



POTENTIAL OF HORMONAL AND STEROIDAL PREPARATIONS IN EUROPEAN MARKETS

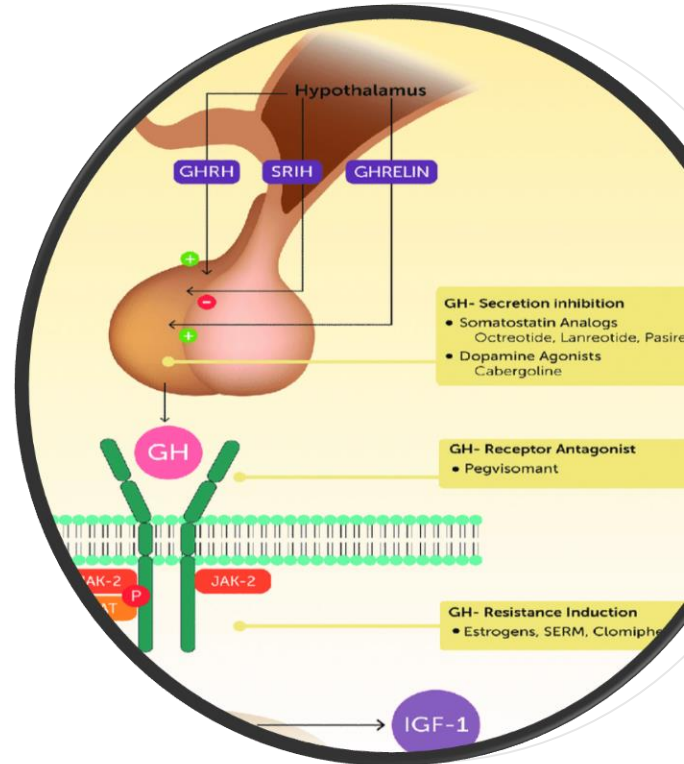
LANREOTIDE:

Indication:

It is used in the management of acromegaly and symptoms caused by neuroendocrine tumors, most notably carcinoid syndrome.

❖ MECHANISM OF ACTION

- Lanreotide is a somatostatin analogue and has mainly inhibitory effects which are mediated via somatostatin receptors (SSTRs) 2 and 5 and include inhibition of growth hormone release in the brain.
- Lanreotide binds to the same receptors as somatostatin, although with higher affinity to peripheral receptors, and has similar activity.
- However, while somatostatin is quickly broken down in the body (within minutes), Lanreotide has a much longer half-life, and produces far more prolonged effects.
- During the initial phase, the molecule Octreotide was also used for the treatment of acromegaly, but Lanreotide was more effective.



Octreotide

- Brand name : Sandostatin
- Sales(2018): \$422bn US
- Growth rate(2017–2018):0.53%
- CAGR (2016–2018) : 0.26%
- Market type: Mixed market

Lanreotide

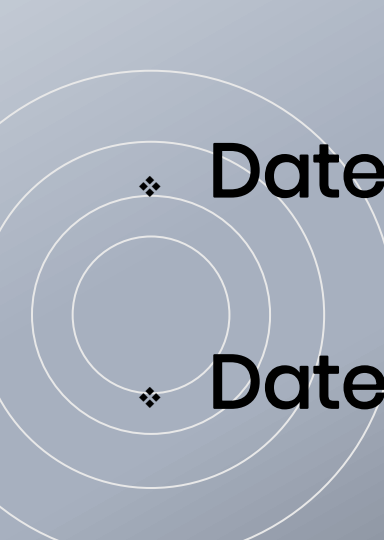
- Brand name : Somatuline P.R.
- Sales(2018): \$400bn US
- Growth rate(2017–2018):10.71%
- CAGR (2016–2018) : 5.22%
- Market type: Patented Product (till 8th March 2020)

Innovator Details:

- ❖ Trade Name: Somatuline P.R.
- ❖ Strength: a)Eq 60mg Base/0.2ml
b)Eq 90mg Base/0.3ml
c)Eq 120mg Base/0.5ml
- ❖ Mode Of Administration:
Subcutaneous Injection
- ❖ Presentation: PF Syringes



Somatuline® Depot
(lanreotide) Injection 120 mg

- 
- ❖ **Date Of Patent Approval:** 30 Aug 2007
 - ❖ **Date Of Patent Expiry:** 8th March 2020
 - ❖ **Company:** IPSEN PHARMA (France)
 - ❖ **Mechanism Of Action:** Somatostatin Receptor Agonist



SITUATION ANALYSIS



1

THERAPY AREA

- ✓ **HORMONES (HIC Hypothalamic Hormones)**
- ✓ In this therapy area, there was only one patented product Somatuline P.R. till 8th of March 2020.
- ✓ After this date it is expected that there will be lot of new companies entering in the market.

2

PREVALENCE AND INCIDENCE

- ✓ The prevalence of acromegaly is approximately 2.8 – 13.7 per 100,000 individuals worldwide.
- ✓ The newly diagnosed cases of acromegaly is approximately 0.2 – 1.1 per 100,000 individuals worldwide.

