

Hepatitis C Virus (HCV) - Market Insights, Epidemiology, and Market Forecast - 2030

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Abstracts

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DelveInsight's 'Hepatitis C Virus (HCV) - Market Insights, Epidemiology, and Market Forecast—2030' report delivers an in-depth understanding of the HCV, historical and forecasted epidemiology as well as the HCV market trends in the United States, EU5 (Germany, France, Italy, Spain, and United Kingdom), and Japan.

The HCV market report provides current treatment practices, emerging drugs, HCV market share of the individual therapies, current and forecasted HCV market size from 2017 to 2030 segmented by seven major markets. The Report also covers current HCV treatment practice/algorithm, market drivers, market barriers, and unmet medical needs to curate the best of the opportunities and assesses the underlying potential of the market.

Geography Covered

The United States

EU5 (Germany, France, Italy, Spain, and the United Kingdom)

Japan

Study Period: 2017–2030

Hepatitis C Virus (HCV): Disease Understanding and Treatment Algorithm

Hepatitis C Virus Overview

Hepatitis C is a viral infection that causes liver inflammation and damage, sometimes leading to serious liver disorder. HCV spreads through contaminated blood or body fluids. High-risk settings include IDU and the transfusion of unscreened blood and blood products, unsafe injection practices, unsafe health care. Other possible but less well-characterized risk exposures include tattoos and piercings, needle sticks, and unsafe/traumatic sexual practices.

HCV can range from a mild illness lasting a few weeks to a serious, long-term illness. HCV can be acute or chronic. Acute HCV occurs within the first 6 months after the patient is exposed to HCV. Around 55-85% of infected persons develop chronic HCV infection. Chronic HCV can be a lifelong infection if left untreated. Chronic HCV can cause serious health problems, including liver damage, cirrhosis (scarring of the liver), liver cancer, and even death. Most patients with newly acquired HCV do not exhibit symptoms of infection within the first 6 months. For people who develop symptoms, they usually happen 2–12 weeks after exposure to the HCV and can include yellow skin or eyes, not wanting to eat, upset stomach, throwing up, stomach pain, fever, dark urine, light-colored stool, joint pain, and feeling tired. Most chronic hepatitis C people do not have any symptoms or have only general symptoms like chronic fatigue and depression.

HCV is distinguished into different categories called genotypes based on similar genes. HCV genotypes are 1 (1a and 1b), 2, 3, 4, 5, and 6. In the United States, genotypes 1, 2, and 3 are the most common. Genotype 3 is the second most common HCV subtype in the world and most hard to treat because of the rapid progression of liver disease, increased rates of steatosis (non-alcoholic fatty liver disease), and a higher risk for cancer (hepatocellular carcinoma).

Hepatitis C Virus (HCV) Diagnosis

HCV is diagnosed based on the patient's medical history, a physical exam, and blood tests. If a viral infection is confirmed, doctors may suggest additional tests to check the condition of the liver.

Initial testing for the diagnosis of hepatitis C infection uses serologic assays that detect human antibodies generated as a response to HCV infection. Blood tests for HCV include screening tests for antibodies to the HCV virus, HCV RNA test, Genotype test,

etc.

In Chronic HCV, doctors may recommend additional tests to find out how much liver damage the patient has, or to rule out other causes of liver disease. These tests may include blood tests, Imaging Tests (Transient elastography, Ultrasound, MRI, and CT Scan), and Liver function Tests (ALT, AST, ALP, and total bilirubin). If the liver is damaged due to inflammation, enzymes pass out of the liver into the bloodstream, making ALT and AST levels higher than normal. The doctor may also recommend a liver biopsy if blood tests or imaging studies suggest the patient might have a liver problem. A biopsy can determine the extent of scarring, or fibrosis, in a liver affected by viral hepatitis

Hepatitis C Virus Treatment

New infection with HCV does not always require treatment, as the immune response in some people will clear the infection. However, when HCV infection becomes chronic, treatment is necessary.

