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THE ENABLERS



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A Report

By

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TABLE OF CONTENTS:

Title Page	i
Acknowledgement	ii
Table of contents	iii
Acronyms/Abbreviations	iv
Brand plan	v
Conclusion	vi

ACRONYM/ABBREVIATIONS:

B-cell – Beta cell

CAGR – Compound annual Growth Rate

R & D – Research and Development

Mg – Mega Gram

P&L – Profit and loss

H - Hour

TOPIC FOR THE PROJECT

“Brand plan for the launch of saxagliptin, a DPP-4 enzyme inhibitor”

EXECUTIVE SUMMARY

- My company mainly focus on diabetic medication and currently we develop a drug Zygolipa and it works in type 2 diabetes.
- Saxagliptin is a specialist in another class of meds called dipeptidyl peptidase IV (DPP4) inhibitors.
- By restraining DPP4, saxagliptin causes an expansion in glucagons like peptide-1 (GLP-1), an intestinal hormone that guides in glucose homeostasis and insulin discharge.
- The maker of Zygolipa got an approvable letter from the Food and Drug Administration in late March 2017.
- Zygolipa is planning to dominate the market in next 5 year with CAGR of 20%
- Sales expected for Zygolipa for a year 2,25,000 unit
- Zygolipa is Forecasted to double its sale
- It is commonly taken in the measurement of 2.5–5 mg/day orally.
- Peak level of Saxagliptin in plasma happens inside 2 h following ingestion, with a 4-h top for its dynamic metabolite
- Half-existence of Saxagliptin is 2.5 h while its dynamic metabolite has a half-existence of 3.1 h
- Clinical preliminaries have indicated that Saxagliptin is successful in altogether bringing down glycosylated hemoglobin (HbA1c), fasting plasma glucose, and prandial glucose levels. Beta-cell capacity may likewise be improved.
- The most normal unfriendly impacts in patients getting vildagliptin included cerebral pain, nasopharyngitis, hack, blockage, wooziness, and expanded perspiring.
- In patients rewarded with Zygolipa, cerebral pain (6.5%) was the main unfriendly response revealed at a rate $\geq$ of 5% and more ordinarily than in patients rewarded with fake treatment. In the extra to the preliminary, the rate of fringe edema was higher for different gliptins
- In most investigations, the pace of hypoglycaemias gave off an impression of resembling that of fake treatment.
- In clinical preliminaries of patients with type 2 diabetes mellitus, saxagliptin has

been appeared to decrease HbA1c, fasting plasma glucose levels, prandial glucose levels, and prandial glucagon discharge and to improve β -cell work.

- If Saxagliptin is affirmed for showcasing, it will add to the accessible treatment alternatives for diabetes and will furnish patients and social insurance suppliers with another non-injectable treatment choice.

About us

Company name - Canopus Pharmaceutical Ltd vision

Ranking in India- 15

Brand Name- ZYGOLIPA

Brand Vision- The aim of Zygolipa is to become a transnational pharmaceutical business by launching a wide range of branded and generic drugs into key markets.

Brand Mission-

Zygolipa is committed to bring the healthcare professionals to

innovate the products to improve the health and well-being of individuals.



Assumptions

- Canopus Pharmaceutical Ltd., a top 15 company is planning to launch Saxagliptin for the first time in India
- Canopus has yearly sales revenue of Rs. 1600 crores.
- The company is very strong in the chronic segment.
- They have two oral anti-diabetic drugs viz. metformin 1000 mg sustained release and acarbose.

- They are strong brands.
- They have a field strength of 900 medical reps and 200 first line and second-line managers

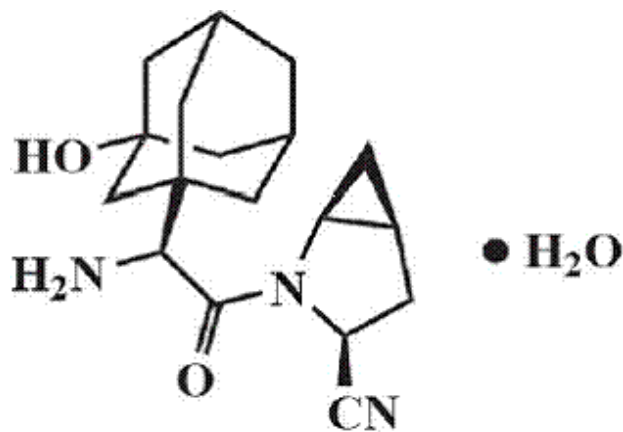
Objective for next 5 years

- Zygolipa is planning to take over the diabetic segment in India in the next five years
- We intended to fortify our sale to five times of present sale and is also planning to dominate
- In another sector as well and enter new segment of Helminthic.
- Also, in the upcoming years we are also going to launch 2 new products in market zygosora 85 and Zygolip 21.

