferred DMT's among Neurologists:

To know the top preferences of neurologist, they were asked to rank the following brands.

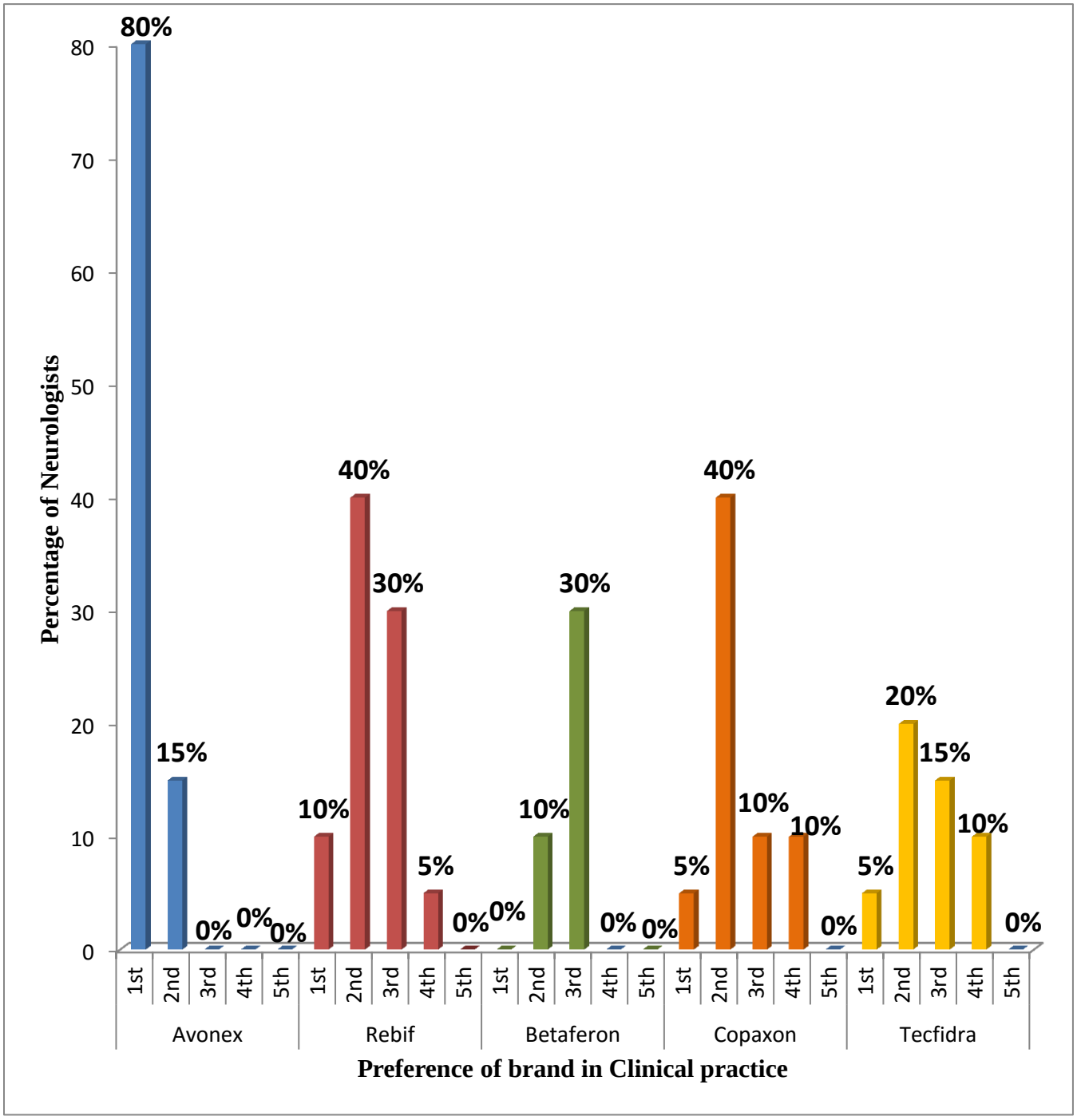



*Figure 4: Most preferred brand in Clinical practices.*

## Interpretation:

- **Avonex®**
  - From the above mentioned chart, it is clear that maximum number of Neurologists i.e. 80% is giving first preference to Avonex®, while 15% is giving it on their second preference.
  - Therefore it can be say that Avonex® is the most preferred brand by neurologists in clinical practice.

