ASTHMA TREATMENT LANDSCAPE IN THE UNITED STATES: MARKET TRENDS, KEY MARKET PLAYERS, PIPELINE DRUGS, AND UNMET NEEDS

Dissertation Submitted to

The IIHMR University, Jaipur

for the partial fulfilment for the award of the degree of

Master of Business Administration (MBA)

in

Hospital and Health Management

By

Tanya Sharma

Under the Supervision and Guidance of

Dr. Anoop Khanna

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PharmaACE

Date: 28/06/2024

TO WHOMSOEVER IT MAY CONCERN

This is to certify that, **Tanya Sharma,** student of IIHMR University, Jaipur has completed her internship with **PharmaACE Analytics LLP** during the period of **April 01, 2024 to June 30, 2024.** During her internship she worked with the Chart Audit department and has successfully worked on the project; **Asthma Treatment landscape in the United States: Market Trends, Key market players, Pipeline drugs, and Unmet needs.**

We wish her every success in life.

Ashima Kumar

Ashima Kumar

Head – Training & Development and Corporate Communications

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled "Asthma Treatment landscape in the United States: Market Trends, Key market players, Pipeline drugs, and Unmet needs" is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

Tanya

(Signature)

Name of Student: Tanya Sharma

Date: 05.07.2024

IIHMR UNIVERSITY

CERTIFICATE BY FACULTY GUIDE AND SCHOOL DEAN

This is to certify that dissertation titled "**Asthma Treatment Landscape in the United States: Market Trends, Key market players, Pipeline drugs, and Unmet needs**" is a record of the research work undertaken by Dr. Tanya Sharma in partial fulfilment of the requirements for the award of the degree of MBA (Hospital and Health Management) from the IIHMR University, Jaipur under my guidance and supervision and her approach to the research study has been sincere, scientific, and analytical.

Dr. Anoop Khanna

Professor

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Date 05/07/2024

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MBA-HM Dean

IIHMR University,Jaipur

Date 04/07/2024.

DECLARATION BY STUDENT

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Name of Student: Tanya Sharma

Date: 05.07.2024

ABSTRACT

Submitted by: Dr. Tanya Sharma Guided by: Dr. Anoop khanna

Roll No. 1642

Title: Asthma Treatment Landscape in the United States: Market Trends, Key market players, Pipeline drugs, and Unmet needs

Asthma is a persistent respiratory condition marked by inflammation and heightened airway sensitivity, resulting in repeated occurrences of wheezing, shortness of breath, chest constriction, and coughing. In the United States, asthma impacts more than 25 million individuals, presenting notable public health concerns.

The size of the worldwide market for asthma treatments was estimated at USD 27.51 billion in 2023 and is projected to expand at a compound annual growth rate (CAGR) of 2.42% between 2024 and 2033, to reach approximately USD 35.06**.**

The research is an observational study in which Secondary data was collected from various clinical studies, research articles, websites and journals to understand about the anticoagulant therapy. The study was conducted between April 1, 2024, to July 1, 2024

The report was developed covering disease overview including epidemiology, treatment options, drugs in pipeline and unmet need for asthma

Key words: Asthma, Asthma types and stages Drugs, Inline drugs, Pipeline drugs, Unmet need

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Dr. Tanya Sharma

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Abbreviations

1. FDA: Food and Drug Administration- Federal Agency
2. US: United States
3. CAGR: Compound Annual Growth Rate
4. CSV: Comma Separated Values
5. SABA: Short-Acting Beta Agonist
6. LABA: Long-Acting Beta Agonist
7. LAMA: Long-Acting Muscarinic Antagonist
8. SAMA: Short-Acting Muscarinic Antagonist
9. FENO: (fractional exhaled nitric oxide)
10. FEV: Forced expiratory volume in one second
11. FVC: Forced vital capacity
12. AAFP: American Academy of Family Physicians

Chapter 1– Introduction

1.1 Asthma Disease Overview

Asthma is defined as a chronic respiratory condition which is marked by inflammation and constriction of the airways, which in turn makes breathing difficult. This inflammation leads to symptoms such as shortness of breath, wheezing (High pitch whistling sound while breathing) coughing, and chest tightness.