About the Product

Drug description

- **Saxagliptin is an orally active inhibitor of the DPP4 enzyme.**
- **Formula-** C₁₈H₂₅N₃O₂
- **Other names-** SGL-2159
- **Elimination half-life-** 2.5 h (saxagliptin), 3.1 h (main metabolite)
- **Metabolism-** Hepatic (CYP3A4 and CYP3A5)



- **Saxagliptin is an anti-diabetic drug that is taken orally. It is majorly used for type 2 diabetes.**
- **The global saxagliptin market is driven by factors such as increasing incidence of diabetes, growing risk factors such as changing lifestyle, reduced physical exercise that lead to diabetes, complexities in alternative therapies for diabetes, and high obesity.**
- **Be that as it may, an exacting administrative structure for diabetic medications and unfriendly impacts of saxagliptin, for example, upper respiratory plot contamination, urinary lot disease, and cerebral pain will control the market development.**
- **Innovative R&D activities in the field of diabetes therapeutics and growth opportunities in the emerging economies of Asia-Pacific and provide the growth opportunities for the market growth.**
- **The report segments the global saxagliptin market based on dosage and region.**
- **Based on dosage, it is segmented into 2.5 mg tablets and 5 mg tablets.**

Uses

- Saxagliptin is utilized with an appropriate eating routine and exercise program to control high glucose in individuals with type 2 diabetes.
- Controlling high glucose forestalls kidney harm, visual deficiency, nerve issues, loss of appendages, and sexual capacity issues.

- Proper control of diabetes may likewise reduce your danger of respiratory failure or stroke.
- Saxagliptin works by expanding levels of normal substances called incretins. Incretins help to control glucose by expanding insulin discharge, particularly after a feast. They likewise decline the measure of sugar your liver makes.
- It additionally improves glycaemic control in grown-ups with type 2 diabetes mellitus

Limitations

- Saxagliptin is not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis, as it would not be effective in these settings.

Dosage and administration

- The recommended dosage is 2.5 mg or 5 mg once daily taken regardless of meals. The tablets must not be split or cut.

Mechanism of action

- Saxagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor antidiabetic for the treatment of type 2 diabetes.
- DPP-4 inhibitors are a class of aggravates that work by influencing the activity of characteristic hormones in the body called incretins.
- Incretins decline glucose by expanding the utilization of sugar by the body, basically through expanding insulin creation in the pancreas, and by diminishing the creation of sugar by the liver.
- DPP-4 is a film-related peptidase that is found in numerous tissues, lymphocytes, and plasma.
- DPP-4 has two primary components of activity, an enzymatic capacity, and another instrument where DPP-4 ties adenosine deaminase, which passes on intracellular signs utilizing dimerization when actuated.
- Saxagliptin structures a reversible, histidine-helped covalent bond between its nitrile gathering and the S630 hydroxyl oxygen on DPP-4.

- The hindrance of DPP-4 expands levels dynamic of glucagon-like peptide 1 (GLP-1), which restrains glucagon creation from pancreatic alpha cells and builds the creation of insulin from pancreatic beta cells.

Pharmacodynamics

- In patients with type 2 diabetes mellitus, organization of saxagliptin hinders DPP4 catalyst action for a 24-hour time frame.
- After an oral glucose load or a supper, this DPP4 hindrance brought about a 2-to 3-crease increment in circling levels of dynamic GLP-1 and GIP, diminished glucagon fixations, and expanded glucose-subordinate insulin discharge from pancreatic beta cells.
- The ascend in insulin and diminishing in glucagon were related with lower fasting glucose focuses and decreased glucose journey following an oral glucose load or a feast.

About the disease

- Uncontrolled Diabetes may lead to serious consequences like diabetic and Neuropathy
- Disease that occurs when your blood glucose level is too high.
- Blood glucose is the main source of energy and it comes from the food over we eat and the glucose we eat is stored throughout the body primarily in the liver and regulate the amount of sugar in the blood.
- The management of glucose level relies upon the release of insulin by pancreas (beta cells).
- There are two major hormones released by pancreatic exocrine gland.
- Type 2 diabetes can affect all people, regardless of age. Early symptoms of

type 2 diabetes may be missed, so those affected may not even know they have the condition. An estimated one out of every three people within the early stages of type 2 diabetes are not aware they have it.