- **Rebif ®**
  - Majority of neurologists i.e. 40% are giving preference to Rebif® on second number, whereas 30% are giving it third preference, 10% and 5% are giving it first and fourth preference respectively.

- **Betaferon®**
  - For Betaferon®, majority of neurologists i.e. 30% are giving it third preference while only 10% are giving it second preference.
  - None of the neurologists prefer Betaferon® as their first, fourth or fifth preference.

- **Copaxone®**
  - Majority of neurologists i.e. 40% uses Copaxone® as their second preference while 5% are using it as their first preference.
  - Whereas third and fourth preference give to the drug by 10% neurologists.

- **Tecfidera®**
  - The chart shows that 20% of neurologists are using Tecfidera® as their second preference whereas 15% and 10% uses it as their third and fourth preference and only 5% use it as their first preference.

## 5. Existing MS patients on various brand:

This question gives the information regarding the current percentage of patients on the competitive brands.

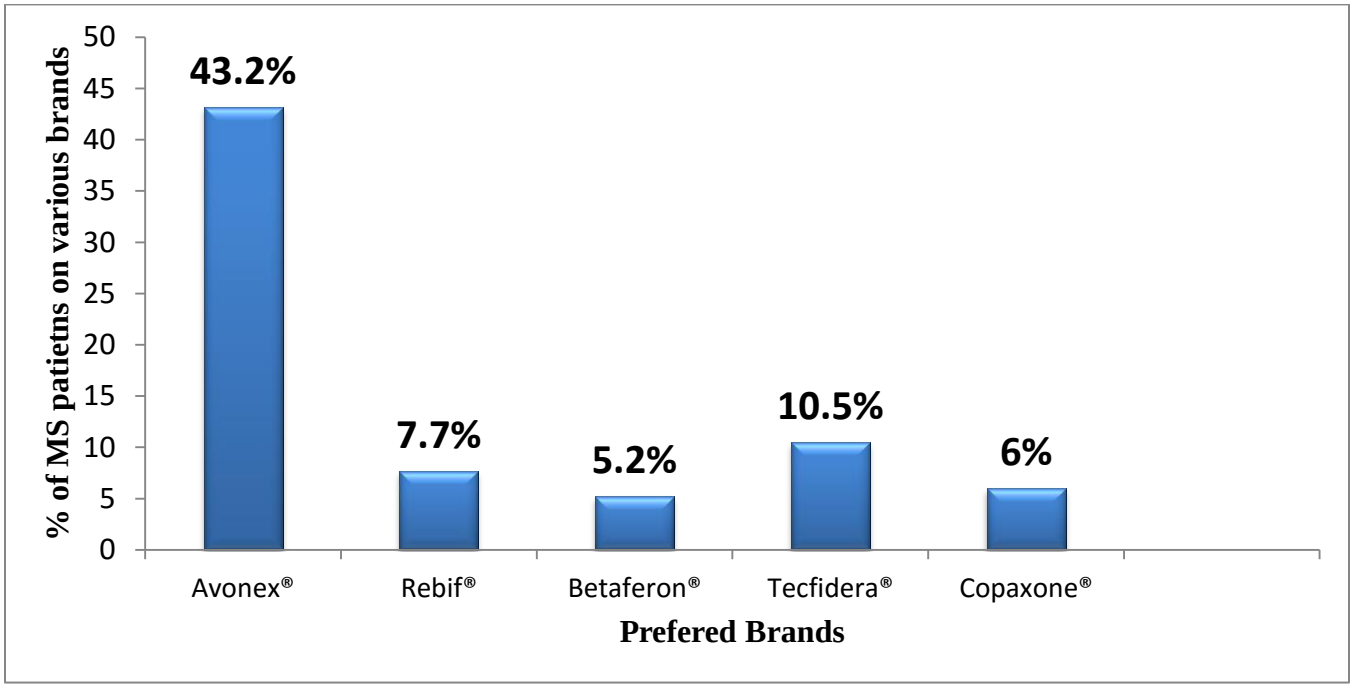



*Figure 5: MS patients on various preferred brands.*

## Interpretation:

- **Avonex®**