The goal of hepatitis C treatment is a cure. HCV can be treated with antiviral medicines that attack the virus and can cure the disease in most cases. Several newer medicines, called direct-acting antiviral medicines, have also been approved to treat HCV. The four classes of DAAs, include NS5B nucleotide inhibitors, NS5B non-nucleoside inhibitors, NS5A replication complex inhibitors, and NS3/4A protease inhibitors (PI).

Harvoni (ledipasvir/sofosbuvir), Viekira Pak (ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets), and Zepatier (elbasvir/grazoprevir) are the DAAs approved for different genotypes of HCV.

Pan genotypic treatments are drugs suitable for all genotypes of HCV. These drugs may simplify treatment by removing the need for genotype testing. Pan-genotypic regimens are recommended as first-line treatment for people with chronic hepatitis C infection. These include Epclusa (sofosbuvir/velpatasvir), Mavyret (glecaprevir and pibrentasvir), and Vosevi (sofosbuvir/velpatasvir/voxilapresvir).

HCV Epidemiology

The HCV epidemiology division provides insights about historical and current HCV patient pool and forecasted trends for every seven major countries. It helps to recognize the causes of current and forecasted trends by exploring numerous studies and views of

key opinion leaders. This part of the DelveInsight report also provides the diagnosed patient pool and their trends along with assumptions undertaken.

Key Findings

In the year 2017, the total prevalent case of HCV was 8,257,162 cases in the 7MM which are expected to grow during the study period, i.e., 2017–2030.

The disease epidemiology covered in the report provides historical as well as forecasted HCV epidemiology [segmented as Total Prevalent Cases of HCV, Total Diagnosed Cases of HCV, Gender-specific Cases of HCV, Age-specific Diagnosed Cases of HCV, Genotype-specific Diagnosed Cases of HCV, Diagnosed Cases of HCV by Impact on Liver and Treated cases of HCV] in the 7MM covering the United States, EU5 countries (Germany, France, Italy, Spain, and the United Kingdom), and Japan from 2017 to 2030.

Country Wise- HCV Epidemiology

Estimates show that the highest cases of HCV in the 7MM were in the United States, followed by Japan, Italy, Spain, France, Germany, and the United Kingdom in 2017.

In the United States, the total number of prevalent cases of HCV was 3,251,471 cases in the year 2017 which are expected to grow during the study period, i.e., 2017–2030.

In the year 2017, the total prevalent cases of HCV were 3,108,919 cases in EU-5 which are expected to grow during the study period, i.e., 2017–2030.

In Japan, the total number of prevalent cases of HCV was 1,896,771 cases in the year 2017 which are expected to grow during the study period, i.e., 2017–2030.

HCV Drug Chapters

The drug chapter segment of the HCV report encloses the detailed analysis of HCV marketed drugs and late stage (Phase-III and Phase-II) pipeline drugs. It also helps to understand the HCV clinical trial details, expressive pharmacological action, agreements and collaborations, approval and patent details, advantages and

disadvantages of each included drug, and the latest news and press releases.

HCV Approved Drugs

Mavyret (Glecaprevir and Pibrentasvir)/AbbVie

Mavyret is a pan-genotypic, once-daily, ribavirin-free, co-formulated next-generation HCV treatment including glecaprevir (broad-genotypic NS3/4A protease inhibitor) and pibrentasvir (NS5A inhibitor). Glecaprevir-pibrentasvir is the first pan-genotypic NS3/4A protease inhibitor-NS5A inhibitor combination to be approved that offers a potent ribavirin free option for the vast majority of patients with chronic hepatitis C, including a potential eight-week option for non-cirrhotic patients with renal disease or HIV co-infection. This drug is not an option for patients with decompensated cirrhosis given the presence of the protease inhibitor.

Vosevi (sofosbuvir, velpatasvir, and voxilaprevir)/Gilead Sciences

Vosevi is the first pan-genotypic fixed-dose tablet that includes medications from three different HCV antiviral classes, specifically for patients with hepatitis C who were previously treated with certain advanced hepatitis C regimens, but could not achieve a functional cure. It is a prescription medicine used to treat adults with chronic (lasting a long time) hepatitis C genotype with or without cirrhosis (compensated) who have previously been treated with an HCV regimen. Vosevi contains an active ingredient sofosbuvir, the medicine that has helped transform HCV treatment, combined with 2 additional medicines Velpatasvir and Voxilaprevir creating a highly effective HCV treatment.