Causes

- **Genetic History:** Individuals with the family history of asthma are at a high risk of developing asthma
- **Allergens**: Pollen, mold spores, dust mites, cat dander, and some foods are a few examples of allergens that can cause allergic reactions leading to asthma symptoms. Sensitization can occur over time when these allergens come into contact with the body repeatedly.
- **Occupational Exposures**: workplace environments expose employees to substances like chemicals, dust or fumes which can contribute to the development of occupational asthma in susceptible individuals
- **Respiratory Infections**: early exposure to viral infectins in childhood can lead to severe asthma exacerbation
- **Environmental factors**: Exposure to environmental pollutants and irritants, such as tobacco smoke, air pollution, chemical fumes, and strong odors, can trigger asthma symptoms or exacerbate existing asthma.
- **Others:** intense physical exertion or exercise, particularly in cold or dry air, obesity, smoking are other factors associated with an increased risk of asthma and can worsen asthma symptoms and control

Symptoms

- **Breathlessness**: This is when you have difficulties in breathing and, at times, a chest feels tight
- **Wheezing**: A squeaky noise during breathing which occurs mostly when exhaling although it can also occur during inhaling
- **Coughing**: Regular cough that worsens at night or early morning hours

- **Chest Tightness**: It feels like there's something heavy on your chest or as if someone is squeezing it on both sides
- **Increased mucus production**: Inhaled excess mucus results in persistent cough with a feeling of phlegm in the throat
- **Insomnia**: At nighttime, asthma symptoms increase interrupting sleep patterns.
- **Exhaustion**: You feel weary and worn out, especially after experiencing attacks of asthma or periods of its worsening

1.2 Types of Asthma

Intrinsic

- Also called adult-onset asthma or non-allergic asthma
- Generally speaking, triggers are non-allergic substances like cold air, exercise, respiratory illnesses, stress, smoke, or irritants like chemicals or strong scents.

Extrinsic

- Likewise referred to as allergic asthma.
- Allergens like mold, dust mites, pollen, cat dander, and specific foods are commonly known as triggers.
- usually starts in early infancy or adolescence
- Individuals who suffer from extrinsic asthma typically have a familial or personal history of hay fever, eczema, or allergies

Types Based on the type of inflammation pathway

a. **Eosinophilic asthma**: Eosinophils are a type of white blood cell of the immune system that are responsible for inflammatory processes in allergic reactions. Eosinophilic asthma is considered a type of allergic asthma because eosinophils are seen in relatively high numbers in the airways. It tends to respond to anti-inflammatory drug treatment (eg, corticosteroids).

b. **Neutrophilic asthma:** These are other types of white blood cell that form part of the inflammatory response, specifically to bacterial infections and some non-allergic triggers. Neutrophilic asthma is associated with more neutrophils than normal in the airways and may respond less well to traditional anti-inflammatory treatments.

c. **Mixed granulocytic asthma**: Here, inflammation in the airways is driven by a mixture of eosinophils and neutrophils that make the condition significantly harder to treat effectively, and can be one form of severe asthma

d. **Non-eosinophilic asthma**: These are subtypes of asthma where there are no raised levels of eosinophils in the airways, and include neutrophilic asthma, as well as other non--eosinophilic inflammatory patterns

1.3 Stages of Asthma

There are primarily 4 main stages of Asthma Namely Intermittent asthma, Mild persistent, Moderate Persistent Asthma, Severe asthma.

Asthma Type	**Severity Level**	**Frequency of Symptoms**	**Nighttime Awakening**	**Impact on Activities**	**Lung Function Test (FEV)**	**SABA Inhaler Use**
Intermittent Asthma	Least severe	About 2 days a week or less often	2 or fewer times each month	Symptoms do not interfere much	≥ 80% of normal values	≤ 2 days per week
Mild Persistent Asthma	Least severe form of persisten t asthma	More than twice a week, yet not on a daily basis	3 or 4 times a month	Minor impact on regular activities	≥ 80% of normal values	More frequent than twice a week but not every day
Moderate Persistent Asthma	Second most severe	Daily basis	More often than once a week	Some limitation of regular activities	60–80% of normal values	Daily
Severe Persistent Asthma	Most serious	Throughout the day	Every night	Significan t limitation of activities	< 60% of normal values	Several times a day