  - From the chart it is concluded that majority of MS patients i.e. 43.2% are treated by Avonex®.
- **Rebif ®**
  - 7.7% of MS patients are treated with the help of Rebif®.
- **Betaferon®**
  - 5.2% of MS patients are treated with the help of Betaferon®.
- **Tecfidera®**
  - 10.5% are on Tecfidera®.
- **Copaxone®**
  - 6% of MS patients are treated with Copaxone®.

## 6. Challenges in current treatment options:

- ❖ Major challenges in both the regions which Neurologists face in the current treatment options are as follows:
  - High cost of the therapy
  - Patient compliance
  - Relapse rate

## 7. Awareness of Plegridy® among Neurologists:

Neurologists were asked, to know the awareness of Plegridy®. They were asked about Peginterferon β-1a which is the molecule present in Plegridy®.

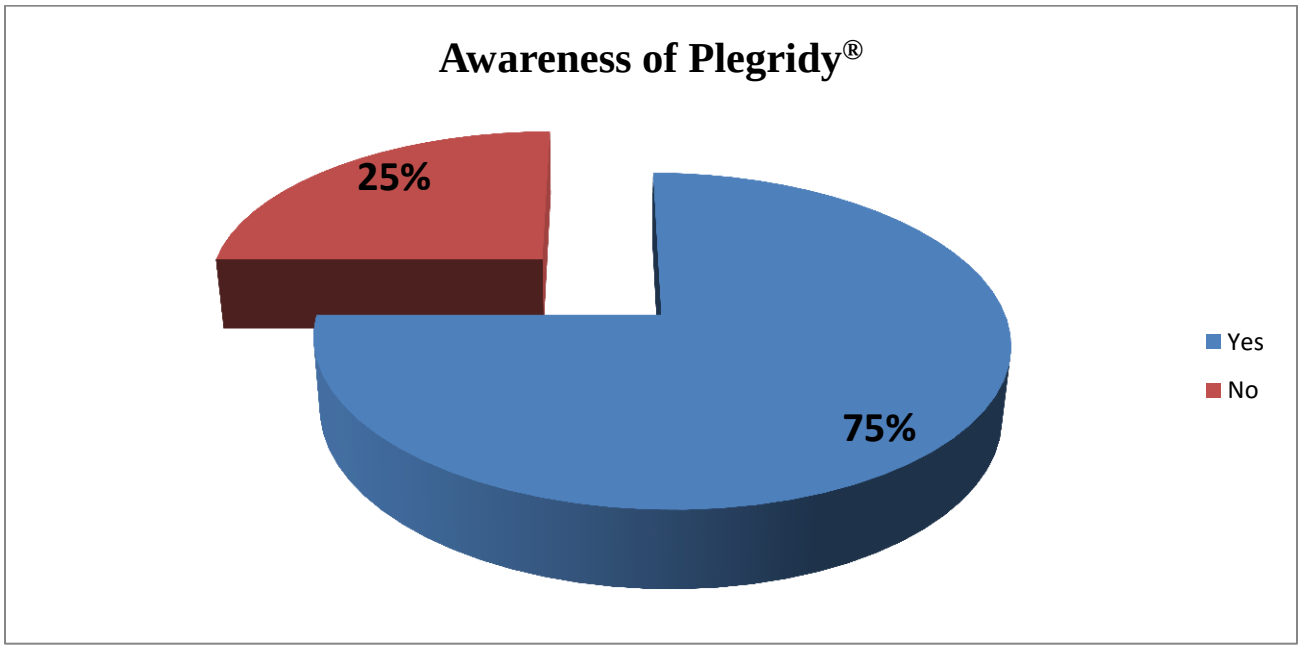



*Figure 6: Awareness of Neurologists about Plegridy®.*

## Interpretation:

- From the above chart it can be clearly understand that majority of Neurologists i.e. 75% are aware of Peginterferon β-1a molecule whereas 25% are not aware of such molecule.
- When respondents said that they are not aware about the drug than the visual ate (show cards) were shown to them in order to give them a brief idea about the new product.