3

HORMONES THERAPY SIZE

- ✓ EUROPE : 4.52 BILLION USD
- ✓ CAGR: 0.7% from year 2016-2018
- ✓ After the careful analysis and understanding of the data, the molecules shortlisted on the basis of Growth%, High value abd CAGR were as follows:

Sr.NO	Name of the Molecule	LC\$ MNF	LC\$ MNF	GROWTH	LC\$ MNF	GROWTH	CAGR(2016-2018)	Units	Units	GROWTH	Units	GROWTH
		MAT Q4 2016	MAT Q4 2017	%	MAT Q4 2018	%		MAT Q4 2016	MAT Q4 2017	%	MAT Q4 2018	%
1	SOMATOTROPIN	861695005	882418323	2.40%	894879878	1.41%	1.91%	3995521	3987431	-0.20%	4026861	0.99%
2	OCTREOTIDE	421654670	420133898	-0.36%	422347480	0.53%	0.08%	2941517	2886893	-1.86%	3024164	4.75%
3	LANREOTIDE	321646688	362100595	12.58%	400891745	10.71%	11.64%	252479	277846	10.05%	300627	8.20%
4	TERIPARATIDE	261229352	274614019	5.12%	277578905	1.08%	3.08%	660871	695448	5.23%	714155	2.69%
5	ULIPRISTAL ACETATE	106428762	132256554	24.27%	69454428	-47.49%	-19.22%	2696546	3193539	18.43%	2589794	-18.91%

- ✓ EUROPE : 400 MILLION USD IN 2018
- ✓ CAGR: 11.64% from year 2016–2018
- ✓ The Big Fours of Europe(U. K , Italy, Germany, France) along with Spain add about 70% of the market share for value of Lanreotide in Europe.
- ✓ The Big Fours of Europe(U. K , Italy, Germany, France) along with Spain add about 69% of the market share for units of Lanreotide in Europe.

Sr.NO	Name of the	LC\$ MNF	Market Share	LC\$ MNF	GROWTH	Market Share	LC\$ MNF	GROWTH	Market Share	Units	Market Share	Units	GROWTH	Market Share	Units	GROWTH	Market Share
	country	MAT Q4 2016	% MAT Q4 2016	MAT Q4 2017	%	% MAT Q4 2017	MAT Q4 2018	%	% MAT Q4	MAT Q4 2016	% MAT Q4 2016	MAT Q4 2017	%	% MAT Q4 2017	MAT Q4	%	% MAT Q4 2018
1	FRANCE	73723179	22.92%	82074652	11.33%	22.67%	88432390	7.75%	22.06%	55755	22.08%	60796	9.04%	21.88%	64402	5.93%	21.42%
2	GERMANY	52336154	16.27%	58597021	11.96%	16.18%	70817026	20.85%	17.66%	16190	6.41%	17788	9.87%	6.40%	20922	17.62%	6.96%
3	ITALY	38693878	12.03%	44896482	16.03%	12.40%	49641434	10.57%	12.38%	40337	15.98%	43173	7.03%	15.54%	46918	8.67%	15.61%
4	SPAIN	29189789	9.08%	31872703	9.19%	8.80%	33985962	6.63%	8.48%	25857	10.24%	28383	9.77%	10.22%	30291	6.72%	10.08%
5	UK	28561375	8.88%	35107757	22.92%	9.70%	40279189	14.73%	10.05%	32726	12.96%	38782	18.51%	13.96%	43356	11.79%	14.42%

PREVALENCE

DIAGNOSIS

Mean age: 40 years in males.
45 years in females.
Race: No racial predilection to acromegaly