1.4 Diagnosis

1. **Medical History**: The healthcare provider will ask about the frequency and severity of your symptoms, as well as any triggers that exacerbate them. They will also request your personal and family medical history, including any allergies or respiratory conditions.
2. **Physical Examination:** physical examination may be conducted to watch for signs of wheezing or other abnormal sounds. The doctor may also assess other symptoms such as nasal congestion or eczema, which can be associated with asthma.
3. **Spirometry**: This is the most common lung function test used for diagnosis using a device called a spirometer. It assesses two main factors: Expiratory Forced Vital Capacity (FVC) and Forced Expiratory Volume in one second (FEV1). The diagnostic criteria include evaluating the FEV1/FVC ratio. If there is an obstruction in the airways, the ability to expel air quickly from the lungs is reduced, resulting in a lower FEV1 and FEV1/FVC ratio
4. **FENO (fractional exhaled nitric oxide):** FENO measures the level of nitric oxide in breath which id directly proportional to the level of inflammation in lungs
5. **Provocation or trigger test:** It includes irritant challenge (The doctor will expose to an irritant to see the response) exercise challenge (some asthma are triggered by exercise the doctor will make you perform a few exercises and then record the response) methacholine challenges (is utilized to evaluate the responsiveness of the airways in individuals suspected of having asthma)
6. **Blood test:** The IgE antibody test, or immunoglobulin E (IgE) test, is a diagnostic examination that measures the concentration of IgE antibodies present in the bloodstream. These antibodies are produced by the immune system in response to allergens, substances that provoke allergic reactions**.**

Additional Tests:

- **Allergy Testing**: Tests for allergies may be performed to identify triggers that can worsen asthma symptoms
- **Imaging Tests:** Occasionally, imaging such as chest X-rays or CT scans may be required to exclude other conditions or evaluate the extent of asthma severity.

1.5 Epidemiology

- About 29 million individuals in the USA are affected by asthma, equating to approximately 1 in 12 people, with a prevalence rate of 8.9% in 2022[1,2]
- Asthma is more prevalent among adult females than males. Approximately 10.8% of adult females are affected by asthma, compared to 6.5% of adult males
- It is a leading chronic disease in children[3] Currently, there are about 4.5 million children under the age of 18 with asthma[2]

Chapter 2 – Review of Literature

Table 2.1

Study Title	Authors	Key Findings	Treatment Options Discussed	Epidemiology & Demographics	Gaps & Unmet Needs
1. Evolution of Asthma Treatment	Smith et al. (2023)	Advances in personalized medicine, digital health tools, treatment adherence	SABAs, LABAs, ICS, Biologics	High prevalence among ethnic minorities, socio-economic disparities	Need for better adherence strategies, integration of digital health tools
2. Mechanism of Action of Asthma Drugs	Johnson et al. (2023)	Detailed MoA for various asthma drugs, including monoclonal antibodies and interleukin antagonists	Anti-IgE antibodies, IL-5 receptor antagonists, Leukotriene modifiers	Specific populations benefiting from biologics	Inadequate response in certain patient populations, need for more targeted therapies
3. Market Analysis and Future Forecast	Clarivate Analytics (2024)	Market trends, key players, forecast for pipeline drugs	Current market drugs, pipeline drugs, combination therapies	Market segmentation, competitive landscape, forecast for market growth	Development needs for targeted therapies, market opportunities

4. Efficacy and Safety of New Treatments	Lee et al. (2021)	Comparative efficacy and safety of new biologics and traditional therapies	Mepolizumab, Reslizumab, Dupilumab	Efficacy in eosinophilic asthma, demographic variations in treatment response	High costs, accessibility issues
5. Asthma Management Strategies	Williams et al. (2017)	Strategies for effective management, importance of early intervention	ICS, LABAs, LTRAs, Biologics	High prevalence in children, disparities in treatment access	Need for early intervention, disparities in access to care
6. Pediatric Asthma Management	Martinez et al. (2011)	Challenges and strategies in managing pediatric asthma	ICS, LABAs, Biologics	High prevalence among children, impact on quality of life	Pediatric-specific treatment needs, long-term safety of therapies
7. Advances in Asthma Treatment	Nguyen et al. (2021)	Recent advances in treatment options, impact of new drug approvals	SABAs, LABAs, ICS, Biologics	Varied response among different demographics, personalized treatment approaches	Need for more personalized treatments, addressing treatment-resistant asthma

Chapter 3 - Methodology

3.1 Objective

- To analyze the different types of asthma and their epidemiology in the US
- To review the approved therapies for asthma and the current market landscape
- To identify the key drivers of treatment decisions in asthma management
- To assess the key market players and analyze the pipeline drugs
- To explore current trends and unmet needs in the asthma treatment market

3.2 Scope

The study was carried out to understand the various aspects of asthma treatment within the US market. It aims to investigate current trends, upcoming innovations in treatment pipelines, and the prominent entities involved in the asthma treatment landscape.

Asthma management primarily involves bronchodilators and corticosteroids, yet significant unmet needs remain, such as suboptimal patient adherence and the need for more effective treatments beyond symptom relief.