Epclusa (sofosbuvir/velpatasvir)/Gilead Sciences

Epclusa is a pan-genotypic drug used to treat adults and children 6 years of age and older or weighing at least 37 lbs (17 kg) with chronic (lasting a long time) HCV genotype 1, 2, 3, 4, 5, or 6 infections without cirrhosis or with compensated cirrhosis and with advanced cirrhosis (decompensated) in combination with ribavirin. It also provides a much-needed option for patients with HCV genotype 3 infections. Epclusa contains a combination of sofosbuvir and velpatasvir. Sofosbuvir and velpatasvir are antiviral medications that prevent HCV from multiplying in the body.

Harvoni (ledipasvir and sofosbuvir)/Gilead Sciences

Harvoni is a fixed-dose combination containing ledipasvir and sofosbuvir for oral administration. Sofosbuvir is a nucleotide analog HCV polymerase inhibitor, and it blocks the polymerase enzyme which the virus must use to reproduce. Ledipasvir is an HCV NS5A replication complex inhibitor that interferes with another protein HCV uses to reproduce. The fixed-dose combination of ledipasvir-sofosbuvir provides an effective and well-tolerated one-pill once-a-day option for treatment of genotypes 1, 4, 5, and 6 chronic HCV infection. This direct-acting antiviral regimen was the first FDA-approved interferon- and ribavirin-free regimen to treat hepatitis C.

Note: Detailed Current therapies assessment will be provided in the full report of HCV

HCV Emerging Drugs

CC-31244 (Cocrystal Pharma)

CC-31244 is an investigational, oral, non-nucleoside inhibitor (NNI). It is a potential best-in-class pan-genotypic inhibitor of NS5B polymerase for the treatment of hepatitis C infection. It has the potential to be an important component in an all-oral ultra-short duration HCV combination therapy. It has been designed and developed using the Company's proprietary structure-based drug discovery technology to have a high barrier to drug resistance and to be a highly potent, selective NNI that is active against all HCV genotypes (1-6) with low-level cytotoxicity in multiple cell types. Currently, CC-31244 is under development and has recently completed its phase IIa stage in the US.

AT-777 (Atea Pharmaceuticals)

AT-777 is a novel NS5A inhibitor, being developed as a treatment for HCV. AT-777 is a purine nucleotide prodrug, which is being developed as an orally administered, direct-acting antiviral therapy for the treatment of patients with HCV. The use of nucleoside and nucleotide analogs to inhibit the viral RNA polymerase, thereby preventing propagation of the virus, is a well-documented and historically successful approach to the treatment of various viral diseases, including HCV infections.

Other than the previously mentioned candidates, AT-527 and AT-777, Atea Pharmaceuticals is also developing AT-787 as the lead candidate for the treatment of HCV patients. AT-787 is Atea's proprietary pan-genotypic product candidate. This direct-acting antiviral is a single fixed-dose tablet that combines AT-527 and AT-777 (purine nucleotide prodrug NS5B polymerase inhibitor and novel NS5A inhibitor, respectively) that has potent pan-genotypic activity against HCV replication in vitro. AT-787 is

believed to have the potential to offer a short duration protease-sparing regimen for HCV-infected patients with or without cirrhosis. Due to this potential, Atea Pharmaceuticals has announced that rather than AT-527 and AT-777, AT-787 is the selected product candidate for the treatment of HCV.

Note: Detailed emerging therapies assessment will be provided in the final report.