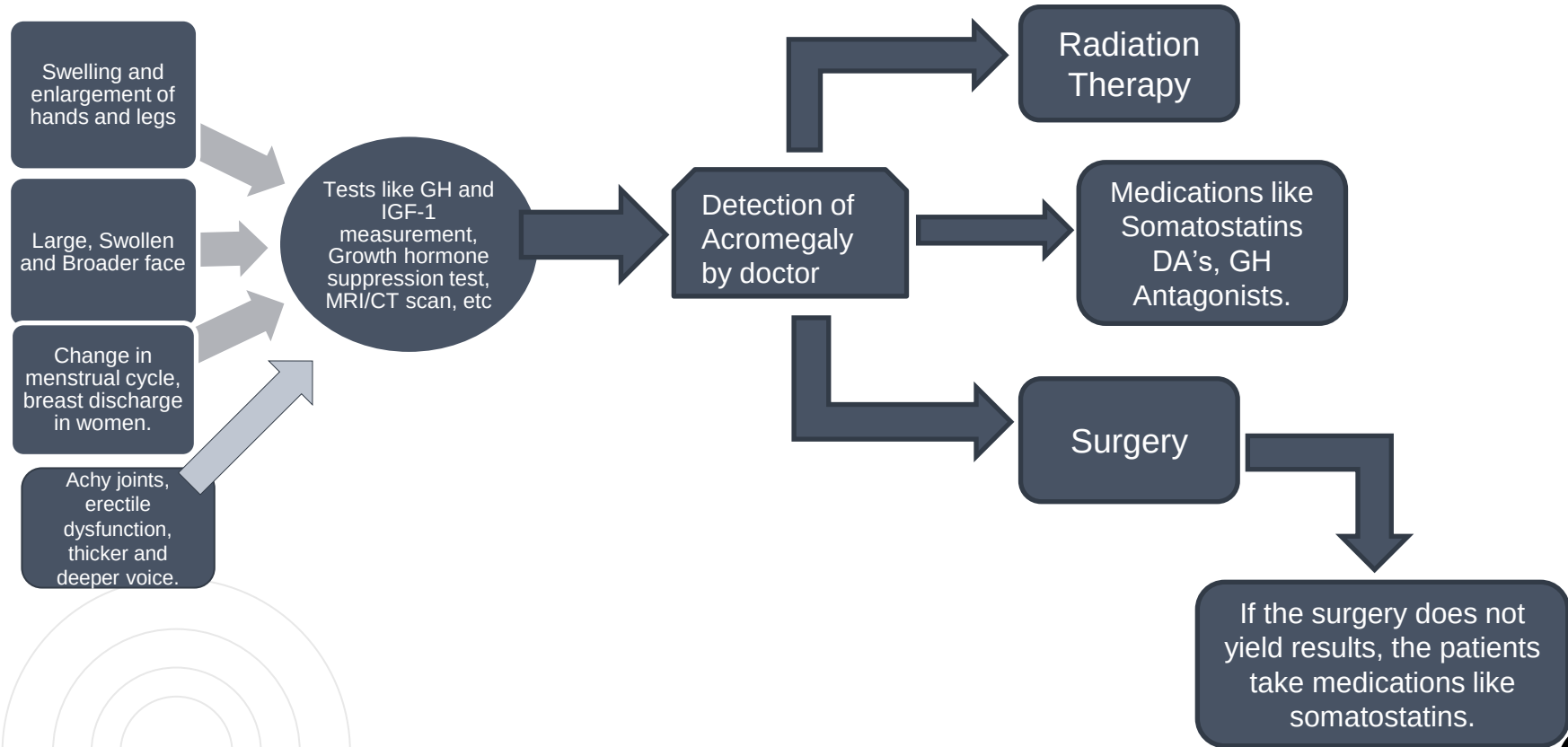
AFFORDABILITY

1. GH and IGF-1 measurement
2. Growth hormone suppression test
3. Imaging like MRI or CT scan

2.8 – 13.7 per
100,000
individuals
worldwide.

Medicinal
costs:\$12000-
\$14000/Annum.
In case of surgery, it
may reduce the annual
costs.

PATIENT JOURNEY





STRENGTHS

WEAKNESSES

OPPORTUNITIES

THREATS

SWOT ANALYSIS OF LANREOTIDE



S

- ✓ Low frequency of administration as against combination therapy of DA's and GH antagonists.
- ✓ Better Affordability
- ✓ Highly effective therapy for GEP-NET's (Gastroenteropancreatic-Neuroendocrine Tumors), Carcinoid syndrome and Acromegaly.
- ✓ Effectively reduces use of Short acting Somatostatins.



W

- ✓ Lack presence on the social media.
- ✓ Less awareness among the masses.
- ✓ High costs on marketing.
- ✓ Can only be administered by HCP's.

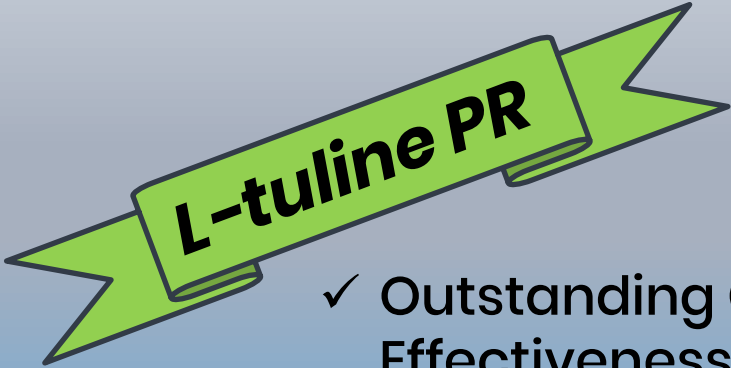


- ✓ To increase presence on the social media.
- ✓ To reach out to the lower income groups with low cost medicines.
- ✓ To target HCP's in Hospitals, Clinic's and Govt tenders.
- ✓ To establish strong Supply Chain for increased availability.



T

- ✓ Presence of established players in the market.
- ✓ Increase in the new entrants.
- ✓ Changing policies of the government.
- ✓ Environmental factors.
- ✓ Acceptance by the HCP against the branded product.