- Diabetes meddles with the body's capacity to utilize starches for vitality, prompting elevated levels of glucose. These constantly high glucose levels increment an individual's danger of creating genuine medical issues.
- Type 1 Diabetes: - It is a condition wherein our insusceptible framework obliterates insulin making cell in our pancreas. These are called beta cells. The condition is normally analyzed in youngsters and youngsters, so it is called as adolescent diabetes.
- Type 2 Diabetes: - it is an incessant ailment wherein sugar, or glucose level develop in our circulation system. For this situation our body's cells can't react to insulin.
- Gestational Diabetes: - It is a condition wherein our glucose level turns out to be high during pregnancy. It influences up to 10% of ladies who are pregnant. It happens when we eat, at that point our pancreas discharge cells, which use it for vitality. During pregnancy, our placenta makes hormones that cause glucose to develop our blood then a lady experiences gestational diabetes.

Management

- Diabetes is a serious disease that you cannot treat by own.
- Treatment of diabetes requires keeping close watch over your blood sugar level, first line therapy is exercise, and diet if then also sugar level is not controlled then medication were given by physician.
- By paying close attention to what and when we eat, we can also

minimize the effect of rapidly changing blood sugar levels, which can require quick changes in medication dosages, especially insulin.

- Various other factors include
 - Diabetes drugs
 - Nutrients and meal timing are determined
 - Proper exercise
 - Use medical device kit to detect diabetes
 - Other (natural factors)
 - Herbal Remedies
 - Supplements like vitamins and minerals (vitamins B6 & B12, Vitamins C, Vitamins E, Magnesium)
 - Diet Exercise
 - Relaxation Techniques

Problems faced by Diabetic Patients

- In India most of the peoples suffers from type 2 diabetes it is a common disease in all over India.
- More than 60 million people with diabetes live in India.
- It causes Cardiovascular disorder, {these are the long-term diabetic complication if sugar level is not controlled Retinopathy, Nephropathy, Peripheral Neuropathy} which are responsible for severe morbidity and mortality cases in India.
- The main reason for ever increasing diabetic case in India is due to Lack of awareness of prediabetes

How we can solve the problems faced by Diabetic Patients

- We can provide some awareness with the help of campaign and advertisement
- Also, we could conduct various webinar sessions and workshop
- We could provide them with a proper diet plan and instruction them about the disease effect and importance
- we could guide them in obtaining sufficient knowledge regarding medicines

Situational Analysis

Company name: - Canopus Pharmaceuticals

Ranking in india-15

Sales turnover 1600 crore a year

Field force- 900 medical reps and 200 field line manager

- **Has some strong brands in their portfolio including linagliptin, which contribute to around 35% of the revenue of Canopus.**
- **Plans to launch Saxagliptin a DPP4 receptor antagonist to help Canopus in diabetes portfolio**

WHY SAXAGLIPTIN

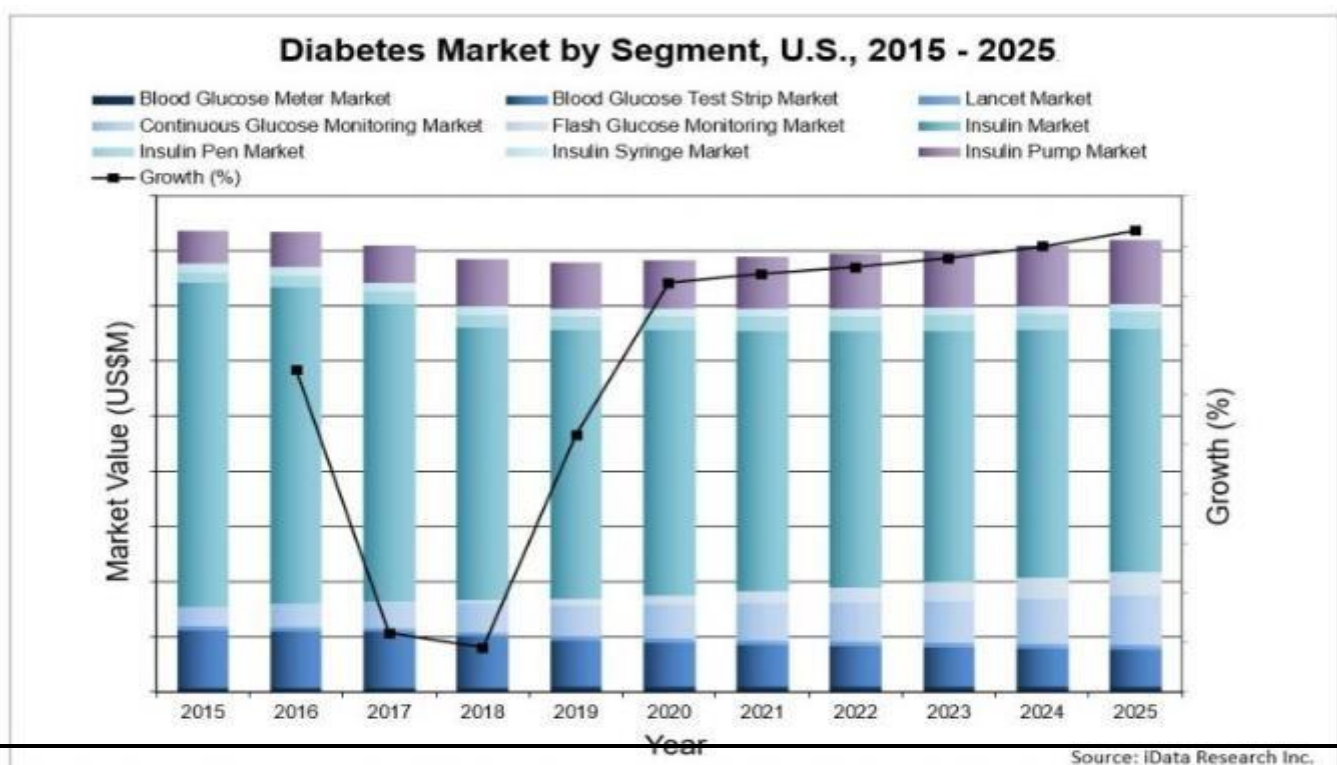
Why is this medication prescribed?

