Antiretroviral Market Potential and Identification of molecule to Prepare Marketing Plan for Europe Territory

By

Manisha Sharma

Dissertation submitted for the partial fulfillment of the

MBA Pharmaceutical Management

Academic year, 2018-2020

The IIHMR University, Jaipur

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Blue Berry Pharma Advisory

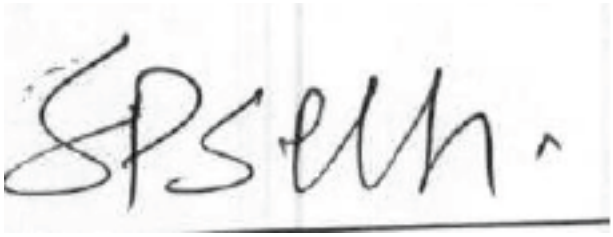
2nd June 2020

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Ms. MANISHA SHARMA student of PGDM AT IIHMR, JAIPUR has undergone summer internship project from 20th February and finished on 22nd May 2020.

The candidate has successfully carried out the study designated during dissertation and her approach to the study has been sincere, and demonstrated positive attitude.

I wish her all the success in her future endeavor.



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THE IIHMR UNIVERSITY, JAIPUR

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled **Antiretroviral Market Potential and Identification of Molecule to Prepare Marketing Plan for Europe Territory** and submitted by **Manisha Sharma** Enrolment No**. IIHMR-U/02/2018-20/0138** under the supervision of **Dr. Sandeep Narula** for award of MBA in Pharmaceutical Management carried out during the period from **February 20th, 2020 to May 22nd, 2020** embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other institute or other similar institution of higher learning.

Signature

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depth knowledge of the working of a hospital.

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TABLE OF CONTENT

SL.NO	TOPIC	page no
1	INTRODUCTION	9
2	RATIONALE OF THE STUDY	19
3	RESEAERCH QUESTION	19
4	RESEARCH OBJECTIVE	19
5	REVIEW LITERATURE	20
6	RESEARCH METHODOLOGY	21
7	TrioLAD PRODUCT DESCRIPTION	22
8	UNDERSTANDING THE SELECTION CRITERIA	23
9	SITUATIONAL ANALYSIS OF ANTIRETROVIRAL MARKET IN EUROPE	25
10	PATIENT FUNNELING OF HIV PATIENT IN EUROPE	27
11	GOAL AND OBJECTIVE FOR TrioLAD	29
12	PATIENT JOURNEY	30
13	SWOT ANALYSIS	31
14	SEGMENTATION, TARGETING AND POSITIONING	33
15	DRIVERS AND BARRIERS OF TrioLAD	36
16	LPBO TABLE	37
17	BRAND STRATEGIES AND TACTICS	38
18	MARKETING MIX	41
19	VISUAL AID FOR TrioLAD	42

TABLE OF FIGURES

Figure 1: People living with HIV by WHO region, 2018…….....14

Figure 2: People receiving ART by WHO region,2018…….……....14

Figure 3: Distribution of new HIV infection by population, Global, 2018…….…….....15 Figure 4: Mechanism of action of TrioLAD……..22Figure 5: The graph represents percentage of the molecules that have grown in value sales$ from year 2016-2018…. 23Figure 6: The graph represents percentage of the molecules that have grown in Unit sales from year 2016-2018……..24Figure 7: Transmission of HIV in Europe…… 25 Figure 8: Awareness of HIV status among the HIV patient in Europe…….....25 Figure 9: Therapy size of Antiretroviral market in Europe and top 2 molecule's market size and share, percentage of business generated from retail and hospital sector…….....……..26Figure 10: Patient funneling of Europe for HIV-1 treatment…….....27Figure 11: Incidence rate and male and female ratio of HIV patient…….……27 Figure 12 : Patient journey of HIV patient…….....30Figure 13: Top 5 countries which contributes 75% of market share in Europe…….....…33Figure 14: Market share of rest of the Europe countries in Anti retroviral market…….....……33Figure 15: percentage of HIV patient with age in Europe…….....…34Figure 16: Education of HIV patient in Europe…….....……34 Figure 17: Distribution channel for TrioLAD…….…...……40 Figure 18: Visual Aid for TrioLAD.……...…….…….42

LIST OF TABLES

Table 1: Global Prevalence and incidence rate of HIV…….....…….....14

Table 2: FDA Approved Antiretroviral drugs……...…….……..21

Table 3 : Percentage of market share of value sales$ and unit sales in 2018…….....…….....25

Table 4: Patient expiration of Antiretroviral drugs from 2005-2022……...……..…27

Table 5: Forecasted market share in value sales $ of Triumeq in Europe……..…….....29

Table 6: Estimated revenue generation for TrioLAD with market share percentage in value sales $.....29

Table 7: Forecasted market share in unit sales $ of Triumeq in Europe……..…...29

Table 8: Estimated revenue generation for TrioLAD with market share percentage in unit sales……...….....29

Table 9: Four top brands of single table regimen…….....…...32

Table 10: Leverage Points Behavioural Objectives…….…….....37

Table 11: Strategies and tactical plan……...……..37

1. INTRODUCTION

1.1 Global Pharmaceutical Market

The worldwide pharmaceuticals worth was $934.8 bn in 2017 and will reach $1170 bn 2021, developing at 5.8%, as indicated by an ongoing pharma statistical surveying report by The Business Research Company.

This is a quickened pace contrasted with 5.2% for the years before 2017 yet is slower than the other two enormous m edicinal services sections, medical equipment, and healthcare services. Medicinal services in general is developing at over 7% year on year.

1.2 European Pharmaceutical Market

The Pharmaceutical Market in EU has an estimation of more than 183 Million €, situating Europe as the second grea test pharmaceutical market on the planet, with Germany, France, Italy, United Kingdom and Spain as top 5 nations. The biggest market is Germany with around 48 Million € which represents 24% of the market.

Europe represents 22% of world pharmaceutical deals and during the period 2012-
2017 and 18% of deals of new medications were on the European market. The all-
out volume of restorative items devoured all around is set to develop about 3% yearly through 2021 and estimations point to a compound yearly development pace of 4% by 2022.

Therapeutic items are progressing at an astounding rate, anyway there are difficulties. The guideline of medications includes thorough gauges and complex administrative condition. Costs and conveyance edges are commonly fixed by governments, and Vat rates contrast altogether from nation to nation in Europe.

Despite these conditions, European pharma advertise keeps up and figures a broad development example and Euro pe is getting progressively appealing to financial specialists. Most likely, for organizations of pharma-
emerging markets is the best an ideal opportunity to investigate openings and business in the European market. Eur ope has embraced all around recognized norms and prerequisites, and the specialists' endeavours to search out new enthusiasm to make a progressively serious and in this way increasingly open market.

Globally,
Antiretroviral therapy Market is valued at 24.48 USD Billion in 2018 and expected to reach USD 33.83 Billion by 2 025 with the CAGR of 4.73% over the forecast period**.**

The Antiretroviral therapy market in Europe was approximately $6.34 bn in 2018.

Acquired Immune Deficiency Syndrome (AIDS)

On June 5th, 1981, the United States Centers for Disease Control and Prevention (CDC) published a *Morbidity and Mortality Weekly Report* (*MMWR*), describing five cases of a rare lung infection, *Pneumocystis carinii* pneumonia (PCP), in young, oth erwise healthy, gay men. Which was later called the **Acquired Immune Deficiency Syndrome (AIDS)** epidemic.[1]

Challenges.

- Long term side effects (e.g. metabolic and cardiovascular) and drug-drug interactions remain a concern.[2]
- Lackoflong term data over a lifetime guide therapy.[3]
- Lackofaccess to HIV therapy.[4]
- The current WHO guidelines recommend that all patients are started on ARV therapy regardless of CD4 T-lymphocyte count.[5]
- Issues related to women surrounding contraception and ARV therapy remain same.

Human Immunodeficiency Virus(HIV)

HIV is the virus that causes HIV infection and AIDS (Acquired Immunodeficiency Syndrome). There are two typ es of HIV viruses, HIV-1 and HIV-
2, which belong to the retrovirus group. This virus also has numerous subtypes. These viruses can only reproduce wi thin a host cell by copying their genetic blueprint onto the genes of a person's cells.

AIDS is the most advanced form of HIV infection. Both HIV-1 and HIV-2 can cause AIDS, but HIV-
2 is less easily transmitted and takes longer for the illness to appear.

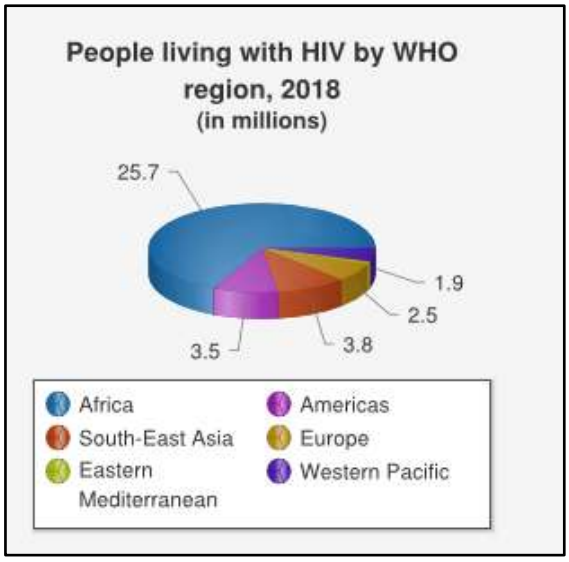
Prevalence and Incidence rate of HIV globally.