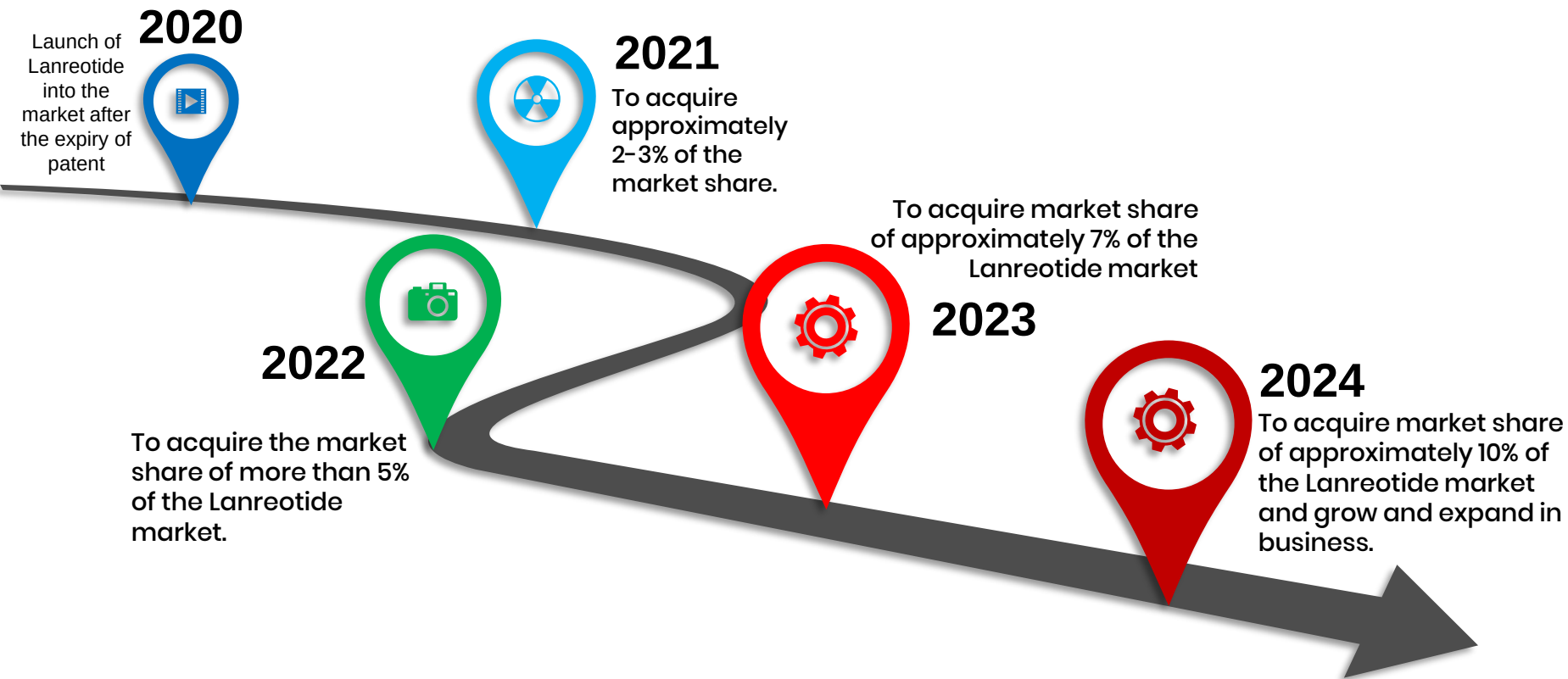
L-tuline PR

PRODUCT OFFERING

- ✓ Outstanding Clinical Success with safety and Effectiveness in the treatment of GEP-NET's and Carcinoid syndrome.
- ✓ Provided with adequate and varying doses to meet the patients need.
- ✓ Proper and advanced mechanism for the proper delivery of the doses.
- ✓ Cost effective alternative to Branded products.
- ✓ An innovative tool along with the product so as to break the needle to avoid its reuse.

By: Global Pharma Pvt Ltd 

GOALS AND OBJECTIVES



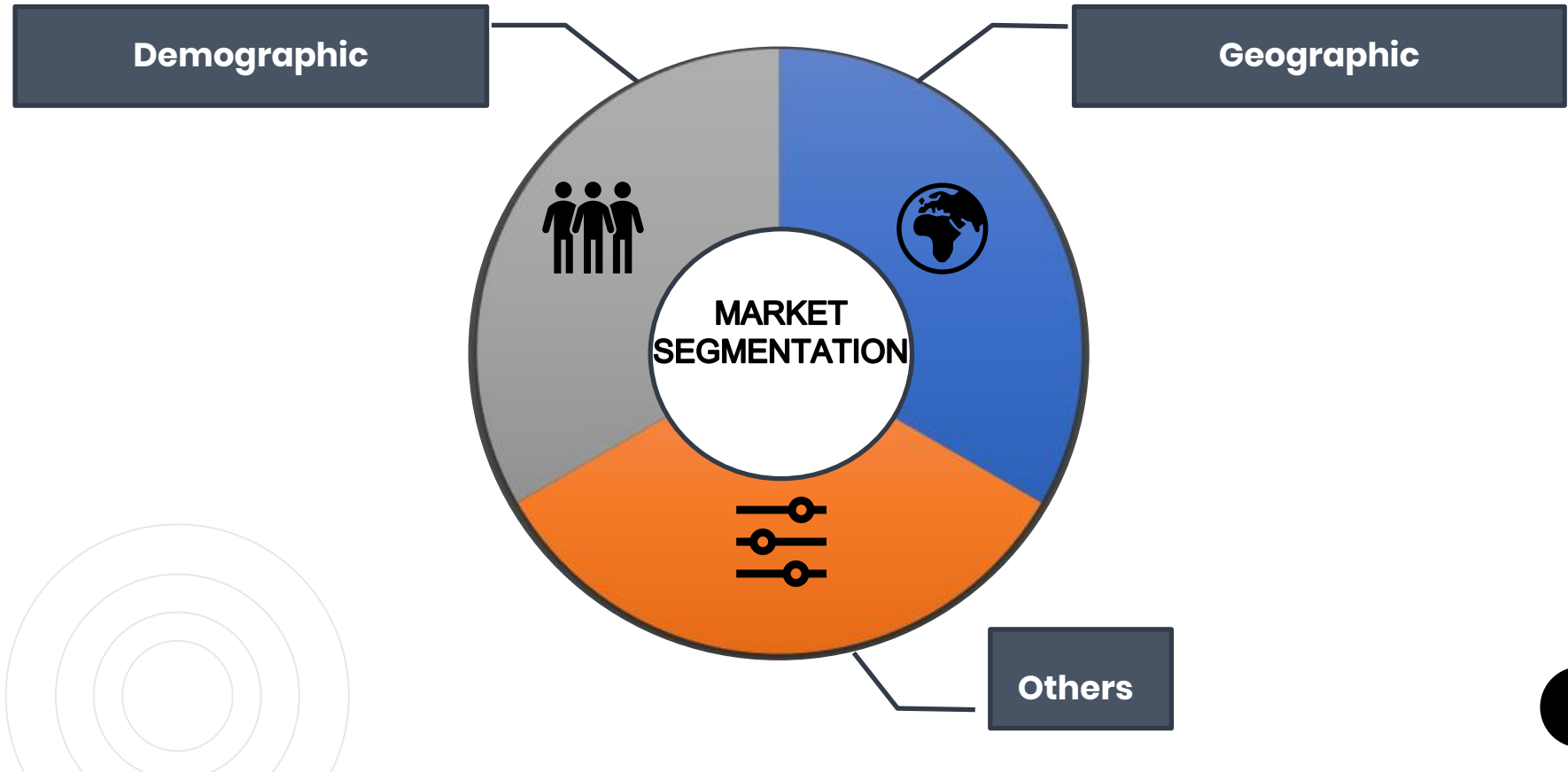
GOALS AND OBJECTIVES

Year	MAT Q4 Value	
2016	Existing value of the Lanreotide market	\$321,646,688.00
2017		\$362,100,595.00
2018		\$400,891,745.00
2019	Forecasted value of Lanreotide market	\$440,980,920.00
2020		\$480,669,203.00
2021		\$519,122,739.00
2022		\$555,461,331.00
2023		\$594,343,624.00
2024		\$630,004,241.00

Expected revenue generation from L-tuline till 2024

Year	Market Share	Revenue(\$)
2021	3%	\$ 15,573,682.00
2022	5%	\$ 27,773,066.00
2023	7%	\$ 41,604,053.00
2024	10%	\$ 63,000,424.00