## 8. Patient preference for Plegridy® :

The question was asked to the neurologists, that what type of patients they will prescribe the new DMT.

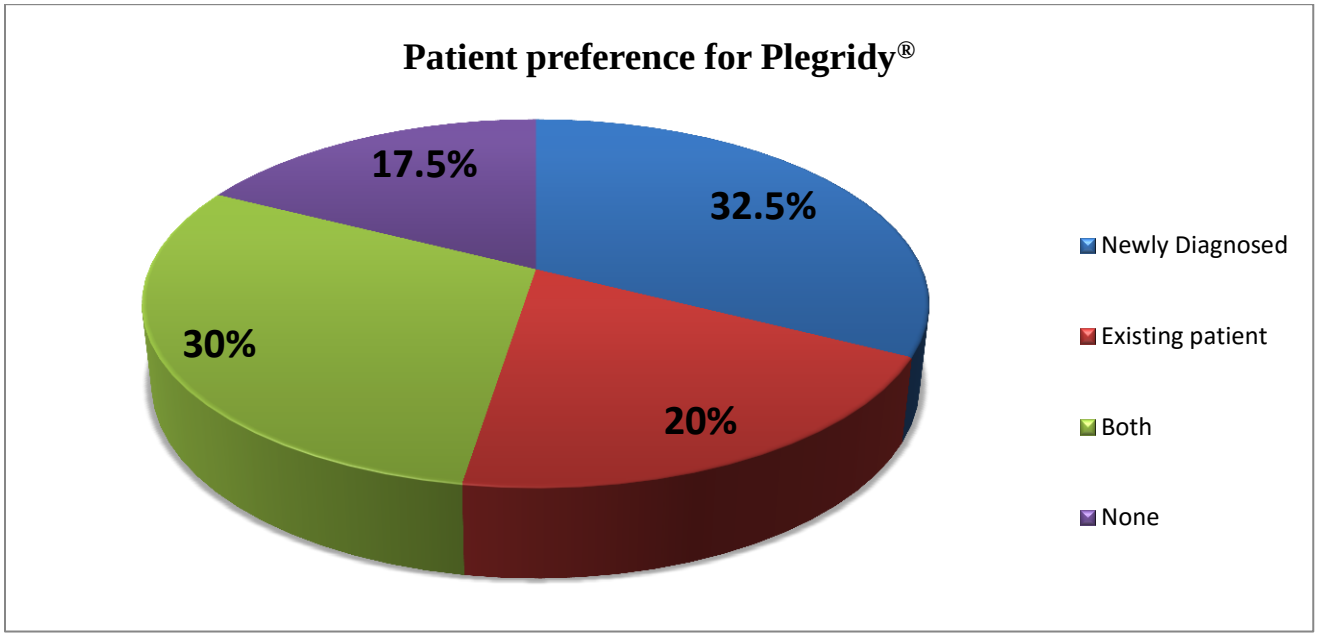



*Figure 7: Preferred patients for Plegridy® by neurologists.*

## Interpretation:

- From the above chart, it can be derived as 32.5% of neurologists will prefer to prescribe Plegridy® to the newly diagnosed patient, 20% of them said they will prescribe it to the existing patients on interferon.
- While 30% said they will prefer both kind of patients i.e. newly diagnosed as well as existing patients and 17.5% said they will not prefer to prescribe the drug to anyone.
- Hence from the chart it is clearly visible that most of the neurologist would like to give it to the newly diagnosed MS patients, and rest will shift their existing patients to the new therapy.

## 9. Number of newly diagnosed patients would be on Plegridy® :

An estimation to find out the percentage of new diagnosed patients to who doctors would like to give the new therapy.