3.3 Research Methodology

- Methodology: Secondary Research Type
- Secondary Research Setting: Organization Setting (PharmaAce Innovations LLP) Study
- Duration: 3 Months Data was gathered through secondary research from clinical trials, research papers, and reputable websites specializing in asthma treatment and management.

Chapter 4 - Results

4.1 Current Treatment Options

- **Bronchodilators**: These relax the muscles around smaller airways, rapidly opening the airways with a goal of easing symptoms during an asthma attack.
- **Quick-acting beta-agonists (SABA):** are short-term medications to alleviate symptoms. They act quickly and hence must be taken soon after the symptoms start. They are effective for four to six hours and keep the airways open.
- **Short acting muscarinic- antagonists (SAMA**): are quick-relief medicines for short-term use, when alongside with a short-acting beta agonist. They open airway from four to six hours.
- **Long acting beta-agonists (LABA**) are controller medicines,only accessible in composite products that include an inhaled corticosteroid, not as separate medications on their own. It will keep the bronchial tree patent for up to 12 hours with its effect starting rapidly only in one LABA – formoterol
- **Long acting muscarinic- antagonists (LAMA**) are also known as controller medicines. These may be also called anticholinergics, and should be taken 12–24 h before relief of bronchodilatation can occur. Daily usage, but no immediate relief of an attack is guaranteed
- **Theophylline** is a controller medicine which comes in the form of a tablet, capsule, solution, and syrup to take by mouth which should be taken daily and will not relieve sudden symptoms

Corticosteroids

- **Inhaled Corticosteroids:** These are corticosteroids that imitate the natural corticosteroids provided by your adrenal glands. As they control or prevent asthma symptoms thus known as controllers .They concentrate only on the respiratory tract
- **Oral corticosteroids:** These drugs are occasionally used as a "rescue" medication for attacks of severe asthma that do not respond rapidly to other asthma medications, but these agents have significant long-term adverse effects

Biologics

These are administered through injections or infusions after every few weeks. They work by inhibiting certain cells or proteins that are involved in the inflammation of the airways. Used in

moderate to -severe asthma that is uncontrolled with inhaled corticosteroids and/or other medications, or in those that are corticosteroid-dependent examples include omalizumab, mepolizumab, benralizumab, dupilumab)

Other Treatment options

Leutrokene modifiers these medications block the action of leukotrienes, substances in the body that cause asthma symptoms. They can be taken orally and include montelukast, zafirlukast, and zileuton.

4.2 Asthma Market Overview

4.2.1 FDA Approved Drugs

Brand name	Molecule	MoA	Company	Approval	Indication
Tezpire	Tezepelumab	thymic stromal lymphopoietin (TSLP) blocker	Amgen	2021	Additional treatment of adult and pediatric patients severe asthma
Dupixent	Dupilumab	interleukin-4 receptor alpha antagonist	Regeneron	2017	additional maintenance therapy for adults and children (6 years of age and older) with oral corticosteroid-dependent asthma or moderate-to-severe asthma marked by an eosinophilic phenotype
Fasenra	Benralizumab	interleukin-5 receptor alpha-	Astra Zeneca	2017	additional maintenance

		directed cytolytic monoclonal antibody			treatment of individuals with eosinophilic phenotype who have severe asthma and are 12 years of age or older.
Cinqair	Reslizumab	Interleukin 5 antagonist monoclonal antibody	Teva	2016	additional maintenance treatment of individuals with eosinophilic phenotype who have severe asthma and are 18 years of age or older
Nucala	Mepolizumab	Interleukin 5 antagonist monoclonal antibody	GlaxoSmithKline	2015	Add on maintenance treatment for severe asthma and who exhibit an eosinophilic phenotype(patients aged 12 years and older who have)
Accolate	Zafirlukast	leukotriene receptor antagonist	Astrozeneca	2015	chronic treatment of asthma in adults and children 5 years of age and older.
Xolair	Omalizumab	anti-IgE antibody	Genentech	2003	6 years of age and older patients with moderate to severe

					persistent asthma whose symptoms are not well managed by inhaled corticosteroids
Singulair	Montelukast sodium	leukotriene receptor antagonist	Merck & Co.	1998	Indicated in cases of chronic asthma patients 12 months of age and older
Zyflo	Reslizumab	leukotriene receptor antagonist	Abbott Labs	1996	chronic asthma in adults and children 12 years of age and older.