- Saxagliptin is used along with diet and exercise to lower blood sugar levels in patients with type 2 diabetes (condition in which blood sugar is too high because the body does not produce or use insulin normally).
- Saxagliptin is in a class of medications called dipeptidyl peptidase-4 (DPP-4) inhibitors.
- It works by increasing the amount of insulin produced by the body after meals when blood sugar is high.

- Saxagliptin is not used to treat type 1 diabetes (condition in which the body does not produce insulin and, therefore, cannot control the amount of sugar in the blood) or diabetic ketoacidosis (a serious condition that may develop if high blood sugar is not treated).
- Over time, people who have diabetes and high blood sugar can develop serious or life-threatening complications, including heart disease, stroke, kidney problems, nerve damage, and eye problems.
- Taking medication(s), making lifestyle changes (e.g., diet, exercise, quitting smoking), and regularly checking your blood sugar may help to manage your diabetes and improve your health.
- This therapy may also decrease your chances of having a heart attack, stroke, or other diabetes-related complications such as kidney failure, nerve damage (numb, cold legs or feet; decreased sexual ability in men and women), eye problems, including changes or loss of vision, or gum disease.
- Your doctor and other healthcare providers will talk to you about the best way to manage your diabetes.

MARKET VALUE PERSPECTIVE

- By 2019, the U.S. diabetes monitoring, treatment, and drug delivery market was valued at \$15.7 billion while the European market was valued at €6.8 billion.
- The US market is expected to grow by 0.6% and reach \$16.4 billion by 2025.
 - However, the European diabetes market is expected to experience a higher growth of 4.3% and reach €9 billion by 2025.



- Reference taken from I Data Research

COMPETITORS

- Key players that operate in the market include Bristol-Myers Squibb Company and AstraZeneca plc.
- Also includes some top Indian MNC companies like Dr. Reddy's, Torrent, Intas, Sun pharma



- Januvia (Sitagliptin 25mg, 50mg, 100mg tablets)
- Janumet (sitagliptin and metformin)
- Galvus (vildagliptin)

BRAND NAMES OF COMBINATION PRODUCTS

- Kombiglyze XR (containing Metformin, Saxagliptin)
- Qtern (containing Dapagliflozin, Saxagliptin)
- Qternmet XR (containing Dapagliflozin, Metformin, Saxagliptin)

SWOT analysis

Strength

- Strong growth in emerging market
- Zygolipa is very strong in the chronic segment.
- Big market for gliptins i.e. zygolipa with
- CAGR of 8% growth rate of other gliptins like vildagliptins
- Zygolipa is prescribed by huge
- set of doctors like diabetologist, endocrinologist, consulting physicians

Weakness

- Not yet approved by US-FDA
- Often may be required to be combined with metformin.
- Late entrant in the marketplace among (gliptin)

Opportunity

- Growing population of diabetics in India
 - The potential in the Indian market is very high because India is a diabetic capital of the world
 - The large population of young prediabetics who can become diabetic patients
-
- Diabetic patient is becoming epidemic with increase in prevalence in India.
 - Increase in Resistant
 - Unique formulation helps in drug effectiveness compared to existing brands
 - Compliance / dose convenient pack for patients