- 37.9 million people living with HIV in the world, at end-2018.[7]
- 62% of all people living with HIV had access to antiretroviral therapy at end-2018.[7]
- 8.1 million people living with HIV did not know that they have HIV at end-2018.

Region	%ofAdultsLivingwithHIV(AdultPrevalence)	%ofPeoplelivingwithHIV(%ofglobaltotal)	%ofPeoplenewlyinfectedwithHIV	%ofAIDS-Relateddeaths
Global,Total	**0.80%**	**37.9 million(100%)**	**1.7 million**	**7,70,000**
Eastern and Southern Africa	7.00%	20.6mn (54%)	8,00,000	3,10,000
Western and Central Africa	1.50%	5mn (13%)	2,80,000	1,60,000
Asia and the Pacific	0.20%	5.9mn (16%)	3,10,000	2,00,000
Western and Central Europe and North America	0.20%	2.2mn (6%)	68,000	13,000
Latin America	0.40%	1.9mn (5%)	1,00,000	35,000
Eastern Europe and Central Asia	0.90%	1.7mn (4%)	1,50,000	38,000
The Caribbean	1.20%	340,000 (<1%)	16,000	6,700
Middle East and North Africa	<0.1%	240,000 (<1%)	20,000	8,400

NOTES: Reflects 2018 data.
SOURCES: UNAIDS. *AIDSinfo* website; accessed July 2019. UNAIDS. *Core Epidemiology Slides*; July 2019.[8]

Table 1: Global Prevalence and incidence rate of HIV



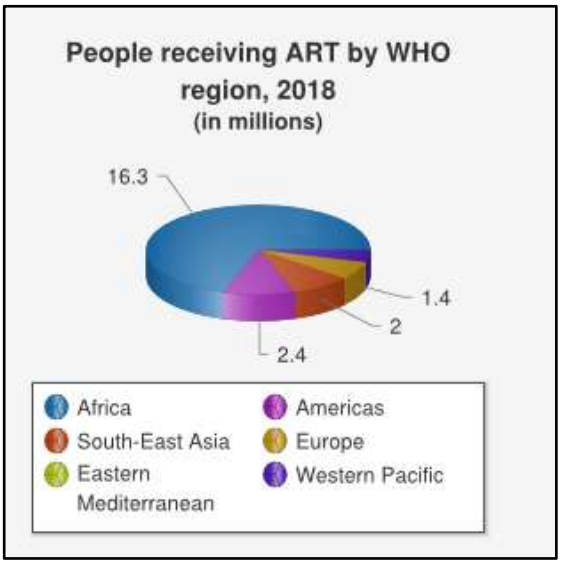


Figure 1: People living with HIV by WHO region, 2018Figure 2: People receiving ART by WHO region,2018 Source: *https://www.who.int/hiv/data/en/*

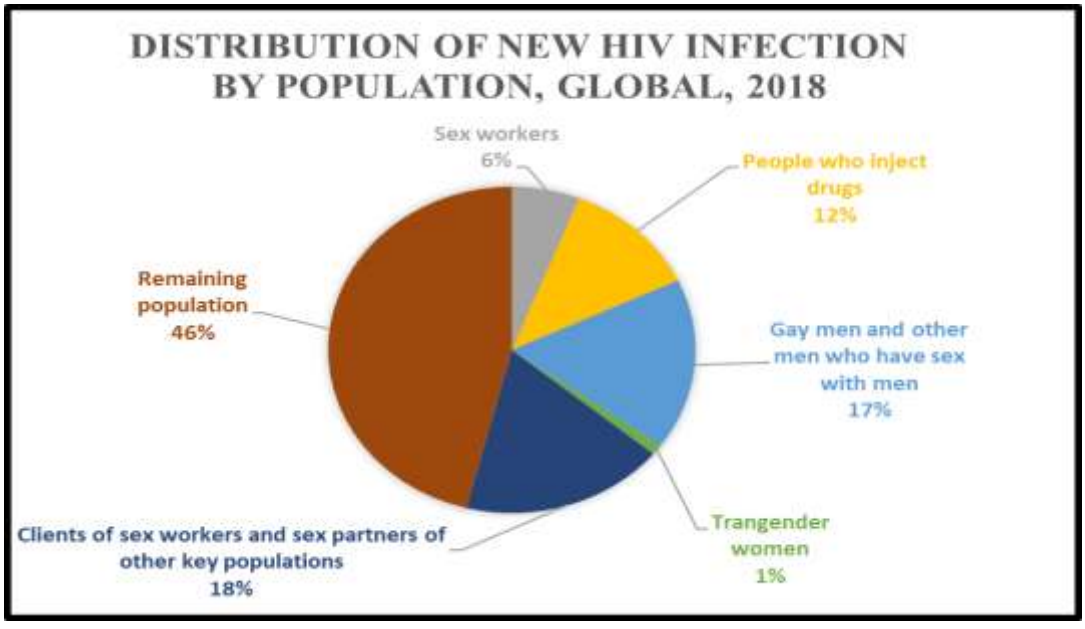


Figure 3: Distribution of new HIV infection by population, Global, 2018

PATHOGENESIS OF HIV

Lymphocytes(white blood cells) are one of the main types of immune cells that make up the immune system. There are two types of lymphocytes: B cells and T cells.

B cells secrete antibodies(proteins) into the body's fluids to ambush and attack antigens.T cells directly attack and d estroy infected or malignant cells in the body.

There are two types of T cells: helper T cells and killer T cells. Helper T cells recognize the antigen and activate the k iller T cells. Killer T cells then destroy the antigen.

When HIV is introduced into the body, this virus is too strong for the helper T cells and killer T cells. The virus then i nvades these cells and starts to reproduce itself, thereby not only killing the CD4 T cells, but also spreading to infect otherwise healthy cells.

The HIV virus cannot be destroyed and lives in the body undetected for months or years before any sign of illness ap pears. Gradually, over many years or even decades, as the T cells become progressively destroyed or inactivated, ot her viruses, parasites or cancer cells(called "opportunistic diseases") which would not have been able to get past a h ealthy body's defence, can multiply within the body without fear of destruction.

LIFE CYCLE OF HIV

The seven stages of the HIV life cycle are:

1).Binding: HIV binds itself to receptors on the CD4 cell surface

2)Fusion: HIV envelope and CD4 cell membrane fuse, which allows HIV to enter the CD4 and HIV virus enter the C D4 cell.

3)Reverse transcription: HIV releases and uses reverse transcriptase to convert HIV RNA into HIV DNA which all ows the entry of HIV to CD4 cell nucleus and combine with the cell's genetic material0 cell DNA

4)Integration: HIV releases integrase to insert its viral DNA into the DNA of the CD4 cell.

5)Replication: Once the HIV is integrated into the CD4 cell DNA, HIV begins to use CD4 cell machinery to make lo ng chain of HIV proteins.

6)Assembly: New HIV proteins and HIV RNA move to the surface of the cell and assemble into immature HIV.

7)Budding: The immature HIV pushes itself out of the host CD4 cell and releases protease, protease breaks up the lo ng protein chains in the immature virus and creates mature virus.

Stages of HIV infection

- **Acute HIV infection:** it develops within 2 to 4 weeks after getting infected with HIV. Flu-like symptoms are seen. Here the virus attacks and destroys the CD4 cells of the immune system. As the viral loa d is very high in the blood during this phase, the risk of transmission is high.
- **Chronic HIV infection:** Patient normally do not show any HIVRelate4d symptoms. Virus continues to multipl y, but with slower rate, and the viral load is less. If left untreated within 10 years, it is full- blown to AIDS.
- **AIDS:** it is final HIV infection stage and destroys the immune system and the body cannot fight off opportunisti c infections. Its CD4 cell count is less than 200cells/mm3. Without the treatment, patient can survive for about 3 years.

HIV symptoms

- Anxiety and depression.
- Neuropathy, dementia, and Seizures.
- Flu-like symptoms
- Eating problem, tongue trouble and mouth ulcers.
- Heart strain, Hypertension, and respiratory infection.
- Shingles, aches, and pains.
- Immune system under attack.
- Kidney damage.

According to the **Center for Disease Control and Prevention**, a person is considered to have AIDS when they hav e a T cell count of 200 or less (healthy T cell levels range from 500 to 1500). It takes 10-15 years to go from HIV to AIDS.

Transmission of HIV

HIV spreads through bodily fluids like blood, semen, vaginal secretions, rectal fluids, and breast milk. The ways in which HIV can be transmitted are as follows:

- Sharing needles and syringes.
- Using unsterilized tattoo equipment.
- From mother to her baby during pregnancy or delivery or breastfeeding.
- Giving baby food chewed by an HIV infected person.
- When an open wound gets infected with HIV infected blood.
- Oral sex if you have open sore in the mouth of the genitals.

The Life Expectancy with HIV

HIV patient can have a normal lifespan with proper treatment. The lifespan also depends on the CD4 cell count, viral load, the presence of opportunistic infections, drug use, smoking, age, and other health conditions. when HIV infect ion advances to AIDS, without treatment life expectancy is reduces to 3 years.

Antiviral drugs

Antiviral drugs are a class of medication used to treat viral infections. Antiviral drugs include antibiotics, anti-fungal and anti-parasitic drugs. They are harmless to the host, and therefore can be used to treat infections.