SEGMENTING, TARGETING AND POSITIONING

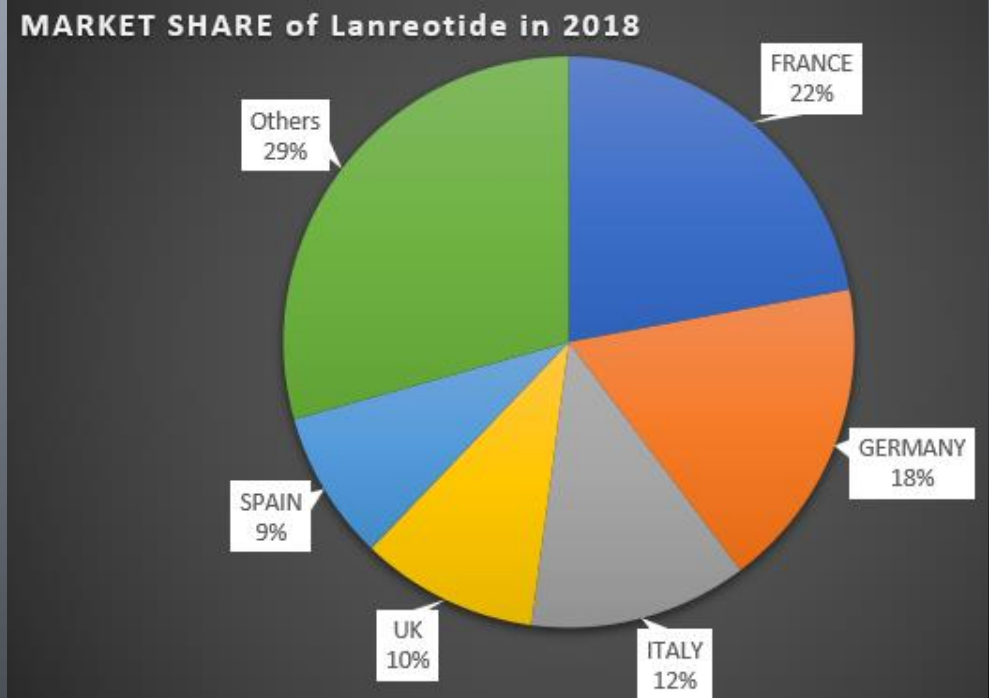


DEMOGRAPHIC SEGMENTATION



GEOGRAPHIC SEGMENTATION

- In Europe, the Big Fours(France, Germany, Italy, U.K) along with Spain contribute about 71% of the market share.
- The remaining 29% of the market share is contributed by the remaining 20 countries.



GEOGRAPHIC SEGMENTATION

- Based on the following data, the countries that can be targeted based on the high value, CAGR and Growth rate.
- The prospective countries are Germany, U.K. Austria, Slovakia.

Sr.NO	Name of the	LC\$ MNF	LC\$ MNF	GROWTH	LC\$ MNF	GROWTH	CAGR	Units	Units	GROWTH	Units	GROWTH	CAGR	Price	Price	Price
	Country	MAT Q4 2016	MAT Q4 2017	%	MAT Q4 2018	%	(2016-2018)	MAT Q4 2016	MAT Q4 2017	%	MAT Q4 2018	%	(2016-2018)	MAT Q4 2016	MAT Q4 2017	MAT Q4 2018
1	ROMANIA	1943504	2671112	37.44%	3288726	23.12%	30.08%	2706	3585	32.48%	4258	18.77%	8.98%	1254.196146	1253.758603	2191.137894
2	SLOVAKIA	1963851	2152412	9.60%	2892310	34.38%	21.36%	1935	2096	8.32%	2778	32.54%	15.13%	3554.783535	2861.089249	2857.766232
3	UK	28561375	35107757	22.92%	40279189	14.73%	18.75%	32726	38782	18.51%	43356	11.79%	5.73%	9690.863084	7185.363421	7185.69924
4	GERMANY	52336154	58597021	11.96%	70817026	20.85%	16.32%	16190	17788	9.87%	20922	17.62%	8.45%	122056.9687	127054.1381	170183.2778
5	IRELAND	2868251	3384898	18.01%	3855067	13.89%	15.93%	2317	2691	16.14%	3097	15.09%	7.28%	8080.515395	8002.628468	7957.928912
6	AUSTRIA	5008881	6306502	25.91%	6687320	6.04%	15.55%	3459	4281	23.76%	4503	5.19%	2.56%	9943.299524	15304.73405	16806.78148
7	ITALY	38693878	44896482	16.03%	49641434	10.57%	13.27%	40337	43173	7.03%	46918	8.67%	4.25%	5856.192816	6170.240092	6170.356534
8	FRANCE	73723179	82074652	11.33%	88432390	7.75%	9.52%	55755	60796	9.04%	64402	5.93%	2.92%	9399.874129	9396.147714	9394.526892
9	SPAIN	29189789	31872703	9.19%	33985962	6.63%	7.90%	25857	28383	9.77%	30291	6.72%	3.31%	6951.352366	6933.622825	6933.618073

TARGETING

A) Doctors like:

- 1) **ENT Specialists**
- 2) **Surgeons**
- 3) **Endocrinologists,**
- 4) **Gastroenterologists,**
- 5) **Oncologists,**
- 6) **Surgeons And Intensive Care Specialists.**



B) Patients diagnosed with:

- 1) **GEP-NET's**
- 2) **Carcinoid syndrome**
- 3) **Acromegaly.**



POSITIONING

Positioning statement:-

- 1. Leveraging expertise from development to commercialization.**
- 2. Best in class innovative solutions along entire treatment paradigm.**

For : ENT SPECIALISTS, SURGEONS, ENDOCRINOLOGISTS, GASTROENTEROLOGISTS, ONCOLOGISTS, SURGEONS AND INTENSIVE CARE SPECIALISTS.