4.2.2 Drugs by class and Type of Asthma

Drug	**Drug class**	**Type of Asthma**
Tezepelumab	Anti-inflammatories; Antiasthmatics	Severe asthma without limitations based on specific phenotype or biomarkers.
Dupilumab	Anti-inflammatories; Antiallergics; Antiasthmatics	Moderate to severe asthma with an **eosinophilic phenotype**
Benralizumab	Anti-inflammatories; Antiallergics; Antiasthmatics	Severe asthma **eosinophilic phenotype**
Reslizumab	Antiasthmatics	Severe asthma with **eosinophilic phenotype**
Mepolizumab	Anti-inflammatories; Antiallergics; Antiasthmatics	Severe asthma and with an **eosinophilic phenotype**.

Zafirlukast	Antiallergics; Antiasthmatics	chronic asthma in adults and children 12 years of age and older.
Omalizumab	Antiallergics; Antiasthmatics	moderate to severe persistent **allergic asthma**

4.2.3 Market analysis

The global market for asthma treatments was valued at USD 27.51 billion in 2023 and is expected to grow at a compound annual growth rate (CAGR) of 2.42% from 2024 to 2033, which may be reaching around USD 35.06 billion. (4)

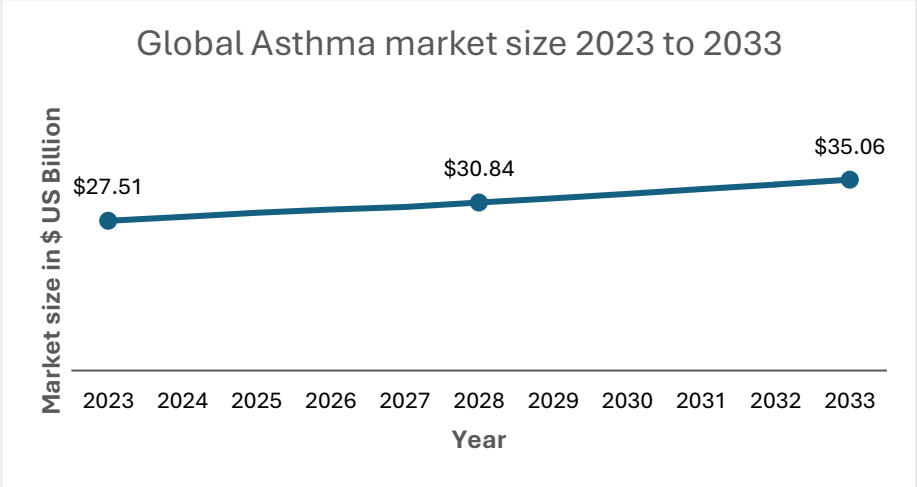

Figure 4.2.2 Global Asthma Market Size 2023 to 2033

In 2023, the market size for asthma treatments in the United States was estimated at USD 10.82 billion, with a projected increase to approximately USD 12.86 billion by 2033, reflecting a compound annual growth rate (CAGR) of 1.71% from 2024 to 2033 (4)

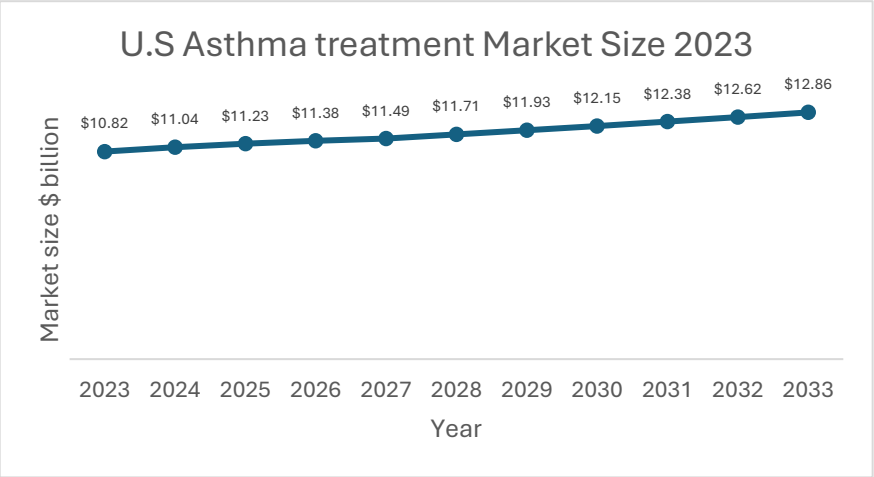

Figure 4.2.3 U.S. Asthma Treatment Market Size 2023

4.3 Market drivers

a. Increasing Prevalence of Chronic Respiratory Diseases:

The increasing prevalence of asthma patients is a driving factor for the market. Asthma is considered the most common chronic disease worldwide, which has led to a growing need for advanced therapeutics for asthma treatment. According to AAFP, over 27 million people in USA have asthma, increasing prevalence of asthma patients will be a driving factor for the therapeutics market[5]

b. Increase in air pollution:

It has been noted that both adults and children are affected adversely by the respiratory outcomes of asthma due to air pollution. Children who are exposed to traffic fumes, nitrogen oxide and second-hand smoke (SHS) have an enormous risk of suffering from childhood asthma. Wheezing, reduced lung function and asthma attacks can all be triggered by exposure to external pollutants. Asthmatics can be more vulnerable when they inhale minute particles as well as noxious gases irritate their lungs thereby making the disease worse[5]

c. Impact of air pollution on DNA associated asthma:

The relationship between air pollution and asthma is discussed by a recent study funded by the Environmental Protection Agency and research points that the air pollution may suppress genes that controls the immune system of the body to differentiate between an allergen could and a potentially dangerous foreign substance such as a virus or bacteria. After that, the

immune system may overreact which can futher triggeri an inflammatory reaction that results in asthma.

d. Childhood asthma is associated with exposure to coarse particulate matter:

younger children's respiratory systems are still developing and they spend more time outdoors than adults. In a nationwide sample of American children, children who are exposed to outdoor coarse particulate matter (PM 10-2.5), PM10 examples: dust, pollen, mold, PM2.5 examples: combustion particles, compounds, metals, smoke, and soot, emissions, were more likely to develop asthma and require emergency room or hospital treatment for asthma

e. Increasing Knowledge and Call for Better Results of Asthma Treatment:

An increasing number of asthma patients are getting concerned about the disease and its devastating effects. Apparently, this is followed by the need for more focused and effective therapies which have been pushing the research in this field.

f. Launch of Novel Asthma Treatments

Ongoing research and development in the realm of asthma treatment has resulted in the introduction of novel medications like Tezspire, which has obtained FDA approval for managing severe asthma.[6]

4.4 Key market players

Pharmaceutical firms that create and produce asthma drugs are important participants in the US asthma market. Among the well-known participants in the market are Astra Zeneca, Amgen, GlaxoSmithKline, Merck & Co, Regeneron, Teva, Genentech.

After analysing the pipeline drugs and approved drugs strong asthma drug portfolio of Amgen, AstraZeneca &GlaxoSmithKline help them to maintain a leading position

4.5 Key Pipeline therapies for Asthma - US Market

Following are the steps used for extracting drugs in pipeline which are under clinical trials for treatment of asthma

1. Go to site Clinicaltrials.gov
2. Select Asthma as disease/condition
3. Apply filters
4. In Recruitment: select all except suspended, terminated and withdrawn
5. In study type: Select Interventional
6. In funder type: Select industry
7. Download CSV/Excel format

Phase 3 clinical trials of Asthma

Trial name/ NCT ID	Company	PCD	Study type	Intervention
NCT03560466	Sanofi	Mar -2025	Active_Not_Recruiting	Dupilumab, Asthma Controller Therapies Prednisone/Prednisolone, Asthma Reliever Therapies
NCT05202262	AstraZeneca	Mar-2025	Recruiting	Budesonide And Formoterol Fumarate Metered Dose Inhaler, Open-Label Symbicort

NCT05755906	AstraZeneca	Sept-2024	Recruiting	Budesonide And Formoterol Fumarate Metered Dose Inhaler
NCT06052267	Teva Branded Pharmaceutical.	Jul-2026	Recruiting	Tev-56248, Albuterol Sulphate
NCT05748600	Areteia Therapeutics	Mar-2025	Recruiting	Dexpramipexole Dihydrochloride, Placebo
NCT05398263	AstraZeneca	Sept-2025	Recruiting	Tezepelumab, Placebo
NCT05292586	Chiesi Farmaceutici S.p.A.	Jun-2024	Recruiting	Beclomethasone, Dipropionate/Formoterol Fumarate, Beclomethasone Dipropionate
NCT05813288	Areteia Therapeutics	Jun-2026	Recruiting	Dexpramipexole, Dihydrochloride, Placebo
NCT04718389	GlaxoSmithKline	Sept-2025	Recruiting	Gsk3511294, Depemokimab Mepolizumab, Benralizumab, Placebo
NCT06023589	AstraZeneca	Apr-2027	Recruiting	Tezepelumab, Placebo
NCT05763121	Areteia Therapeutics	Jun-2026	Recruiting	Dexpramipexole Dihydrochloride: Placebo
NCT04609904	AstraZeneca	Mar-2025	Recruiting	Budesonide, Glycopyrronium, And Formoterol Fumarate Metered Dose Inhaler, Symbicort