HCV Market Outlook

Currently, treatment strategies for HCV mainly include Direct-Acting Antiviral agents. The development of new generation DAAs with much higher SVR rates has dramatically improved the prospects for people infected with HCV. DAAs directly target the HCV in different ways to stop it from reproducing. There are four classes of direct-acting antivirals that combine in various ways to make up the different HCV DAA treatments. NS3/4A protease inhibitors work by blocking a viral enzyme (protease) that enables the HCV to survive. NS5A Inhibitors block a virus protein, NS5A, which HCV needs to reproduce. Non-Nucleoside NS5B Polymerase Inhibitors inhibit HCV from reproducing. Nucleoside and Nucleotide NS5B Polymerase Inhibitors directly target the HCV to inhibit making copies of itself in the liver. Oral antiviral medications include Zepatier (elbasvir and grazoprevir), Harvoni (ledipasvir and sofosbuvir), Viekira Pak (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets), Mavyret (glecaprevir and pibrentasvir), Epclusa (sofosbuvir and velpatasvir), Vosevi (sofosbuvir, velpatasvir, and voxilaprevir).

At present, some companies have indulged themselves in initiating clinical trials that investigate new treatment options or studying how to use existing treatment options better. Current ongoing trials evaluate combinations of antivirals with high genetic barriers and investigate optimal treatment doses and durations. Key players such as Cocrystal Pharma (CC-31244), Atea Pharmaceuticals (AT-527, AT-777, and AT-787), PRISM Pharma and Ohara Pharmaceuticals (PRI-724), GeneCure Biotechnologies (HCVax (Therapeutic HCV vaccine)), and several others are investigating their candidates for the management of HCV in the 7MM. Companies like Medivir are investigating their candidate in the early stages of clinical development.

Key Findings

The HCV market size in the 7MM is expected to change during the study period 2017–2030. The therapeutic market of HCV in the seven major markets was USD 10,445 million in 2017 which is expected to decline during the study period

(2017–2030). According to the estimates, the highest market size of HCV is found in the United States followed by Japan in the year 2017.

The United States Market Outlook

In 2017, the total market size of HCV therapies was USD 6,929 million in the United States which is expected to decline in the study period (2017–2030).

EU-5 Countries: Market Outlook

In 2017, the total market size of HCV therapies was USD 2,330 million in the EU-5 countries which is expected to decline in the study period (2017–2030).

Japan Market Outlook

The total market size of HCV therapies in Japan was USD 1,187 million in 2017 which is expected to decline in the study period (2017–2030).

HCV Pipeline Development Activities

The drugs which are in pipeline include:

CC-31244 (Cocrystal Pharma)

AT-527 (Atea Pharmaceuticals)

PRI-724/OP-724 (PRISM Pharma and Ohara Pharmaceuticals)

AT-777 (Atea Pharmaceuticals); AT-787 (Atea Pharmaceuticals)

HCVax/Therapeutic HCV vaccine (GeneCure Biotechnologies)

Note: Detailed emerging therapies assessment will be provided in the final report.

HCV Drugs Uptake

Currently, the HCV market is almost entirely dominated by direct-acting antiviral agents (DAAs) which represent a revolution in HCV drug discovery. DAAs were developed to

improve the SVR rates, reduce adverse events, and improve adherence to therapy among HCV patients. Among DAAs, the majority of the market is currently dominated by Mavyret, Epclusa, and Harvoni. Among emerging therapies, Cocrystal Pharma (CC-31244) and Atea Pharmaceuticals (AT-787) are evaluating the potential of their regimens in the HCV market.

Access and Reimbursement Scenario in HCV Therapies

Glecaprevir–pibrentasvir was recommended by NICE in 2018, within its marketing authorization, as an option for treating chronic hepatitis C in adults, only if the company provides the drug at the same price or lower than that agreed with the Commercial Medicines Unit. Glecaprevir–pibrentasvir is suitable for all genotypes and has a shorter treatment duration than most other direct-acting antiviral treatments. Also, Elbasvir–grazoprevir was recommended by NICE, within its marketing authorization, as an option for treating genotype 1 or 4 chronic hepatitis C in adults.

KOL-Views

To keep up with current market trends, we take KOLs and SME's opinion working in the HCV domain through primary research to fill the data gaps and validate our secondary research. Their opinion helps to understand and validate current and emerging therapies treatment patterns or HCV market trends. This will support the clients in potential upcoming novel treatment by identifying the overall scenario of the market and the unmet needs.