Antiviral drugs classification

1. Anti-
Herpes virus: Idoxuridine, Trifluridine, Acyclovir, Valacyclovir, Famciclovir, Ganciclovir, Cidofovir, Foscarnet , Fomivirsen

2. Anti-Influenza virus: Amantadine, Rimantadine, Oseltamivir, Zanamivir, peramivir.

3. Anti-Hepatitis virus/Nonselective antiviral drugs:

- For hepatitis B: Lamivudine, Adefovir dipivoxil, Tenofovir
- For hepatitis C: Ribavirin, Interferon α

4. Anti-Retroviral drugs:

Antiretroviral medications are a group of drugs that inhibit different steps in the HIV replication process. They can s uppress HIV infection but never eliminate it from the body. The World Health Organisation (WHO) recommends t he use of certain combinations of ARV drugs for the optimal suppression of HIV infection, known as Highly Active Anti-Retroviral Therapy (HAART).[6]

There are four categories of ARV medications: -

- Nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs)
- Non-nucleoside reverse transcriptase inhibitors(NNRTIs).
- Protease inhibitors(PIs).
- Fusion / Entry inhibitors. (FI/EI)
- Integrase inhibitors. (II)
- Single tablet/fixed dose combination(ST/FDC)

Currently there are 40 individual and combination medications approved for the treatment of HIV and one approved for the pr evention of HIV infection.[10] The life expectancy of a person living with HIV nears that of a person not living with HIV.[11] "Tre atment as prevention" and PrEP(pre-exposure prophylaxis) have led to a decrease in new infection

Different Mechanism of action – FDA approved drugs

Year of approval	Nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs)	Non-nucleoside reverse transcriptase inhibitors (NNRTIs).	Protease inhibitors (PIs).	Fusion/ Entry inhibitors. (FI/EI)	Integrase inhibitors. (II)	Single tablet/fixed dose combination (ST/ FDC)
Mode of action	Block the HIV replication cycle by inhibiting viral reverse transcriptase.	Bind to a different site on the viral reverse transcriptase enzyme, inhibiting its activity.	Inhibit the activity of another viral enzyme, HIV protease, which is required to assemble more HIV particles.	Stop HIV from entering human cells	Stop the virus from inserting itself into the DNA of human cells.	
1987	Zidovudine					
1991	Didanosine					
1992	Zalcitabine					
1994	Stavudin					
1995	Lamivudine		Saquinavir			
1996		Nevirapine	Ritonavir, Indinavir			
1997		Delavirdine	Nelfinavir			Lamivudine + Zidovudine
1998	Abacavir	Efavirenz				
1999			Amprenavir			
2000			Lopinavir/ritonavir			Abacavir + Lamivudine + Zidovudine
2001	Tenofovir					
2003		Emtricitabine	Atazanavir Fosamprenavir	Enfuvirtide		
2004						Abacavir+ Lamivudine+ Tenofovir +Emtricitabine

2005			Tipranavir			
2006			Darunavir			Efavirenz+ Emtricitabine+ Tenofovir
2007				Maraviroc	Raltegravir	
2008		Etravirine				
2011		Rilpivirine Nevirapine XR				Rilpivirine + Emtricitabine+ Tenofovir
2012						Stribild
2013					Dolutegravir	
2014					Elvitegravir	Triumeq
2015						Evotaz Genvoya Prezcobix
2016						Descovy Odefsey
2017						Juluca
2018		Doravirine				Biktarvy Cimduo Delstrigo Symfi Symtuza Temixys
2019						Dovato

Table 2: FDA Approved Antiretroviral drugs

- Post-Attachment Inhibitor(PAI):- Ibalizumab-uiyk. (2018)
- Pharmacokinetic Enhancer:- Cobicistat. (2014)

Manufacturers of Antiretroviral drug.

- ViiV HealthCare.
- Meditabs Specialities Pvt Ltd.
- Hetero labs limited.
- Aurobindo Pharma Ltd.
- Cipla Ltd.
- Mylan Laboratories Ltd.
- Microlabs Ltd.

- Gilead.
- Boehringer Ingelheim.
- Janssen Pharmaceuticals.
- AbbVie.
- Bionor Pharma.
- Vertex Pharmaceuticals.
- Others.

2. RATIONALEOFTHESTUDY

Thedatasetprovidedbytheorganizationincludedidealsinformationfortheantiretroviralmarketin Europewhichincludedmoleculesandtheirpharmaceuticalproductsforthecountriesin Europe.Thedatasetincluded MATQ4ofallmoleculefromtheyear2016-2018.Theinformationwasprovidedby IQVIA.

Thisexaminationprovidesinformationon:

- Theparametersutilizedforshortlistingthemoleculeshavingpotentialinmarketingiveninformationalindex.
- Thesituationalinvestigationoftheshortlistedpotentialmolecule.
- Thepossiblemarketingplanthatcanbeadoptedtomarkettheshortlistedmolecule.

3. RESEARCHQUESTION

- Whataretheparametersutilisedforshortlistingamoleculewithmarketpotentialineachdataset?
- Whatisthesituationalanalysisoftheshortlistedmolecule?
- Whatwouldbethepossibleplantomarketthegenericversionofthebrandedproduct?

4. RESEARCHOBJECTIVE

- Tounderstandtheselectioncriteria.
- Tofindoutthemoleculewithhighmarketpotential.
- Todothesituationalanalysisofthetherapy.
- Torecommendpossiblemarketingplansofthegenericversionlaunchedincompetitionwiththeproduct.

5. REVIEWOFLITERATURE

SL.No.	Titleofthestudy	Authorofthestudy	DateofPublication
1.	CentersforDiseaseC.Pneumocystispneumonia--LosAngeles.*MMWRMorbMortalWkly.*	MSGottlieb(MD),HMSchanker(MD),PTFan(MD),ASaxon(MD),JDWeisman(DO)	October1980-May1981
2.	JointUnitedNationsProgrammeonHIV/AIDS(UNAIDS)	GlobalAIDSupdate	2019
3.	Globalhealthpolicy,TheGlobalHIV/AIDSEpidemic	GlobalHIV/AIDSEpidemic	Sep09,2019
4.	MayoFoundationforMedicalEducationandResearch(MFMER)HIV/AIDSinformation	HIV/AIDSintroduction	1998-2020
5.	WhatDrivesHIV/AIDSEpidemicinpoorcountries	ChrystelleTsafackTemah	2009/5
6.	Typesofantiretroviralmedication	AmeliaJones	May2019
7.	TheEffectsofHIVonbody	HealthlineMedia,Inc.isanAmericanwebsiteandproviderofhealthinformationheadquarteredinSanFrancisco,CA.	
8.	GuidelinesfortheuseofantiretroviralagentsinadultandadolescentswithHIV	AIDSinfo(OFFERINGINFORMATIONONHIV/AIDS TREATMENT,PREVENTION,ANDRESEARCH)	
9.	TheGlobalFundtoFightAIDS,TuberculosisandMalaria	BillGates,MelindaGates,KofiAnnan,JeffreySachs,AmirAttaran	28January2002
10	ReductionofMaternal-InfantTransmissionofHumanImmunodeficiencyVirusType1withZidovudineTreatment	EdwardM.Connor,MohammedBey,WilliamShearer,RobertL.Jacobson,EleanorJimenez,EdwardO'Neill,etal.,	Nov31994
11	3-yearSuppressionofHIVViremiawithIndinavir,Zidovudine,a	RMGulick[1],JWMellors,DHavlir,JEron,AMeibohm,JHCondra,FTValentine,DMcMahon,CGonzalez,LJonas,EAEmini,JAChodakewitz,RIsaacs,DRichman	July4th,2000

	ndLamivudine		
12	AntiretroviralTherapyforthePreventionofHIV-1Transmission	MyronS.Cohen,M.D.,YingQ.Chen,Ph.Detal.	September 1st2016
13	ClinicalImplicationsofAgingwithHIVInfection:PerspectivesandtheFutureMedicalCareAgenda	GiovanniGuaraldi1,FrankJPalellaJr	July1st 2017
14	RoleofTenofovirAlafenamide(TAF)intheTreatmentandProphylaxisofHIVandHBVInfections	ErikDeClercq	December 7th2017
15	TreatingandPreventingHIVwithGenericDrugs—BarriersintheUnitedStates	ErikaG.Martin,Ph.D.,M.P.H.,andBruceR.Schackman,Ph.D.	January25th 2018
16	RitonavirandSaquinavirCombinationTherapyfortheTreatmentofHIVInfection	DWCameron1,AJJapour,YXu,AHsu,JMellors,CFarthing,CCohen,DPoretz,MMarkowitz,SFollansbee,JBAngel,DMcMahon,DHo,VDevanarayan,RRode,MSalgo,DJKempf,RGranneman,JMLeonard,ESun	February4th 1999

6. RESEARCHMETHODOLOGY

- **LocationofStudyArea:**

  EuropeanUnion

- **StudyTime:**

  20th February – 22nd May 2020.

- **Research Design:**

  Descriptive study

- **SourcesofDataandSampling:**

  ThedataprovidedbyorganizationwasobtainedfromIQVIAandotherinformationwascollectedfromresearchpapers,Google,Wikipediaetc.Thestudywasdoneuponsecondarydata.Thisincludessalesoutputdataof2016-

2018ofallthedrugmoleculesofEuropeinAntiretroviralmarket.Thisstudyalsoincludesbrandshavingmarketshareinantiretroviralsegmentinindianpharmaceuticalmarket.Thisdatashowstheunitsalesandsalesrevenuefor3years,companiesmanufacturingtheantiretroviraldrugandpriceoftheantiretroviraldrugs.

- **DataRepresentationandAnalysis**
  ThedatawasanalysedusingMicrosoftexcelandMSwordisusedforanalysingthedataandforgraphicalrepresentation.