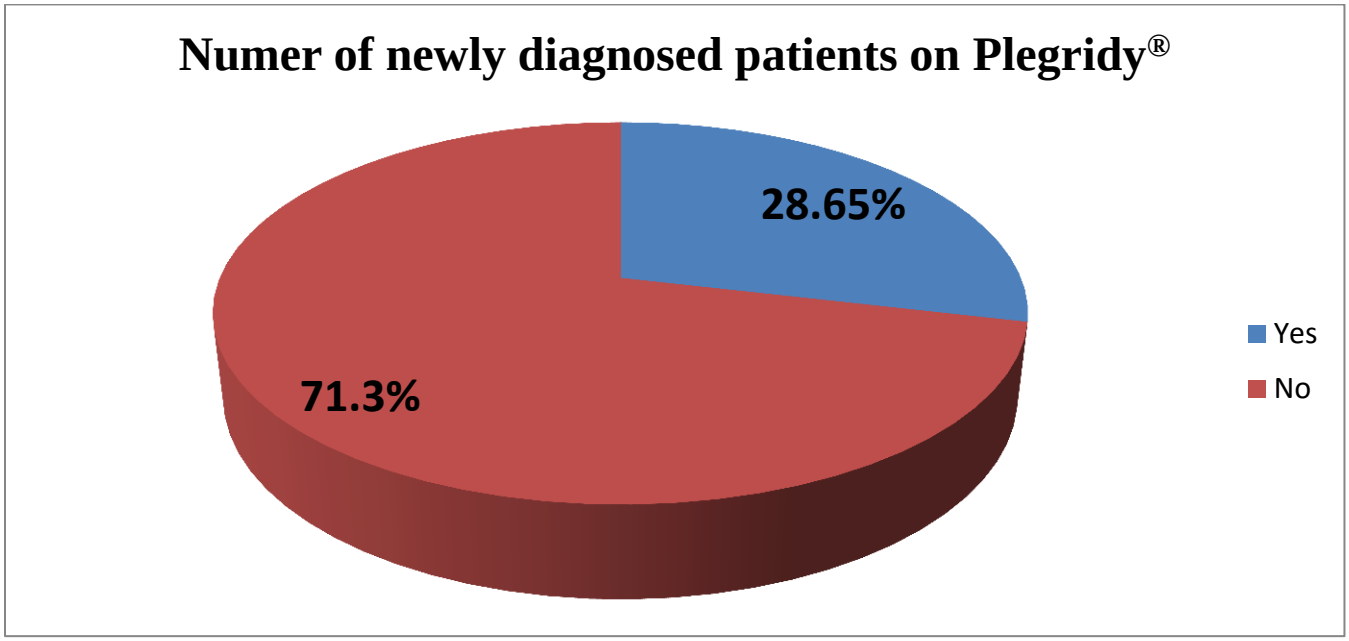



*Figure 8: Estimated value of newly diagnosed patients on Plegridy®.*

## Interpretation:

- The above chart shows that 71.3% of neurologists will not prescribe the newly diagnosed patients Plegridy® as they will consider various factors before prescribing it which can influence their prescription pattern, while 28.65% of neurologists will prescribe it to the newly diagnosed MS patients.

- Major factors which majority of neurologists will look while prescribing the new therapy drug will be:
  - Cost of the new drug i.e. PLEGRIDY®.
  - Affordability of patients whether they can afford the new therapy or not.
  - And some needed supportive clinical evidence.

## 10. Patient shift from existing therapy to the new therapy :

In the process of marketing survey, it is essential to determine whether neurologists prefer the same DMT's for MS treatment or would like to shift them to the new therapy. The main purpose of finding this is to know the market move or shift from the existing brand to the new one i.e. Plegridy®. The finding of analysis is as:

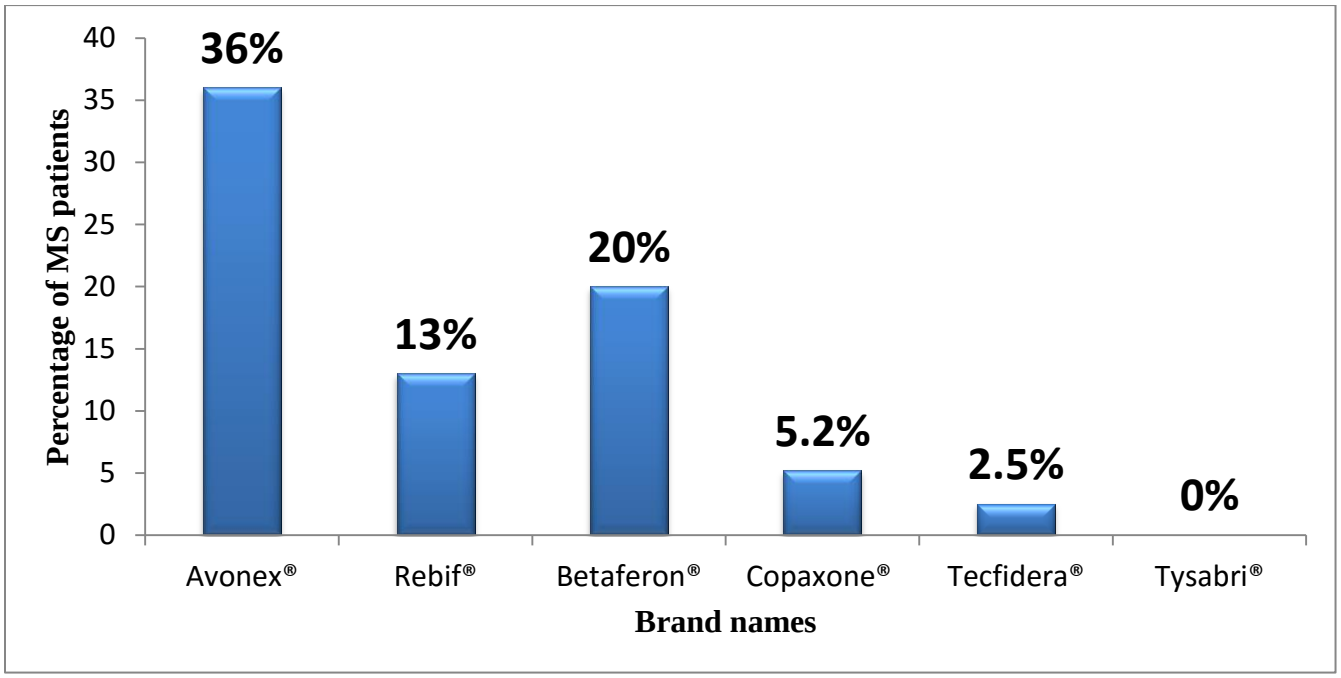



*Figure 9: Number of patient shift from existing therapy to the new therapy.*

## Interpretation:

- From the above facts & feedbacks collected in research process, it can be said that there is a major shifting of MS patients from brands like Avonex®, Rebif® and Betaferon® i.e. 36%, 13% and 20% respectively. Whereas patients shifted from Copaxone® and Tecfidera® is 5.2% and 2.5% respectively.
- None of the patients on Tysabri® will be shifted to the new therapy.
- Hence from the analysis it is clear that there will be an major patients shift from the available big brands.

# FINDINGS FROM THE RESEARCH

An important fact of research is "the analysis and positioning of available Disease Modifying Therapies (DMT's), and discuss opinion about the PLEGRIDY® (Peginterferon β- 1a) before the launch in the Indian market". PLEGRIDY® has been available in International market for years, but the availability of the new molecule in India solely depends on the UCB India Pvt. Ltd.
It is essential to study the detailed performance of available Interferons in the market, in the Disease Modifying Therapy category. This would determine the Market positioning of PLEGRIDY® (Peginterferon β- 1a).

- From the research, it has been figured out that 'Cost' is the most important characteristics that individual seek in an Interferons.
- Avonex has been in the top of the list in the DMT's preferred by Neurologists, followed by Rebif, Betaferon, Copaxone and Tecfidera respectively.
- From the study it was found that the maximum numbers of patients of MS are on Avonex (43.2%).
- Also there will be an shift from the newly diagnosed patients to the new therapy, which in turn bring the market of the existing brand towards the new one i.e. Plegridy®.
- It was found that in some areas of Delhi, 15% of Neurologists are prescribing Azathioprine as a substitute to MS patients because of the high cost of existing DMT's.
- At the time of market survey it was found that there are certain factors that influence the doctors to shift their patients on existing therapy of Interferon to the new drug are as follows:
    - Cost of the therapy
    - Failure of existing Disease Modifying Therapy.
    - Supportive clinical evidence

# CONCLUSION

The pharmaceutical industry currently represents a highly competitive environment. Pharmaceutical companies have to operate in a highly regulated environment; the degree of regulation to a significant extent depends on the country and type of the product. One of the most important aspects of government regulation for pharmaceutical companies is price regulation, and different countries have different policies on this issue. As the result of price control, prices of the same products can significantly differ in different countries.