NCT04609878	AstraZeneca	Mar-2025	Recruiting	Budesonide, Glycopyrronium, And Formoterol Fumarate Metered Dose Inhaler, Symbicort
NCT05243680	GlaxoSmithKline	May-2025	Recruiting	Gsk3511294 (Depemokimab)
NCT05692180	AstraZeneca	May-2030	Recruiting	Benralizumab, Placebo
NCT05505734	Bond Avillion Development LP	Mar-2025	Recruiting	Budesonide/Albuterol Sulphate (Bda) Metered Dose Inhaler (Mdi)] With As [Albuterol Sulfate
NCT04719832	GlaxoSmithKline	Nov-2023	Active_Not_Recruiting	Depemokimab, Placebo
NCT05274815	AstraZeneca	Sep-2024	Active_Not_Recruiting	Tezepelumab
NCT04718103	GlaxoSmithKline	Apr-2024	Active_Not_Recruiting	Depemokimab,Placebo

Phase 2 clinical trials of Asthma

Trial name/NCT ID	Company	Study Name	Study type	Intervention
NCT05421598	Sanofi	Oct-2024	Recruiting	Amlitelimab, Placebo
NCT05363670	ARS Pharmaceuticals, Inc.	Jan-2024	Recruiting	Albuterol ,Placebo
NCT06196879	Upstream Bio Inc.	Feb-2026	Recruiting	Verekitug (Upb-101), Placebo
NCT06033833	Sanofi	Jun-2029	Recruiting	Amlitelimab,Placebo
NCT06376045	Amgen	Aug-2026	Recruiting	Rocatinlimab,Placebo
NCT06102005	Sanofi	Jun-2026	Recruiting	Lunsekimig,Placebo
NCT03028350	Cumberland Pharmaceuticals	Apr-2024	Active_Not_Recruiting	Ifetroban,Placebo
NCT05851443	Incyte Corporation	Dec-2024	Recruiting	Povorcitinib,Placebo,Ics-Laba
NCT05251259	AstraZeneca	Jan-2025	Recruiting	Atuliflapon,Placebo
NCT06020014	AstraZeneca	Sep-2025	Recruiting	AZD4604,Placebo
NCT04773678	Suzhou Connect Biopharmaceuticals, Ltd.	Aug-2023	Active_Not_Recruiting	CBP-201,Placebo

NCT04773678	Suzhou Connect Biopharmaceuticals, Ltd.	Aug-2023	Active_Not_Recruiting	CBP-20, Placebo

Phase 1 clinical trials

Trial name/ NCT ID	Company	Study name	Study type	Intervention
NCT05602025	GlaxoSmithKline	Oct-2023	Active_Not_ Recruiting	Biological: Depemokimab
NCT05830071	Chiesi Farmaceutici S.p.A.	Oct-2023	Recruiting	Formoterol Fumarate, Glycopyrronium Bromide, Moxifloxacin Hydrochloride,Placebo
NCT05332834	SinoMab BioScience Ltd	Sep-2023	Recruiting	Sm17,Placebo

4.6 Unmet Needs

There remains a unmet need for asthma treatment in the United States, especially for people with severe asthma whose symptoms are not well controlled by available treatments. There is still a need for more potent treatments even with the abundance of bronchodilators and anti-inflammatory drugs.

a. Lack of therapy for severe asthma

Significant asthma management challenge is represented by severe asthma, with poor treatment options in place. Biologic therapies approved for severe asthma, while the pipeline of new therapies is promising. Nevertheless, there are vast needs among patients with severe asthma and limited number of approved treatments. Despite maximal therapy using conventional medications, patients with severe asthma continue to suffer frequent exacerbations which lead to reduced quality of life and high healthcare resource utilizations. By developing new biologics that target various inflammatory pathways; however, this gap can be bridged thus providing personalized medicine to those who do not respond well to currently available treatments.

b. Misdiagnosis

Diagnosis of asthma is complicated because its symptoms vary from time to time and it may mimic other respiratory or non-respiratory problems such as airflow obstruction.This diversity hinders accurate identification of the disease from other similar conditions like chronic obstructive pulmonary disease (COPD), vocal cord dysfunction (VCD), heart failure (HF) and anxiety disorders among others. Research has shown that a significant proportion of patients could be misdiagnosed with bronchial asthma due to some factors such as inattention[7]

c. Ineffective Inhaler Technique

According to GINA Guidelines (80% patients) use inhalers the wrong way Proper inhaler technique is essential for effective drug delivery to the lungs in the treatment of asthma. Despite the availability of various inhalers, studies show that a large proportion of patients their inhalers. Common errors include improper respirator and mechanical alignment, failure to shake the respirator before use, and improper maintenance of the respirator Improper use of the respirator, can lead to decreased inhalation of drugs in the lungs, leading to poor control of symptoms, risk of unnecessary exacerbations and exacerbations therapy to earth, using an inhaler correctly is essential to getting medication into the lungs. If they do not utilize their metered-dose inhalers many patients—especially those using them—may not receive the entire dose of medication. Exacerbations and insufficient symptom management may result from this.