TrioLAD

DrugClass: Oralantiretroviralcombinationdrug(Singletabletregimens)

Molecule: Abacavir+Dolutegravir+Lamivudine.

Dosageform:-Tablet.

Strength:-Abacacvir600MG+Lamivudine300MG+Dolutegravir50MG.

USE:-FDAApprovedindications(HIV-1treatment).

USP:-Booster-freedosing.

Highbarrierstoresistance.

Highsafety,efficacyandtolerability.

Lowpillburden(1pillonceaday).

Quality:-FDAAPPROVED

Mechanismofaction:-

1.Dolutegravirbindstotheintegraseactivesiteandblocksthestrandtransferstepofretroviral DNAintegrationtoinhibit HIVintegrase.

2.AbacavirandlamivudineinhibitHIVreversetranscriptaseand,byincorporatingmonophosphate,formachaintermination ontheDNAviralchain.

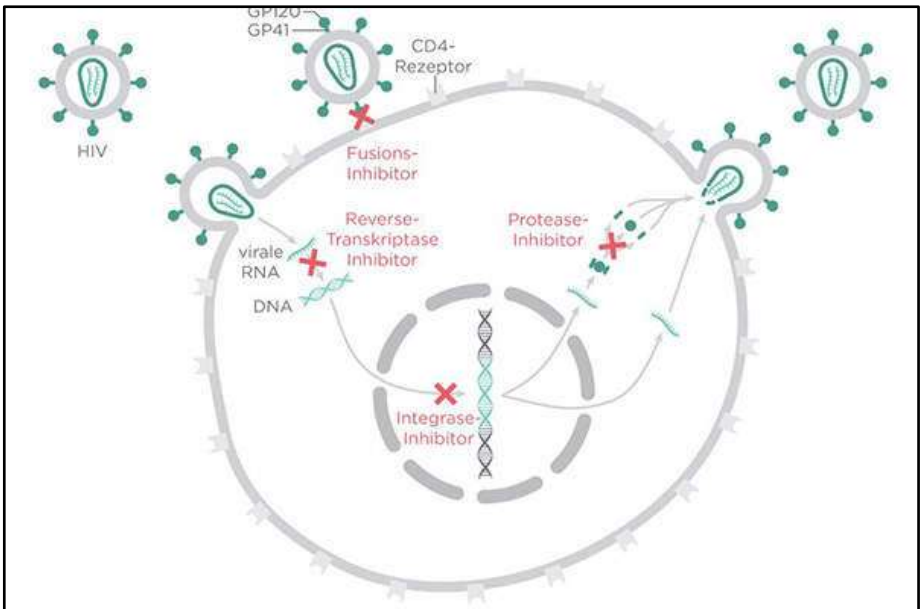


Figure4:MechanismofactionofTrioLAD

Source:https://images.app.goo.gl/iswvzrp5JFsTFnp57

7. UNDERSTANDINGTHESELECTIONCRITERIA

Thedataprovidedconsistedsalesdataof44moleculesin30countriesfortheyears2016-2018.Thedatawasfirstcategorizedcountrywise,moleculewiseandsectorwise(HospitalandRetail).Afterdoingsothe growthpercentagesandmarketsharewascalculated.

Themoleculeswerecategorizedintotwoparametersasfollows:

1. MoleculesgrowinginUnitSales.
2. MoleculesgrowinginValuesales$.

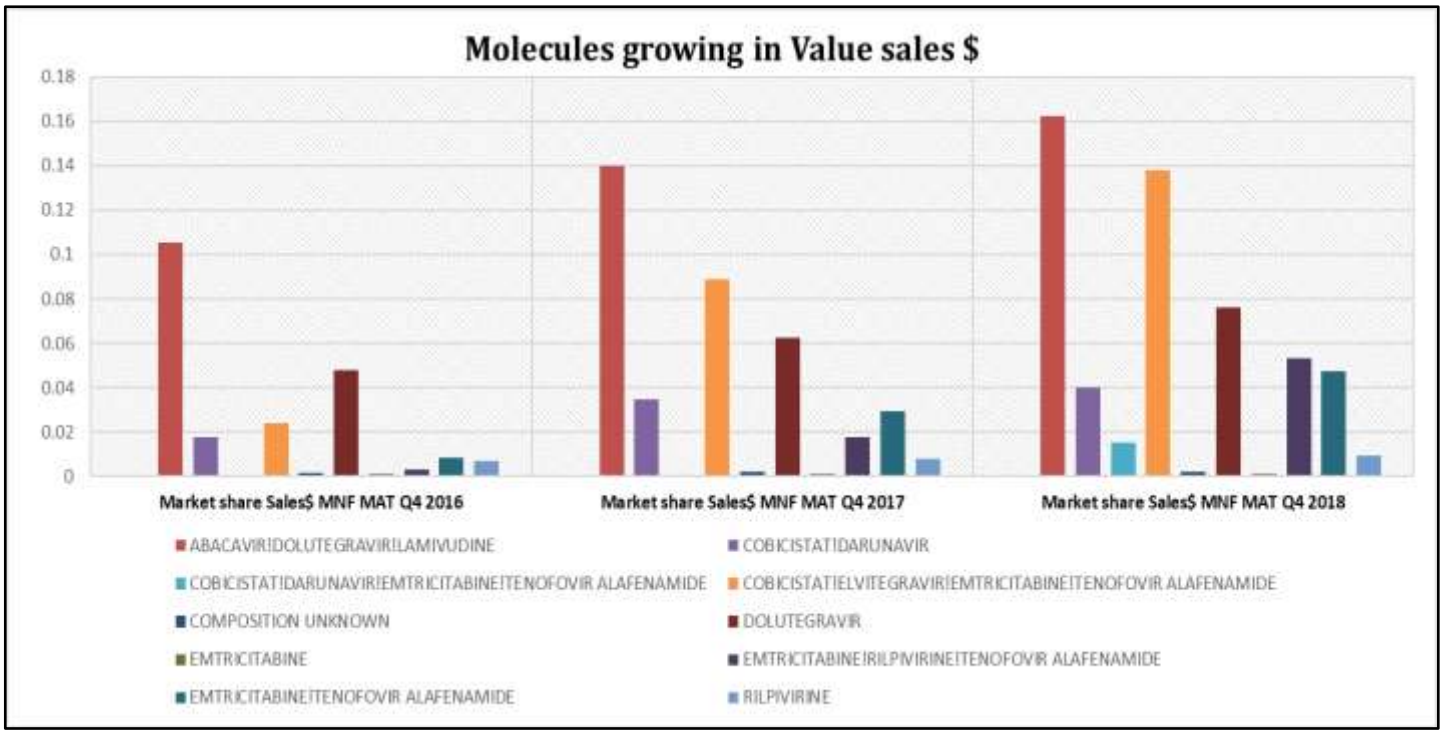


Figure5: ***Thegraphrepresentspercentageofthemoleculesthathavegrowninvaluesales$fromyear2016-2018***

Theabovegraphrepresentsthemoleculesgrowinginvaluesales$percentageinwhichAbacavir+Dolutrgravir+Lamivudinecontributesthehighestvaluesales$of16%andCobicistat+Elvitegravir+Emtricitabine+TenofovirAlafenamidecontributes14%.

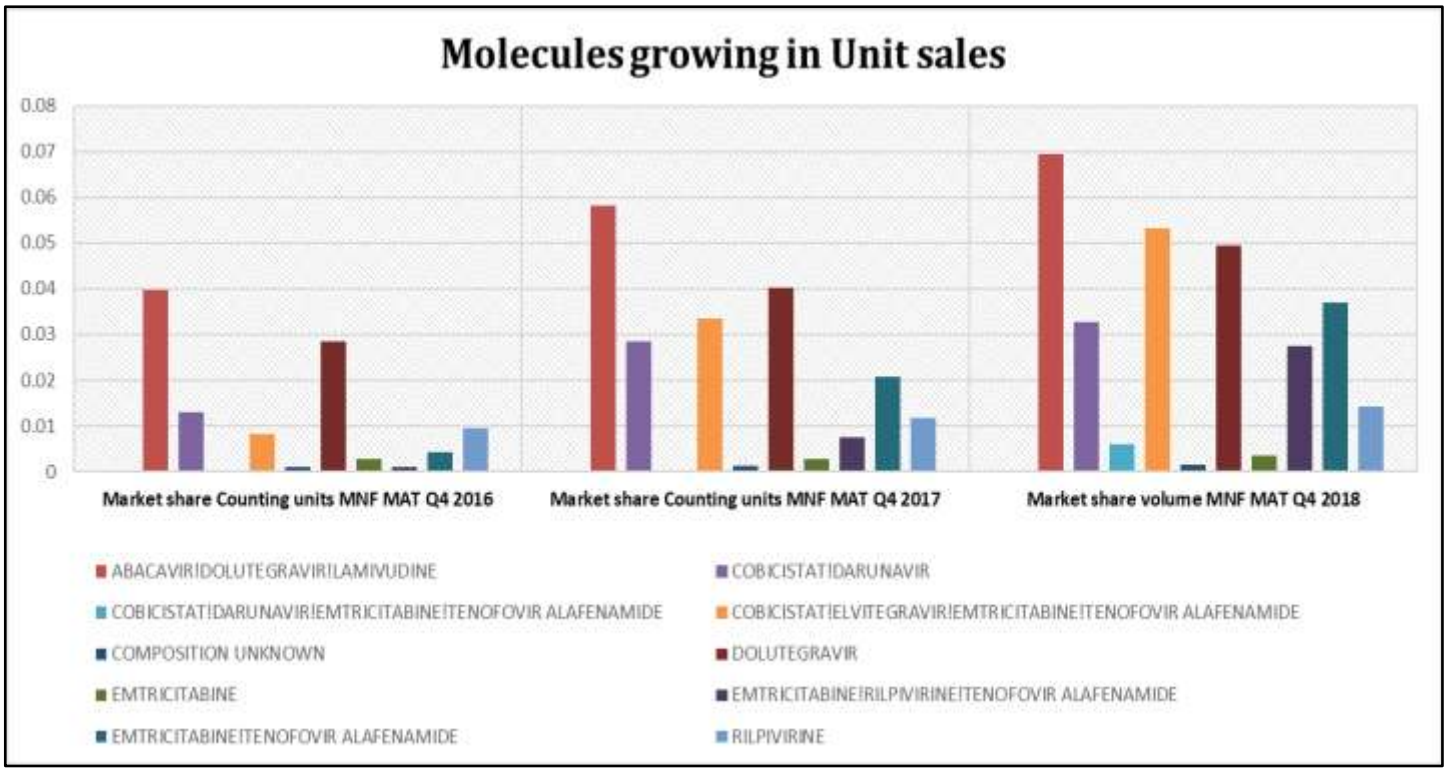


Figure6: ***Thegraphrepresentspercentageofthemoleculesthathavegrowninunitsalesfromyear2016-2018***