UCB India Pvt. Ltd. has been enjoying the long run of its monotonous market in terms of its product Avonex®. With the new product launch Plegridy®, it wouldn't be wrong to say that company will enjoy the similar situation, if price being the competitive factor.

With the Avonex® occupying the maximum market shares in DMT category; it would be easy to be replaced by Plegridy®. Since, it is pegylated form to extend its half-life and prolong its exposure in the body, enabling for a less frequent dosing schedule (Once in two week). Prior to its launch and clinical use Plegridy® has been well positioned as Interferon. Hence, it has good positioning in terms of need of extended life and less frequent dosing. Pleginterferon beta-1a being one of the safest molecule and ease of administration amongst the DMT's available in the market, it can pick up in the market quiet well. But in the research it has been found that 'Cost' and 'Supportive clinical evidence' are the most important characteristics that doctor seek before prescribing it.

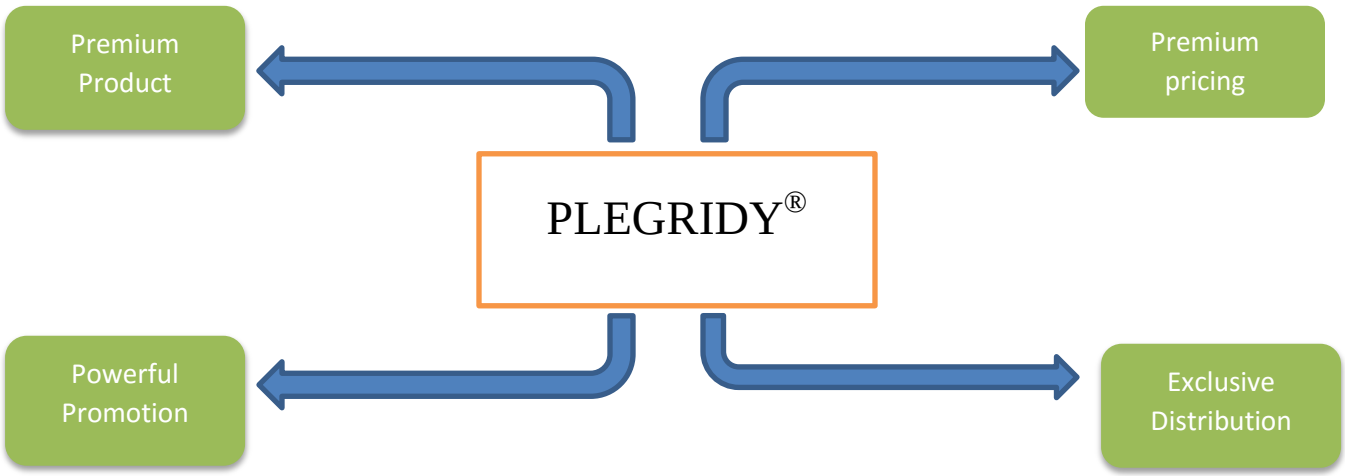
Hence, it can be considered that the market condition and initial opinion about the product is ideal for the launch of Plegridy®.

# SUGGETIONS

The main challenges for drug companies come from four areas. First, they must deal with competition from within and without. Second, they must manage within a world of price controls that dictate a wide range of prices from place to place. Third, companies must be constantly on guard for patent violations and seek legal protection in new and growing global markets. Finally, they must manage their product pipelines so that patent expirations do not leave them without protection for their investment.