- Patient type :** Male and Female (Age: 40-45 and above)
- It is :** Used in the management of acromegaly and most notably neuroendocrine tumors, carcinoid syndrome that inhibits growth hormone release in the brain.

Initiative For In-clinic Effectiveness of Sales Force.

Prior appointment and activity during meeting with the doctor

Launch with a grouped activity during JCC(Joint Call Coverage)

Start with delivering inputs.

Frequent reminder calls on whatsapp, emails and other social platforms.

Campaigning activities with CME's and other inputs.

Supplying to the hospitals, clinics of the HCP and Govt driven hospitals.

Long call: Opening, Interview, Demo, Validation and Closing.

Short call: Opening, Demo and closing.

Brand awareness, reminders, engagement of doctors with various activities, etc.

Prescription watch

Campaign on special days: Doctors day, World Cancer day etc.

Global Pharma CARE

Care, Assistance, Reimburse, Educate

About L-tuline

About diagnosis

Support & Assistance



Help patients navigate the insurance coverage process to determine out-of-pocket costs for treatment



Help with copay assistance for eligible* patients



Provide information on Nurse Home Health Administration



Provide free medication to eligible patients through the Patient Assistance Program



Help minimize delays or interruptions to treatment



Coordinate medication deliveries through specialty pharmacies

1. THE SOCIAL MEDIA PRESENCE:

To create a feeling of trust and likeness towards our company.

2. TO INCREASE INCLINIC EFFECTIVENESS:

To enable the remembrance and brand recall for more sales.

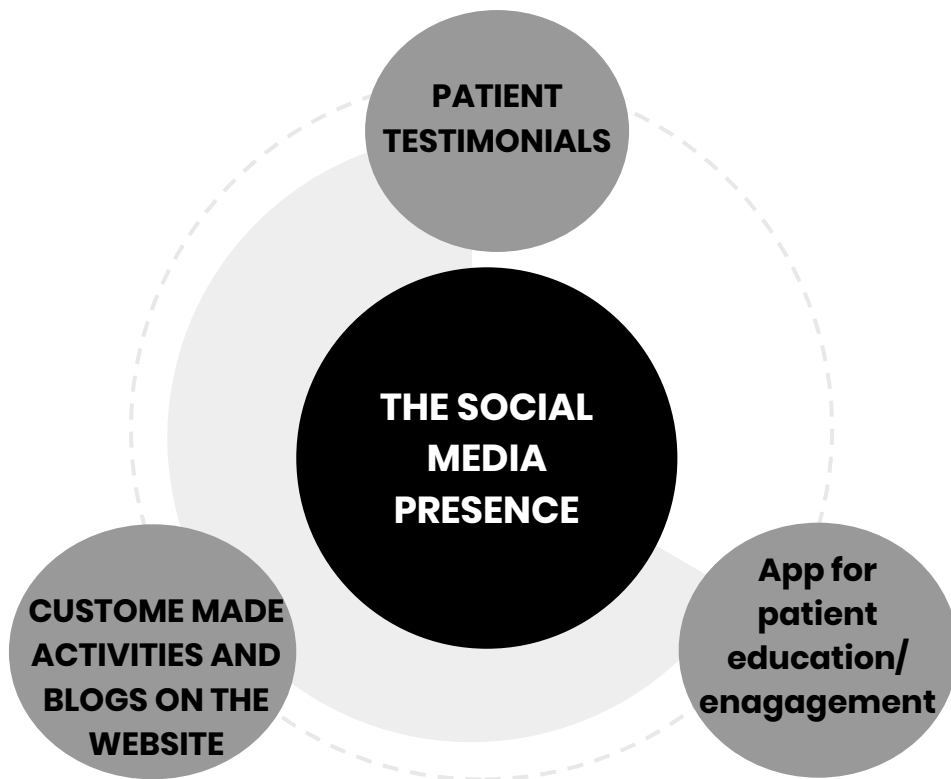
3. TO CREATE AWARENESS/BRAND IMAGE:

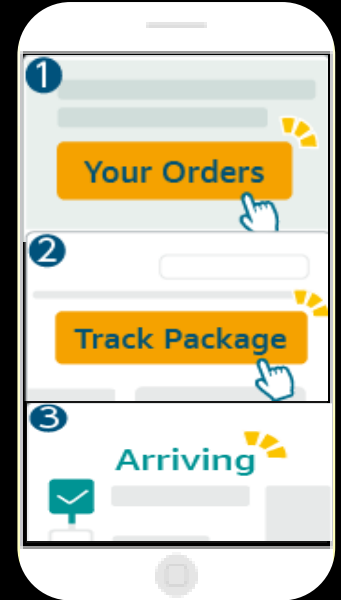
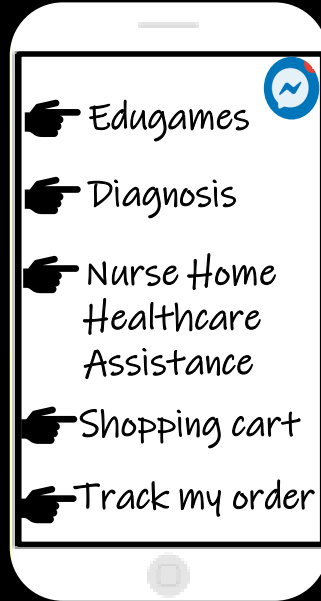
To establish a brand image among the common people.