Theabovegraphrepresentsthemoleculesgrowinginvaluesales$percentageinwhichAbacavir+Dolutrgravir+Lamivudinecontributesthehighestvaluesales$of5%andCobicistat+Elvitegravir+Emtricitabine+TenofovirAlafenamidecontributes 5%.

SituationalAnalysisofAntiretroviralmarketinEurope

- TherapysizeofAntiretroviralmarketinEuropeis$6.34bn.
- Thereare44antiretroviralmoleculesinEuropemarketoutofwhich10moleculesaregrowingbothinvolumesalesandvaluesales,1moleculegrowingonlyinvolumesale,1moleculegrowingonlyinvaluesalesand1moleculewhichhasnegativegrowth,butvolumeandvaluesaleisveryhigh.

NOTE:

1.Green highlight indicates molecules growing both in volume sales and value sales.

2.Yellow highlight indicates molecules growing in volume sales.

3.Blue highlight indicates molecules growing in value sales.

4.Brown highlight indicates molecules having negative growth, but volume and value sale is very high

SN	Molecule List	YOY Growth of Sales$ 2018 over 2017 MAT Q4	YOY Growth volume 2018 over 2017 MAT Q4	Market share Sales$ MNF MAT Q4 2018	Market share volume MNF MAT Q4 2018
1	ABACAVIR!DOLUTEGRAVIR!LAMIVUDINE	16%	18%	16%	7%
2	ATAZANAVIR!COBICISTAT	1%	-1%	1%	0%
3	COBICISTAT!DARUNAVIR	15%	15%	4%	3%
4	COBICISTAT!DARUNAVIR!EMTRICITABINE!TI	1773%	2154%	2%	1%
5	COBICISTAT!ELVITEGRAVIR!EMTRICITABINE	55%	57%	14%	5%
6	COMPOSITION UNKNOWN	17%	17%	0%	0%
7	DOLUTEGRAVIR	21%	22%	8%	5%
8	EMTRICITABINE	21%	0%	0%	0%
9	EMTRICITABINE!RILPIVIRINE!TENOFOVIR AL	200%	262%	5%	3%
10	EMTRICITABINE!TENOFOVIR ALAFENAMIDE	60%	76%	5%	4%
11	EMTRICITABINE!TENOFOVIR DISOPROXIL	-34%	-7%	7%	9%
12	RILPIVIRINE	21%	22%	1%	1%
13	TENOFOVIR DISOPROXIL	-24%	7%	3%	6%

*Table3:**Percentageofmarketshareofvaluesales$andunitsalesin2018***

TransmissionofHIVinEurope

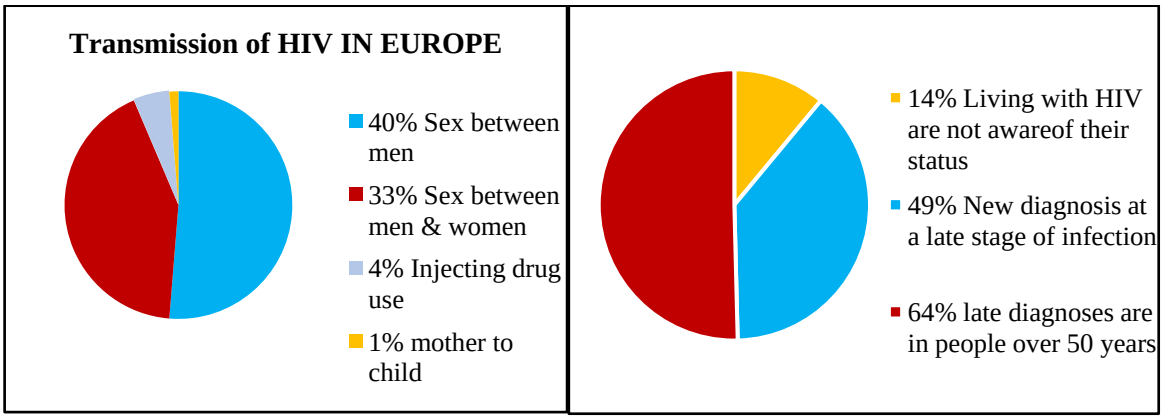


*Figure7:**TransmissionofHIVinEurope**Figure8:**AwarenessofHIVstatusamongtheHIVpatientinEurope***

Thetop2leadingantiretroviralmoleculeinEuropeare:

1.Abacavir+Dolutegravir+Lamivudine.

2.Cobicistat+Elvitegravir+Emtricitabine+TenofovirAlafenamide.

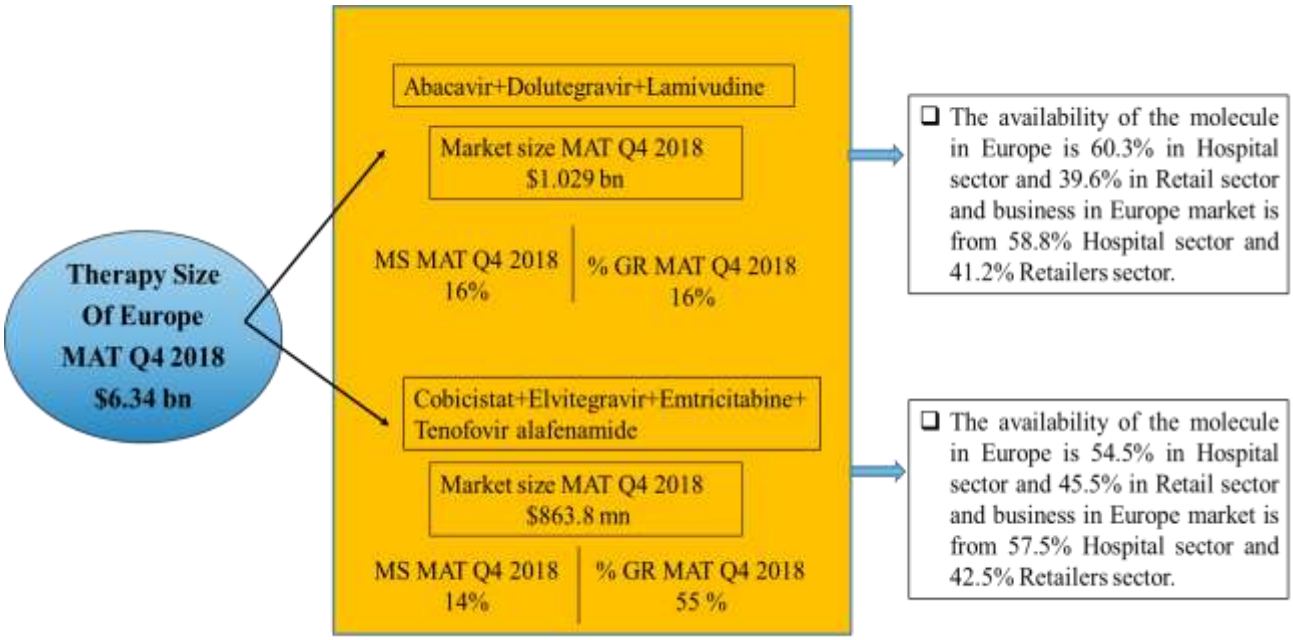


Figure9:<u>TherapysizeofAntiretroviralmarketinEuropeandtop2molecule'smarketsizeandshare,percentageofbusinessgeneratedfromretailandhospitalsector.</u>

BasedupontheabovegraphsandselectioncriteriaofMarketValueandUnitsweconcludethatAbacavir+Dolutegravir+LamivudineisthemoleculethathasahighmarketpotentialintheuropeanPharmaceuticalmarket

- MarketingplanispreparedforthetopleadingAbacavir+Dolutegravir+Lamivudinemoleculeunderthebrandnameof TrioLAD,inthetop5countrieswhichcontributes75%ofmarketshareinEuropeAntiretroviralmarket.
- 49%HIVdiagnosedreportedinEuropehappenedatalatestageofinfection.
- InEurope,thetop5countriescontribute75%ofmarketshareforAbacavir+Dolutegravir+Lamivudine

  1.France19%

  2.Spain23%

  3.Germany11%

  4.Italy12%

  5.UK11%

Therefore,wewill1st targettheabovecountries.