Competitive Intelligence Analysis

We perform Competitive and Market Intelligence analysis of the HCV Market by using various Competitive Intelligence tools that includes – SWOT analysis, PESTLE analysis, Porter's five forces, BCG Matrix, Market entry strategies, etc. The inclusion of the analysis entirely depends upon the data availability.

Scope of the Report

The report covers the descriptive overview of HCV, explaining its causes, signs and symptoms, pathophysiology, and currently available therapies.

Comprehensive insight has been provided into the HCV epidemiology and treatment in the 7MM.

Additionally, an all-inclusive account of both the current and emerging therapies for HCV is provided, along with the assessment of new therapies, which will have an impact on the current treatment landscape.

A detailed review of the HCV market; historical and forecasted is included in the report, covering drug outreach in the 7MM.

The report provides an edge while developing business strategies, by understanding trends shaping and driving the global HCV market.

Report Highlights

In the coming years, the HCV market is set to change due to declining patient populations due to high DAA cure rates, lower average net selling price due to payers pressure; which would compress the size of the market to enable the drug manufacturers to penetrate more into the market.

The companies and academics are working to assess challenges and seek opportunities that could influence HCV R&D. The therapies under development are focused on novel approaches to treat/improve the disease condition.

Major players are involved in developing therapies for HCV.

A better understanding of disease pathogenesis will also contribute to the development of novel therapeutics for HCV.

Our in-depth analysis of the pipeline assets across different stages of development (Phase III and Phase II), different emerging trends, and comparative analysis of pipeline products with detailed clinical profiles, key cross-competition, launch date along with product development activities will support the clients in the decision-making process regarding their therapeutic portfolio by identifying the overall scenario of the research and development activities.

HCV Report Insights

Patient Population

Therapeutic Approaches

HCV Pipeline Analysis

HCV Market Size and Trends

Market Opportunities

Impact of Upcoming Therapies

HCV Report Key Strengths

11 Years Forecast

7MM Coverage

HCV Epidemiology Segmentation

Key Cross Competition

Highly Analyzed Market

Drugs Uptake

HCV Report Assessment

SWOT Analysis

Current Treatment Practices

Unmet Needs

Pipeline Product Profiles

Conjoint Analysis

Market Attractiveness

Market Drivers and Barriers

Key Questions

Market Insights:

What was the HCV Market share (%) distribution in 2017 and how it would look like in 2030?

What would be the HCV total market size as well as market size by therapies across the 7MM during the study period (2017–2030)?

What are the key findings of the market across the 7MM and which country will have the largest HCV market size during the study period (2017–2030)?

At what CAGR, the HCV market is expected to decline in the 7MM during the study period (2017–2030)?

What would be the HCV market outlook across the 7MM during the study period (2017–2030)?

What will be the resultant market size in the year 2030?

How would the market drivers, barriers, and future opportunities affect the market dynamics and subsequent analysis of the associated trends?

HCV patient types/pool where unmet need is more and whether emerging therapies will be able to address the residual unmet need?

How emerging therapies are performing on the parameters like efficacy, safety, route of administration (RoA), treatment duration, and frequencies based on their clinical trial results?

Among the emerging therapies, what are the potential therapies which are expected to disrupt the HCV market?

Epidemiology Insights:

What are the disease risks, burdens, and unmet needs of the HCV?

What is the historical HCV patient pool in the seven major markets covering the United States, EU5 (Germany, France, Italy, Spain, and the United Kingdom), and Japan?

What would be the forecasted patient pool of HCV in the 7 major markets covering the United States, EU5 (Germany, France, Italy, Spain, and the United Kingdom), and Japan?

What will be the growth opportunities in the 7MM concerning the patient population about HCV?

Out of all the 7MM countries, which country would have the highest prevalent population of HCV during the study period (2017–2030)?

At what CAGR the population is expected to grow in the 7MM during the study period (2017–2030)?