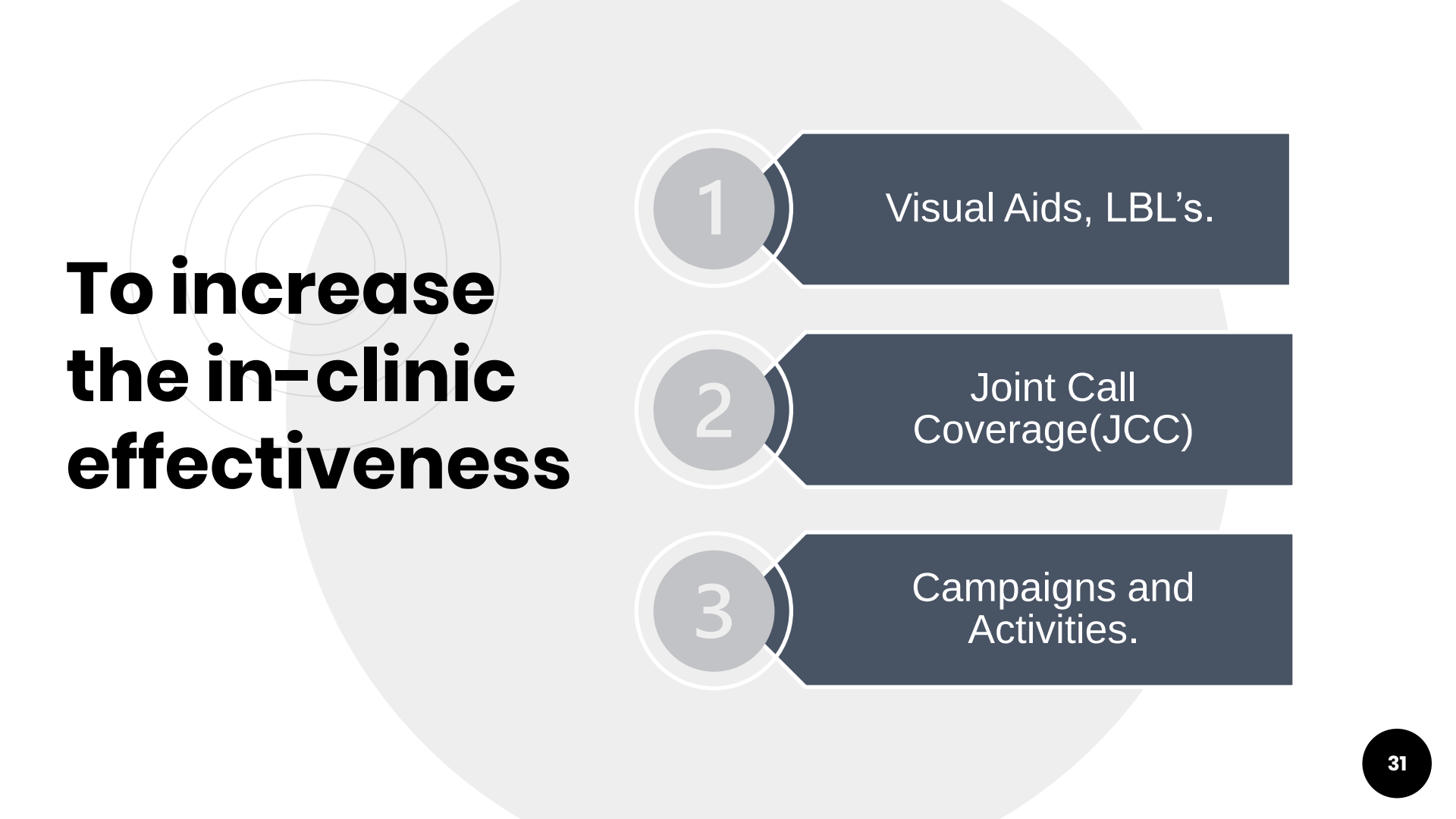


**T
H
E**

SOCIAL MEDIA PRESENCE







To increase the in-clinic effectiveness

1

Visual Aids, LBL's.

2

Joint Call
Coverage(JCC)

3

Campaigns and
Activities.

❖ **LEAVE BEHIND LITERATURE's**

- ✓ This will help developing effective KBL's and KOL's that will be beneficial for the products success.
- ✓ The LBL's help in giving scientific proofs of the Quality standards and the safety profile of the drug along with its proof of treatment.
- ✓ By adding LBL's we can empower the MR's to convince the Doctor's and promote our product thus benefitting the Doctor's, patients and the company.

❖ **JOINT CALL COVERAGE(JCC)**

- ✓ The Joint Call coverage leaves an impact as the HCP's may have unambiguous discussion about the brand thus meeting the expectations of the HCP.



THE MARKETING MIX

PRODUCT:

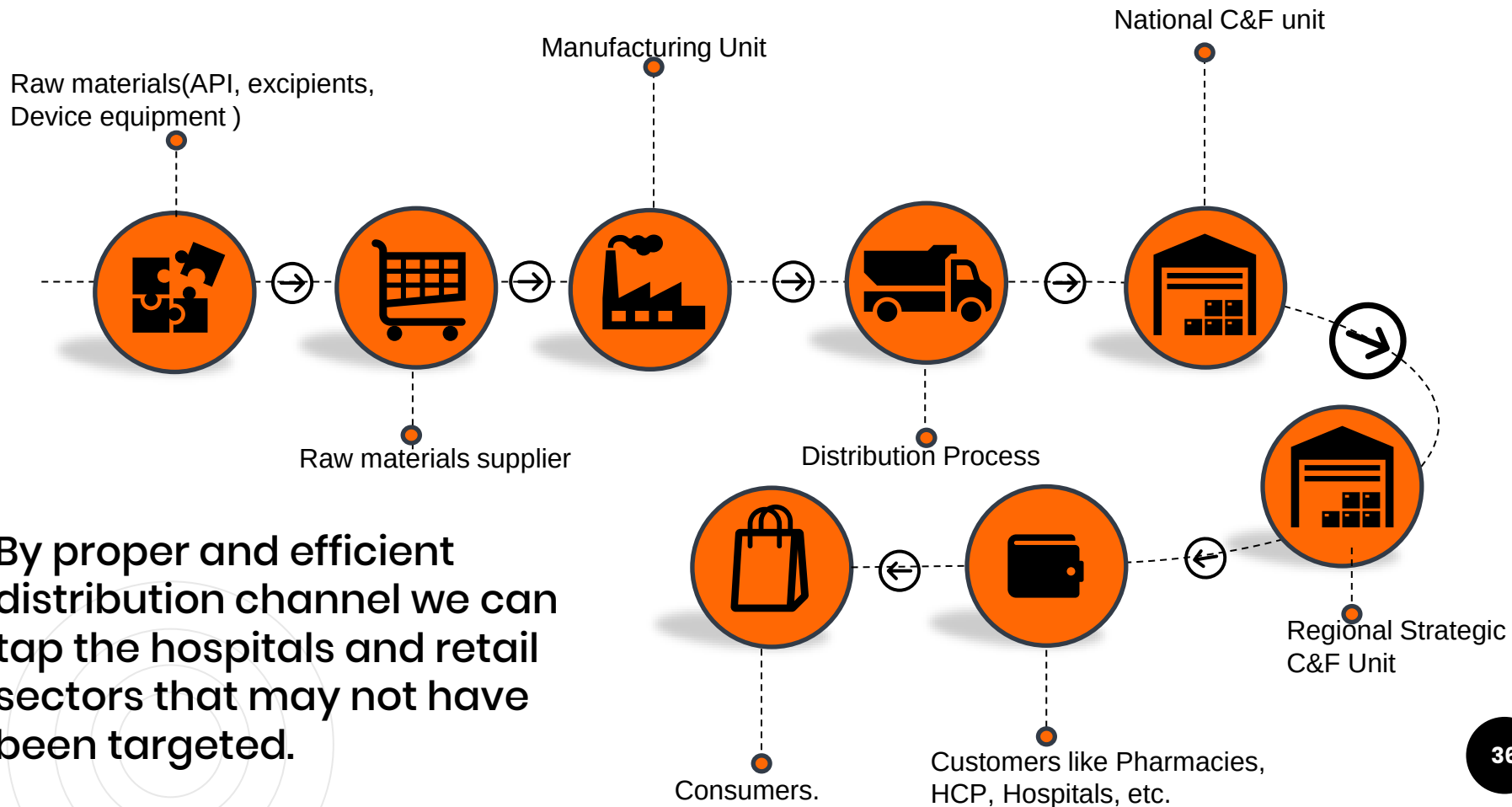
- ❑ **Brand Name:** L-tuline PR
- ❑ **Drug class:** HORMONES (H1C Hypothalamic Hormones)
- ❑ **Strength:** a)Eq 60mg Base/0.2ml
 b)Eq 90mg Base/0.3ml
 c)Eq 120mg Base/0.5ml
- ❑ **Mode Of Administration:** Subcutaneous Injection
- ❑ **Presentation:** PF Syringes
- ❑ **Use:** Used in the management of acromegaly and most notably neuroendocrine tumors, carcinoid syndrome that inhibits growth hormone release in the brain.

PRICE:

- ❖ Since it is a generic product, the price will always be affordable against the Branded product SOMATULINE PR.
- ❖ So, the price for L-tuline depot will be approximately around \$1500/pack.

PLACE:

- In Europe, the availability of the product at Hospitals was only 34.30% whereas in Retail it was 65.70% .
- Thus eyeballing will help enhancing the potential in the Hospital and Retail sector and strengthening the supply chain.



PROMOTION:

- ❖ The promotional techniques have changed over the years and now it involves proof-based marketing like testimonials of the patients, education led marketing.
- ❖ Now a day's doctors have also relied on the various platforms for believing and trusting the products.
- ❖ Also they follow the prescribing patterns of the senior and leading specialists to meet the right treatment methods for the patients.
- ❖ In tough times like the lockdown in COVID-19, the digital marketing hacks play an important role to pitch our product to the doctors thus making a positive impact and developing our KOL's and KBL's.
- ❖ Endorsements, CME's, Community formations for product promotions, Offers, Camps, Special Gifts, etc can be used for the promotion.

CAMPAIGNS AND ACTIVITIES !

1. Activities like CME's can be arranged by the leading surgeons and the doctors thus creating their branding along with our product.

2. Campaign like **"Reasons to Remember"** cases where we will compile and publish a book with some of the complicated cases that the HCP dealt.

Thus making their treatment methods as guideline for future treatments.

3. We will provide **"FOOT SIZE CHART"** that will help the HCP to determine the difference in the size of the feet of their patients over the period of treatment with the particular HCP.

TO CREATE AWARENESS AND BRAND IMAGE

1. Create a community of people who are suffering from the same disease which can bring them together and make it easy to create awareness about the product and their disease.
2. We can carry out campaigns by inviting such communities/patients which will be addressed by leading doctor thus making them aware about the myths and the product.
3. A word-of-mouth will help us establish a stronghold over the people and creating a strong image of our brands into the minds of the people.

By effectively actualizing the exercises referenced in the past slides we would like to advance our brand into the market.



For patients with Acromegaly, GEP-NET's and Carcinoid Tumor.

L-tuline PR

Lanreotide 60mg/90mg/120mg

**Effectively reduces
need of Short Acting
Somatostatins.**

7 Reasons to prescribe L-tuline

- ✓ EASY TO REMEMBER
- ✓ ONCE A MONTH
- ✓ COST EFFECTIVE
- ✓ AVAILABILITY
- ✓ FOR PATIENTS OF ALL INCOME GROUPS
- ✓ QR CODE ON PACK FOR PATIENT EDUCATION .
- ✓ LOW FREQUENCY FOR ADMINISTRATION

First and only
FDA approved
treatment for
GEP-NET's,
Carcinoid
Syndrome And
Acromegaly

**THANK
YOU!**

PRESENTED BY: VIKRANT ATHAVLE, IIHMR UNIVERSITY