Lastly, in terms of PLEGRIDY® the market development is essential which would help the company in creating increased market share. For this purpose UCB India Pvt. Ltd. should focus on following:

- By creating Brand image in the mind of the customer. As both Avonex® and Plegridy® are the products of UCB India Pvt. Ltd. and it was found from the study that Avonex® is the leading brand running in the market and has a good brand image in customer's mind, we can use this image for the promotion of new product i.e. Plegridy®.
- By finding out the "Key Opinion Leaders" that may influence the other neurologists to write Plegridy®.
- By Segmenting the market based on the number of prescription generation by the Neurologists and Target the market accordingly.
- By applying the Michael Treacy and Fred Wiersema model, an effective positioning of Plegridy® can be done, which is done as follows:



# LIMITATION OF THE STUDY

- The sample area and sample size has been limited due to time constraint.
- Doctors (respondents) are reluctant for their feedbacks & opinions, and authenticity of their statements can't be verified too.
- All the observation and recommendation will be made on the feedback obtained from survey.

# ANNEXURE

Date: No.:

## Questionnaire

Name of Doctor: _____ Place: _____

Contact Details: _____

Q1. How many patients of Multiple Sclerosis you meet in a month and out of that what is the percentage of Relapsing Remitting MS?

Ans.

Q2. Out of RRMS what is the percentage of patients treated with Disease Modifying Therapies?

Ans.

Q3. Within RRMS, what are the preferred DMTs?

- ☐ Avonex (Interferon β-1a; 30µg; IM once a week)
- ☐ Rebif (Interferon β-1a; 22or 44µg; SC three times per week )
- ☐ Betaferon (Interferon β-1a; 250 µg; SC every other day)
- ☐ Copaxone (Glatiramer Acetate; 20mg; SC daily)
- ☐ Tecfidera (dimethyl fumarate capsules; orally twice a day)

Q4. What is the percentage of existing MS patients on the following drugs?

- ☐ Avonex
- ☐ Betaferon
- ☐ Glatiramer Acetate
- ☐ Rebif
- ☐ Tecfidera (dimethyl fumarate capsules)

Q5. What are the challenges you face in current treatment options?

Ans.

Q6. Are you aware about Peginterferon β-1a?

☐ Yes ☐ No

*If No, Peginterferon β-1a is the Interferon with once in 14 days dosing, 36% ARR reduction, 54% disability.

Q7. What kind of patients you would prefer to use it?

☐ Newly diagnosed patient ☐ Existing patients on interferon

Q8. What percent of newly diagnosed patients will you prescribe Peginterferon β-1a?

Ans.

Q9. What percent of patients you would like to shift from the following drugs to the new drug treatment?

☐ Avonex(Interferon β-1a) ☐ Rebif (Interferon β-1a)

☐ Betaferon (Interferon β-1a) ☐ Copaxone (Glatiramer Acetate)

☐ Tysabri (Natalizumab) ☐ Tecfidera (Dimethyl fumarate capsules)

# VISUAL AIDS (Show Card)

## PEGINTERFERON BETA 1a – SUBCUTANEOUS INJECTION

- An interferon which is approved as a first line drug for RRMS in US, UK and Most of the EU Countries.
- An interferon beta-1a which is pegylated to extend its half-life and prolong its exposure in the body, enabling for a less frequent dosing schedule (Once in two week).

**CLINICAL DATA:**

- 35.6 % Annual Relapsed Rate reduction versus placebo over 2 years and 54 % Reduction in disability progression.
- 47% patients had Flu like Symptoms in 1st year & 90% patients had Flu like Symptoms as mild/moderate in severity.

| Treatment | Reduction in relapse rate (%) | Reduction in disability progression (%) | Dose frequency (doses per year) |
|---|---|---|---|
| Glatiramer acetate | 29[1] | 12 [not significant[1],*] | QD (365 SC injections) |
| SC IFNβ-1b | 32[2] | 30 [not significant[2],*] | QOD (183 SC injections) |
| SC IFNβ-1a | 32[3] | 30[4],*† | QOD (183 SC injections) |
| IM IFNβ-1a | 32[5],‡ | 37[5],§ | QW (52 IM injections) |
| Drug X | 36%[6] | 54%[6] | Q2W (26 SC injections) |
| Dimethyl fumarate** | 45–53[11,12] | 21–38[11,12] | BID (730 1,095 tablets) |

**ADVERSE REACTIONS:** Injection site erythema, Chills, Headache, Injection site pain, Arthralgia, Myalgia.

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