d. Inadequate Treatment Adherence

According to GINA Guidelines (upto 75% patients) Adherence describes how successfully patients carry out the specified asthma management plan, which includes taking prescription drugs as directed and attending scheduled follow-up visits with a doctor Achieving optimal asthma control relies heavily on patient adherence to prescribed treatment regimens, including medication use and follow-up appointments. Poor adherence remains a prevalent issue in asthma management, with factors such as forgetfulness, complexity of treatment regimens, cost concerns, and perceived stigma associated with medication use contributing to non-compliance. Studies suggest that a substantial proportion of patients may fail to adhere to prescribed therapies, leading to suboptimal asthma control, increased healthcare utilization, and higher economic burden. Addressing barriers to adherence through patient education, simplification of treatment regimens, use of reminder systems, and fostering open communication between patients and healthcare providers is essential to improving outcomes in asthma management. For a variety of reasons, Patients may struggle with forgetting to take their medication regularly, finding it challenging to integrate a complex or time-consuming treatment regimen into their daily routines. Additionally, some may incorrectly use their inhalers, while others might feel embarrassed to use them in public, there may also be cost concerns

e. Comorbidities

Comorbidities affecting asthma control most likely include, but are not limited to, obesity, GERD, rhinitis, sleep apnea, chronic sinusitis with nasal polyps, anxiety/depression, and GERD in patients with asthma. Comorbidities could be directly influencing the degree of asthma control by induction or amplification of symptoms. For example, anxiety might affect treatment compliance or perception of symptom severity, and GERD may induce airway reflux and exacerbate asthma symptoms despite the presence of effective drugs; co-morbidities in asthma patients are relatively common, making their disease more difficult to manage and impacting their response to their therapy. Those disorders may worsen asthma symptoms, increased airway reactiveness, airway inflammation, or compromised pulmonary physiology by different pathways. Secondly, apart from the respiratory system, comorbidities can depress the response to asthma medication, adherence to therapy, and patient's quality of life in general. A comprehensive strategy, therefore, must emphasize multidisciplinary care coordination. Thus, the management of coexisting illnesses is

combined with the treatment of asthma and tailors' therapeutic ways specifically to meet the need of every patient.

Chapter 5 - Conclusion

Asthma is still considered one of the priority health challenges in the presence of effective medications USA. The comprehensive strategies for asthma management, such as personalized action plans, regular asthma reviews, patient education on self-management of their disease or condition, and stratification of risk, have held promise for improving outcomes. However, inconsistencies in their adoption reflect missed opportunities for preventing avoidable asthma exacerbations.

Biologics for eg Tezpire are rapidly joining the ranks of some of the most important treatments, especially for those asthmatic patients whose conditions are serious and not well-controlled using conventional medicine. Targeted biologics against type 2 inflammatory pathways have shown efficacy in reducing asthma exacerbations and improving asthma control.

Looking ahead, further investigation of established and new molecular targets is warranted to make progress in developing novel treatments for severe asthma. It would be critical in the making of new drugs targeting all the mechanisms of asthma and to provide better options for patients not well served by the existing or available treatments. These research steps will translate into more options for treatment and better outcomes for those with difficult-to-control asthma once they are translated into practice.

Successful asthma management therefore calls for a collaborative and very personalized approach by patients and healthcare providers. It should underline supportive self-management strategies that must be tailored to the needs of the patient, education regarding asthma triggers and symptoms, and good communication to promote better treatment adherence for effectiveness. This must be instilled as a practice in routine health care across multidisciplinary teams so there is efficient control of asthma over time.

Improvement of asthma outcomes and reduction of asthma burden require serious consideration of severe asthma, misdiagnosis, inhaler misuse, poor treatment adherence, and comorbidities. Some key steps toward optimal asthma control and improved quality of life among US patients with asthma are adequate research on new therapeutic options, enhancing diagnostic accuracy, proper promotion of inhaler use, implementation of adherence-enhancing strategies, and comprehensive management of comorbidities.

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