- TheinnovatorbrandofAbacavir+Dolutegravir+LamivudineisTriumeqwhoseonepatentforTriumeqwiththelongestvalidityissettoexpirein2029.ExclusivemarketingrightforViiVHealthcareisexpiredinAugust2018.

PatentexpirationofAntiretroviraldrugsfrom2005–2022.Off-patentmoleculeswillincreasethegenericcompetition.

2005	2006	2011	2012	2013
Zidovudine	Stavudine	Lamivudine	Nevirapine	Combivir
	Didanosine		Indinavir	Efavirenz
			Saquinavir	Ritonavir
2014	2016	2018	2019	2022
Abacavir	Trizivir	Tenofovir	Kivexa (Epzicom)	Raltegravir
Tipranavir	Lopinavir	Atripla	Fosamprenavir	Maraviroc
	Emtricitabine	Truvada	Etravirine	
	Darunavir	Atazanavir		

Table4:PatentexpirationofAntiretroviraldrugsfrom2005-2022

PatientFunnelingofEuropeforHIV-1Treatment

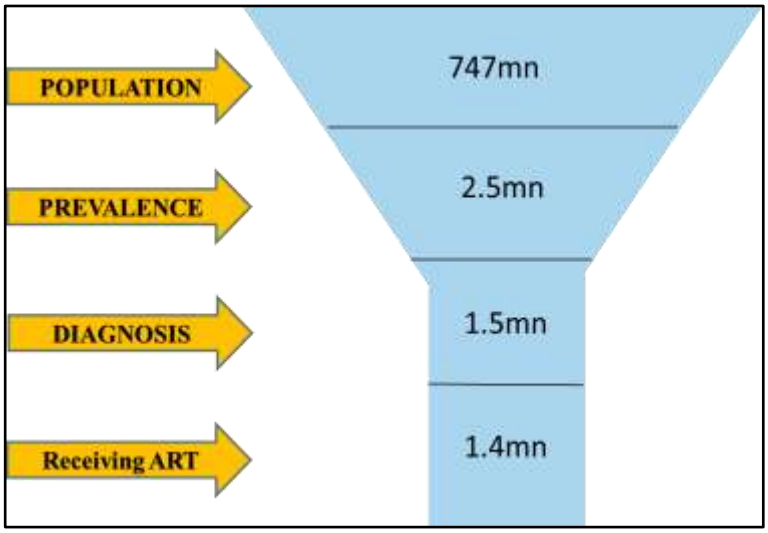


Figure10:PatientfunnelingofEuropeforHIV-1treatment

Incidencerate

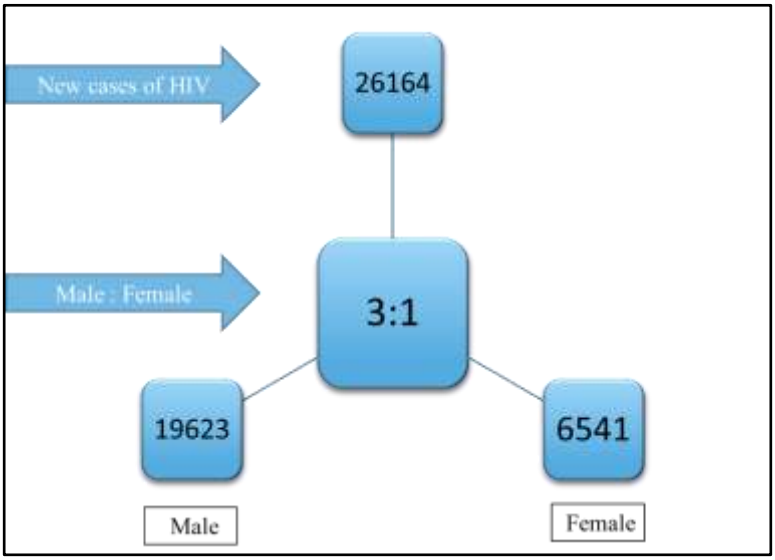


Figure11:IncidencerateandmaleandfemaleratioofHIVpatient

GOAL

Tocapture15%Abacavir+Dolutegravir+LamivudinemarketinEuropeinnext5years.

Valuesales$forecastofAbacavir+Dolutegravir+Lamivudine(Triumeq)inEurope.

SN	Years	Sum of LC$ MNF MAT Q4	Extrapolated figures
1	2016	660234772	
2	2017	889591180	
3	2018	1029590658	
4	2019		1229161423
5	2020		1413839366
6	2021		1598517309
7	2022		1783195252
8	2023		1967873195
9	2024		2152551138

Table5:Forecastedmarketshareinvaluesales$ofTriumeqinEurope

TrioLAD(Abacavir+Dolutegravir+Lamivudine)Valuesales$forecastinEuropefornext5year.

Market share % in Sales $	YEAR	Revenue in $
5%	1st (2020)	(5% of 1413839366) **70,691,968**
7%	2nd (2021)	(7% of 1598517309) **111,896,212**
9%	3rd (2022)	(9% of 1783195252) **160,487,573**
12%	4th (2023)	(12% of 1967873195) **236,144,783**
15%	5th (2024)	(15% of 2152551138) **322,882,671**

Table6:EstimatedrevenuegenerationforTrioLADwithmarketsharepercentageinvaluesales$

unitsalesforecastofAbacavir+Dolutegravir+Lamivudine(Triumeq)inEurope.

SN	Years	Sum of Counting Units MAT Q4	Extrapolated figures
1	2016	20320020	
2	2017	28194416	
3	2018	33267414	
4	2019		40208011
5	2020		46681708
6	2021		53155405
7	2022		59629102
8	2023		66102799
9	2024		72576496

Table7:Forecastedmarketshareinunitsales$ofTriumeqinEurope

TrioLAD(Abacavir+Dolutegravir+Lamivudine)unitforecastinEuropefornext5year.

Market share % in unit	YEAR	Unit Sales
5%	1st (2020)	(5% of 46681708) **2334085**
7%	2nd (2021)	(7% of 53155405) **3720878**
9%	3rd (2022)	(9% of 59629102) **5366619**
12%	4th (2023)	(12% of 66102799) **7932336**
15%	5th (2024)	(15% of 72576496) **10886474**