Threats

- Growing competition in generic market
- Drug pricing control methods in India
- Competition from developing countries is increasing.
- Transport infrastructure and storage facilities for temperature-sensitive drugs are not readily available.
- More number of me-too products will be launched with lesser price
- Generic variations of Saxagliptin could be sold
- Government regulations like price barrier could be introduced
- 12 brands are already available in the market
- Top 3 brands with low pricing strategy has 30% of market share

STRATEGY AND PLANNING

Segmentation

- My target segmentation is the consulting physician, diabetologist and endocrinologist who detect diabetes and among them one who generally prescribe my competitor brand.

Key benefits of Brand

- Zygolipa has smooth and gentle glycemic control.

USP of Brand

- Zygolipa can be used in mono dual and tri therapy
- It can be employed in various dosage forms and it generally stable
- It can be mix with other composition as well
- It must be taken twice a day only

Value Proposition

- Zygolipa works by increasing levels of natural substances called incretins. Incretins help to control blood sugar by increasing insulin release, especially after a meal

Positioning Statement

- Zygolipa is a product for treating type 2 diabetes
- Zygolipa benefits the hypoglycemic effects and emotional difficulties to executives who go to Diabetologist, endocrinologist and consulting physician with with (executive functions disorder the ability to take decision keeping in mind future events better) than other gliptin.
- We do this by (it energizes the body and maintain the blood sugar level).

Positioning Message

- Zygolipa brings a smile on millions of the patients who are suffering from diabetes”

Forecasting

- In my company 600 medical representative are working and in every month 1 medical representative sell 5 boxes and each strips MRP is 315 Rs
- Annual Forecasting

<u>MONTH</u>	<u>YPPPM (yield per person per month)</u>
MAY 20 – JULY 20	40

AUG 20 – OCT 20	55
NOV 20 – JAN 21	70
FEB 21 – APRIL 21	85

Expected Sales

Sales expected to be performed in year 2020-21 (40+55+70+85*900{MR})

=2,25,000 unit

MRP of Saxagliptin is 320 ₹

Minus GST @18% = ₹262.4

Margin to retailer is @20% of ₹262.4 = ₹209.92

Margin is 10% of 209.92 = ₹188.928

Margin to C&F @1% = ₹187.038

NRV = 320 ₹ – 187.038 ₹

=132.962 ₹

Sales revenue will be- Total unit * NRV

=2,25,000*132.962

=2,99,16,450 ₹

NRV-COGM (cost of goods and manufacturing)-SPE (sales promotional expenses)

=132.962-53.1848

=79.778

Budgeting

Expenses	Rupees
Advertisement	15,00,000
Literature	20,000
Mailing	1,00,000
Exhibition	60,000
Symposia (national)	1,00,000
Symposia (international)	1,80,000
Sponsorship	80,000

Gift	1,00,000
Other contingency	75000
Total Expenses	1421500

Profit and loss Statement

BRAND P&L	Total
Sales (Rs.)	2,99,16,450
Less Cost of goods (COGS) (40% of sales)	1,19,66,580
Gross Margin (Rs.)	1,79,49,870

Less Advt. & Promo (A&P) (20% of sales)	59,83,290
Less Selling Expenses (4% of sales)	11,96,658
Less Marketing Expenses (20% of sales)	59,83,290
Less Distribution Expenses (5% of sales)	14,95,822.5
Gross Profit Before Tax (PBT)	2,99,16,450-1,46,59,060.5 =1,52,57,389.5

Conclusion

In conclusion, branding is about building consumer trust in an organization's products. Globalization and communication mediums are making a wider target audience possible. As a result, companies are investing heavily into marketing campaigns that can boost the value of their brand.

Companies like Dr. Reddy's, Torrent, Intas, Sun pharma. understand the impact the brand value has on their sales and profits. They also understand the need for stakeholders to believe in a brand. Hence, they spare no expense when marketing the products that will help them to project the desired image.

Also, branding strategy plays a major role on the general marketing strategy concept. Emotional branding is each day more developed in the contemporary world. Pfizer seems to have made a very good contribution on this sector and this can be seen clearly by looking at its annual reports and the sales volumes. However, as many marketers suggest it is not only the marketing strategy but the overall organization culture that contributes to the brand of the company and how the brand image is perceived by consumers. Nowadays, when competition is too high firms should not disregard this and there should be a continuous investment on how to improve and how to retain their brand image and competitive position in the market.

Execute brand plan

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