Table8:EstimatedrevenuegenerationforTrioLADwithmarketsharepercentageinunitsales

PatientJourneyofHIVpatient

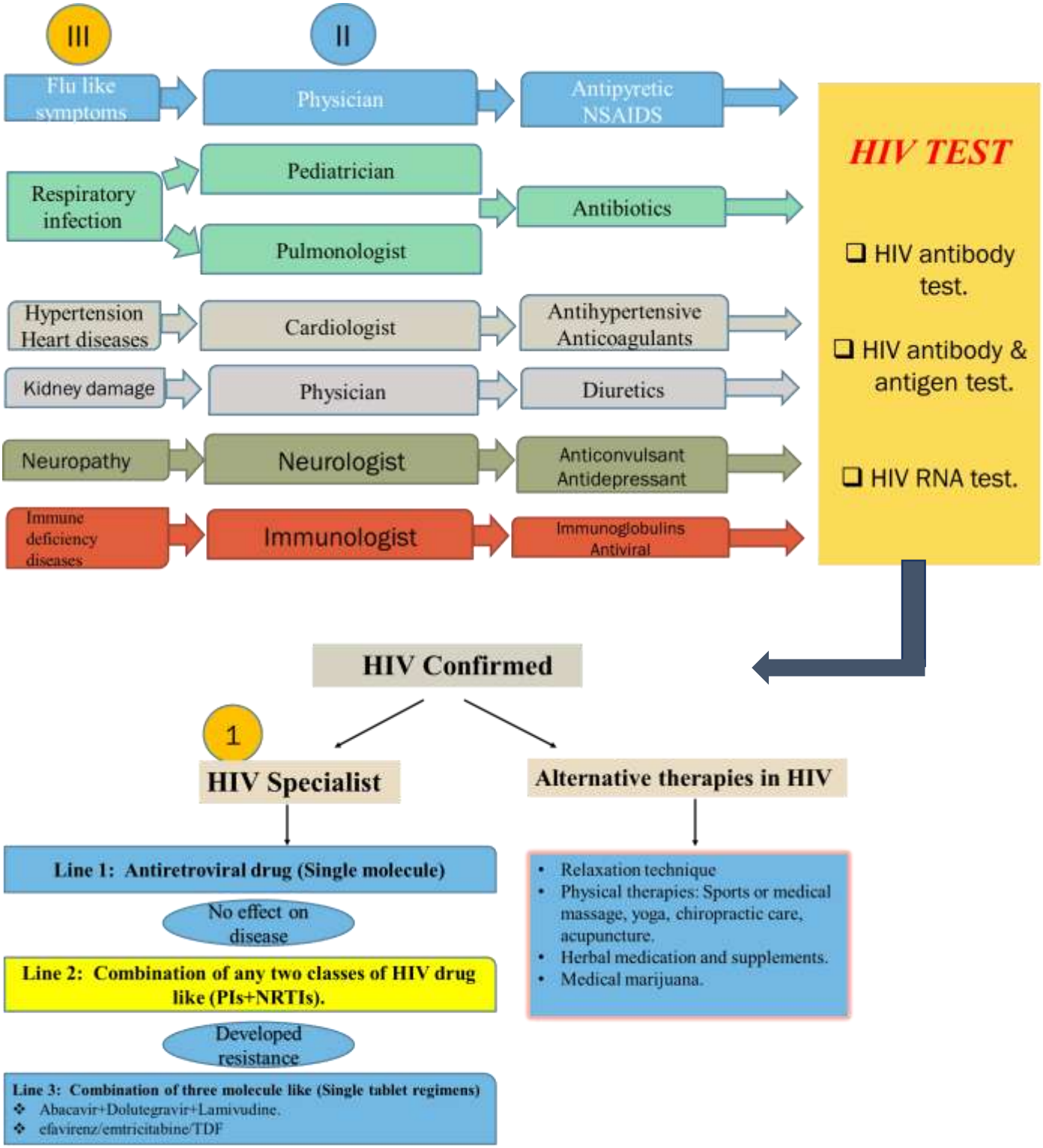


Figure12:PatientjourneyofHIVpatient

SWOTofthemoleculeAbacavir+Dolutegravir+Lamivudine

1.Strength

- RecommendedregimenbyHHSandEACSfortreatmentofHLA-B*5701-negativepatients.
- SuperiorefficacyandtolerabilitytoAtripla(efavirenz/emtricitabine/TDF).
- FDAandEMAapprovalforuseintreatmentnaïveandtreatment-experiencedpatientsmeanshightargetpatientnumbersandhighcommercialpotential.
- Approvedforuseinadolescents≥12yearsofageinadditiontoadults.
- Highbarriertogeneticresistanceofdolutegravircomponent.
- ConvenientSTR.
- Highbarriertoresistance.
- Booster-freedosingandcantakewithorwithoutfood.
- Lowpillburdenandlessdropoutduetolesssideeffects.
- Doesnotaffectkidneyfunctionliketenofovir.
- Reducetheriskofsexualtransmissionbecauseofreducedviralload.
- AssuperiorityagainstReyataz(atazanavir)inwomen.

EACS=EuropeanAIDSClinicalSociety.

EMA=EuropeanMedicineAgency.

HHS=USDepartmentofHealthandHumanServices.

STR=Single-tabletregimen,TDF=TenofovirDisoproxilFumarate

2.Weakness

- LimitedtoHLA-B*5701—negativepatients,whichhasasmallimpactonpatientnumbers.
- Issuesregardingabacavircomponentassociatedwithhypersensitivityandunconfirmedriskofmyocardialinfraction.
- FourthSTRtomarket.

BrandName	Components	YearofFDAApproval
Atripla	•Efavirenz •Emtricitabine •TenofovirdisoproxilFumarate	2006
Comlera	•Rilpivirine •Emtricitabine •Tenofovirdisoproxilfumarate	2011
Stribild	•Elvitegravir •Cobicistat •Emtricitabine •Tenofovirdisoproxilfumarate	2012
Triumeq	•Dolutegravir •Abacavir •Lamivudine	2014

Table9:Fourtopbrandsofsingletableregimen

3.Opportunities

- IncreasingIncidencerate(male:female=3:1)andprevalencerate2.5mnofHIV-1inEurope.
- GrowingAntiretroviralmarketinEurope.
- Usedasaswitchingregimen.
- Indicationfortreatmentofpaediatricpatients.
- Longtermtherapy(Lifelongdisease)
- 14%livingwithHIVarenotawareoftheirstatusthisgivesanopportunitytocreateawarenessofthediseaseandindirectlycanincreasebrandawarenessandbrandimageofTrioLAD.

4.Threat

- Cumulativecompetitivepressurefromfollowingproducts1.**Atripla**(efavirenz(NNRTI),emtricitabine(NRTI),andtenofovirdisoproxilfumarate(NRTI))2.**Complera**(emtricitabine(NRTI),rilpivirine(NNRTI),andtenofovirdisoproxilfumarate(NRTI)3.**Stribild**(elvitegravir(INSTI),cobicistat(CYP3Ainhibitor),emtricitabine(NRTI),andtenofovirdisoproxilfumarate(NRTI)
- Physicianspreferencefortruvada(emtricitabine/TDF)backbone.
- Increasingpricingpressure.
- GenericincursionfollowingpatentexpiryofEpzicomin2019in(EU).

- Genericefavirenzcouldleadtophysiciansbeingurgedtoprescribeindividual Atriplacomponents,whichwouldnegative lyimpactTrioLADsales.
- ThreatfromDovato(Dolutegravir+Lamivudine)approvedinApril2019.
- Threatofnewentry.

SEGMENTATION,TARGETINGANDPOSITIONING

SEGMENTATION

- **Geographicalsegmentation**

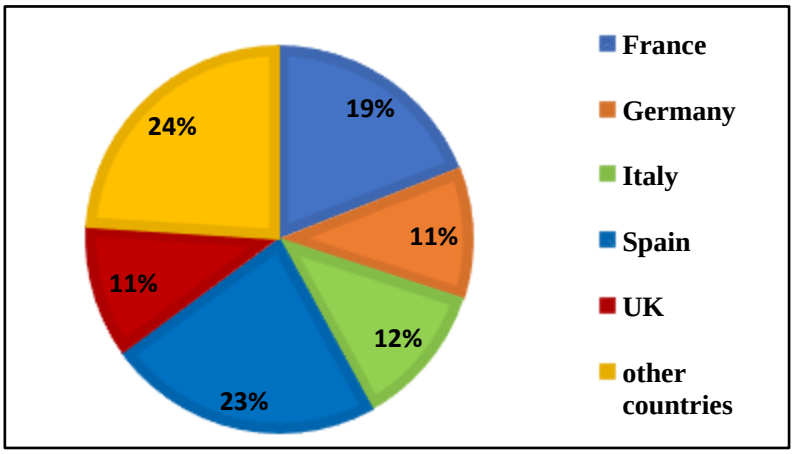


*Figure13:**Top5countrieswhichcontributes75%ofmarketshareinEurope***

InEurope,top5countriescontribute76%ofmarketshareforAbacavir+Dolutegravir+LamivudinethoseareFrance,G ermany,Italy,Spain,andUK.

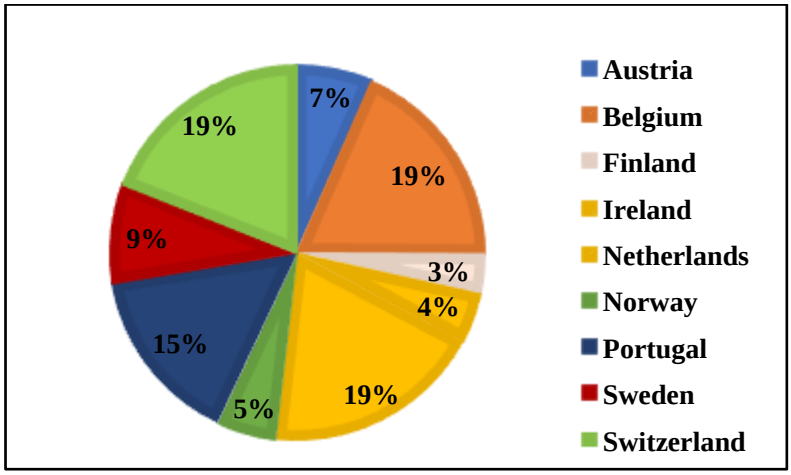


*Figure14:**MarketshareofrestoftheEuropecountriesinAntiretroviralmarket***

InEurope,24%ofmarketshareiscontributedbyrest20countriesoutofwhichthese9countriescontribute22%

- **Demographicalsegmentation**

1. Gender:Male:femaleratioamongHIVpositivepatientis3:1.

2. Age:-

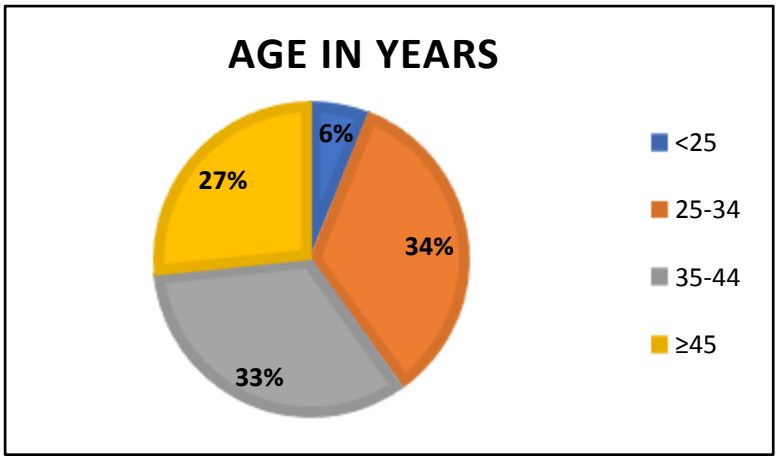


Figure15:percentageofHIVpatientwithageinEurope

TheabovegraphicalrepresentationsuggeststhatHIVpatientsagefrom25-45aremoreaffectedbyHIV.

3. Education

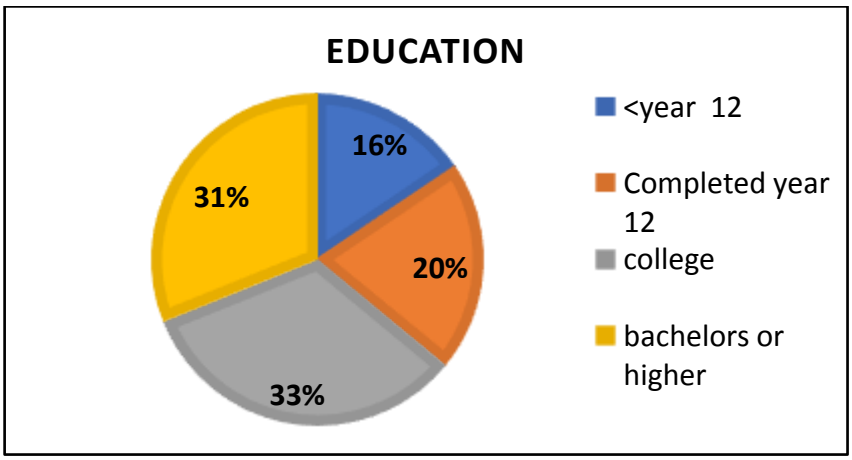


Figure16:EducationofHIVpatientinEurope

TheabovegraphicalrepresentationsuggestsinEuropeHIVpatient'seducationisaround36%havecompletedupto12yearsofeducationand64%havecompletededucationbeyondsecondaryschool

- **HealthCareSegmentation**

  Theprofessionalsaredividedintogroupswhichrespondinsimilarmannertothepromotionalactivities.

  Alliedhealthcareprofessionals

1. Nurses.
2. Mentalhealthproviders.
3. Pharmacists.
4. Nutritionists/dietitians.
5. Dentists.

  Healthcareproviders

1. Medicaldoctors.
2. Nursepractitioners.
3. Physicianassistant.
4. OB-GYNproviders.
5. HIVSpecialist.

  Socialserviceproviders

1. Socialworkers.
2. Casemanagers.
3. Substanceuse/abusespecialists.

  Patientnavigators

TARGETING

- **Specialtyfocus**
  - HIVspecialist.
  - Medicine(md)orDoctorofOsteopathicMedicine(do)
  - Consultantphysicianassistant
  - TenderAuthority.

- **Geographicallocation**
  - France,Germany,Italy,SpainandUK.
- **PatientPopulation**
  - Adolescents≥12years-AdultsHIVpatient.

POSITIONING

"*TrioLAD–EnhanceConfidenceandReassurethehope"*

DRIVERSofTrioLAD

- Highbarriertoresistance.
- Provenvirologicefficacy.
- Boosterfreeandcanbetakenwithorwithoutfood.
- Nodruginteractions.
- Hightolerability.
- Highpatientadherencebecauseoflowpillburdenandlesssideeffects.

BARRIERSofTrioLAD

- Notrecommendedforpregnantwomen.
- LimitedtoHLA-B*5701—negativepatients.
- Abacavirassociatedwithhypersensitivityandunconfirmedriskofmyocardialinfraction.
- CompetitivepressurefromAtripla,CompleraandStribild.

LPBO(LeveragePointBehavioralObjectives)Table

LEVERAGE POINTS	BEHAVIOURAL OBJECTIVES
Lesser diagnosis rate of HIV (Patient education)	• To increase awareness of HIV as a disease (lifestyle) • To increase awareness of diagnostic supplies for HIV (Lab test, OraQuick In-Home HIV test)
Incorrect treatment at the onset of disease (First point of care-Physician)	• To drive healthcare practitioners for better communication with patient for onboarding the therapy and awareness about the HIV symptoms.
Build stronger KOLs & KBLs (HIV Specialist)	• To nurture transactional analysis in physician-patient relationship (soft skill programs for doctors, nurses) to decrease drop off and improve adherence.

Table10:LeveragePointsBehaviouralObjectives

Strategies	What needs to be done	How will it be done
Operational effectiveness	• Technology applications • Training employees	✓ Mobile apps to be connect to doctors and track the HIV patient, partner with OraQuick. ✓ On the job training for medical representatives through mobile app. ✓ New target setting for reaching more HIV Specialist & physicians
Unique activities	• Need based positioning	✓ Physician touchpoints *(lucrative sponsorships, case studies, HIV testing kit for hospitalized patients)*
Strategic of fit	• Reinforcing	✓ Free samples for physicians ✓ Multimedia education at patient waiting rooms

Table11:Strategiesandtacticalplan

BRANDSTRATEGIES

1.Awarenessforpatient

- Patienteducationcampson*WorldsAIDSDay(Dec1st)*
- E-promotionalactivities-SEO,videodetailing,onlineevents
- Mobileapps-pushnotifications,foodsearch,quickquestionredressal
- PartnerwithOraQuickIn-HomeHIVkit.

2.Physiciantouchpoints

- Softskillprogramsfordoctors,nursesandpharmacists
- Symposia's/RTDs
- Lunch&Learn
- DriveKBLtowardsourproduct-lucrativesponsorship,casestudies

3.Adherenceoftherapy

- Patientguidesforwaitingroomexperience
- Examroomexperiencewithmultimediaeducation(articles,videos,3Danatomical)withtextandemailcompatibility
- Importanceofadherenceandriskofmisseddoseanddropoftherapy.

4.Salesforceimprovement

- Callplan(size&frequency)&territorymodeling
- Maintainsalesperformance
- Salescampaign
- Salesforcedevelopment:-

    a. **LearningandDevelopmentdepartment:-**
    L&Ddepartmentandregionalmanagerateast,west,centralregionofEUROPE.
    b. **OJT(OntheJobTraining):-**
        - Productknowledge:Productpharmacology–Pharmacodynamicandpharmacokinetic,productUniquesellingpoints
        - Fieldforceeffectiveness:
        - CME's(ContinuingMedicalEducation)
        - CompetitiveIntelligence:competitors'information.
        - CustomerSatisfaction.
        - DigitalStrategies.

c. Listofparameterscompanyshouldbetrackingonmonthlybasistoenhancethesalesforperformance

- Timespentselling
- Leadresponsetime
- Opportunitywinrate
- Salespipelinecoverageratio
- Customeracquisitioncost
- Customerlifetimevalue

Riskfactorsfacedbycompany

- Increaseincompetitor'sproduct.
- Publicandgovernmentpressuretomakedrugpricemoreaffordableirrespectiveoffactwhetherthe yaregenericorpatent.
- Decreaseinproductivityofsalescall.
- Lowconversionrate.
- Issuerelatedtostockavailability.
- Decreaseinsupplyofproductinmarket.

MARKETINGMIX

- **PRODUCT**
  - **BrandName:TrioLAD.**
  - **OtherNames:**ABC/DTG/3TC,abacavirsulphate/dolutegravirsodium/lamivudine
  - **DrugClass:**CombinationDrug(Singletabletregimens)
  - **Dosageform:**-Tablet.
  - **Strength:**-Abacacvir600MG+Lamivudine300MG+Dolutegravir50MG.
  - **USE:**-FDAApprovedindications(HIV-1treatment).
  - **USP**:-Booster-freedosing.

    Highbarrierstoresistance.

    Highsafety,efficacy,andtolerability.

    Lowpillburden**.**
  - **Quality:**-FDAAPPROVED

- **PRICE**

  AsthegenericpressureislessthepricecanbelessthancompetitorproductTriumeq.

  Triumeq:-Averagepricefor

  Packsize30=27$USD(Singletablet)&809.4$USD(onepacksize30tablets).

  Packsize90=30.6$USD(Singletablet)&22755.5$USD(onepacksize30tablets).

- **PLACE**

  - TheavailabilityofthemoleculeinEuropeis60.3%inHospitalsectorand39.6%inRetailsectorandbusiness inEuropemarketisfrom58.8%Hospitalsectorand41.2%Retailerssector.

  - Thehugeuntappedmarketcreatesopportunitytoplaceourproductbothathospitalandretailbyextensivepr omotionoftheproduct.

  - Thedistributionchannelforourproduct:-

Figure17:DistributionchannelforTrioLAD

- **PROMOTION**

  - Promotion to professionals has experienced a major shift with the development of nonpersonal selling t echniques. These include educational digital asset development, e-learning and direct marketing, including email and direct mail.
  - Doctors are now utilizing more external sources for information about products and bypassing the tradit ional representative.
  - Digital marketing has seen the emergence of search engines, social media, video distribution, blogging and device ubiquity.

- Special offers, Advertising, Endorsements, Users trails, Leaflets/Posters, Free gifts.
- 2-3 brand ambassadors- telling their stories online on our websites, TV etc.
- Interventions with clinical and medical methods
  - Counselling on risk reduction
  - Comprehensive sex education camps
  - Peer education programs
  - Social marketing campaigns(e.g., to promote condom use)
- Intervention that promote healthy behaviors
  - Condoms and Lubricants
  - HIV Testing.
  - Antiretroviral treatment for all.
  - Needle and syringe programs
  - Prevention of transmission.

VisualAidforTrioLAD

Figure18:VisualAidforTrioLAD

Conclusion

AntiretroviralsegmentisagrowingmarketinEuropehaving44moleculesoutofwhich13moleculescontributes66%marketshareinvalue$and45%marketshareinunitsales.Outthese13molecules,thetop2leadmoleculesareAbacavir+Dolutegravir+LamivudineandCobicistat+Elvitegravir+Emtricitabine+TenofovirAlafenamide.Abacavir+Dolutegravir+Lamivudineiswelldevelopedmoleculewith$1.029bnmarketsize,whichgrowsat16%growthrate(IQVIAdata)inEuropeand76%ofmarketshareiscontributedbythetop5countriesFrance,Germany,Italy,SpainandUK.So,tolaunchgenericversionofthisTrioLADisassumedtocapture15%ofmarketshareinnext5years.

AntiretroviraltherapysizeinEuropeMATQ42018-$6.34bn.

MarketsizeofAbacavir+Dolutegravir+Lamivudinemolecule-$1.029bn.

MarketsizeofCobicistat+Elvitegravir+Emtricitabine+TenofovirAlafenamidemolecule-$863.8mn.

TotalAntiretroviraldrugsUnitssoldinMATQ42018–478.9mn

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