What are the various recent and upcoming events which are expected to improve the diagnosis of HCV?

Current Treatment Scenario and Emerging Therapies:

What are the current options for the treatment of HCV?

What are the current treatment guidelines for the treatment of HCV in the US, Europe, and Japan?

How many companies are developing therapies for the treatment of HCV?

How many therapies are developed by each company for the treatment of HCV?

How many emerging therapies are in the mid-stage and late stages of

development for the treatment of HCV?

What are the key collaborations (Industry–Industry, Industry-Academia), Mergers and acquisitions, licensing activities related to the HCV therapies?

What are the recent novel therapies, targets, mechanisms of action, and technologies developed to overcome the limitation of existing therapies?

What are the clinical studies going on for HCV and their status?

What are the key designations that have been granted for the emerging therapies for HCV?

What is the global historical and forecasted market of HCV?

Reasons to buy

The report will help in developing business strategies by understanding trends shaping and driving the HCV market.

To understand the future market competition in the HCV market and insightful review of the key market drivers and barriers.

Organize sales and marketing efforts by identifying the best opportunities for HCV in the US, Europe (Germany, France, Italy, Spain, and the United Kingdom), and Japan.

Identification of strong upcoming players in the market will help in devising strategies that will help in getting ahead of competitors.

Organize sales and marketing efforts by identifying the best opportunities for the HCV market.

To understand the future market competition in the HCV market.

Contents

1. KEY INSIGHTS

2. EXECUTIVE SUMMARY OF THE HEPATITIS C VIRUS (HCV)

3. SWOT ANALYSIS OF HEPATITIS C VIRUS (HCV)

4. HEPATITIS C VIRUS (HCV): MARKET SHARE (%) DISTRIBUTION OVERVIEW AT A GLANCE: BY COUNTRY

5. EPIDEMIOLOGY AND MARKET METHODOLOGY

6. HEPATITIS C VIRUS (HCV): DISEASE BACKGROUND AND OVERVIEW

6.1. Introduction

- 6.1.1. Signs and Symptoms of HCV
- 6.1.2. Risk Factors and Causes of HCV
- 6.1.3. Pathophysiology of HCV
- 6.1.4. Complications of HCV Infection

7. DIAGNOSIS OF HEPATITIS C INFECTION

- 7.1. Screening for HCV infection
- 7.2. HCV RNA Testing
- 7.3. HCV Genotype Testing
- 7.4. HCV Resistance Testing (RAV testing)
- 7.5. Tests to Diagnose HCV
 - 7.5.1. Medical History and Physical exam
 - 7.5.2. Imaging Tests
 - 7.5.3. Liver Biopsy
- 7.6. The differential diagnosis for Hepatitis C

8. PREVENTION OF HCV

9. DIAGNOSTIC GUIDELINES OF HCV

- 9.1. Centers for Disease Control and Prevention (CDC) Recommendations for Hepatitis

C screening among Adults in the United States

9.2. US Preventive Services Task Force (USPSTF) Recommendations for the screening of HCV infection in Adolescents and Adults

9.3. American Association for the Study of Liver Diseases (AASLD) Diagnostic Guidelines

9.4. World Health Organization (WHO) Diagnostic Guidelines

9.5. EASL recommendations on treatment of hepatitis C 2020

10. EPIDEMIOLOGY AND PATIENT POPULATION

10.1. Epidemiology Key Findings

10.2. Assumptions and Rationale: 7MM

11. EPIDEMIOLOGY SCENARIO: 7MM

11.1. Total Prevalent Cases of HCV in the 7MM

11.2. Total Diagnosed cases of HCV in the 7MM

11.3. Gender-specific cases of HCV in the 7MM

11.4. Age-specific Diagnosed Cases of HCV in the 7MM

11.5. Genotype-specific Diagnosed Cases of HCV in the 7MM

11.6. Diagnosed Cases of HCV by Impact on Liver in the 7MM

11.7. Treated cases of HCV in the 7MM

12. THE UNITED STATES EPIDEMIOLOGY

12.1. Total Prevalent Cases of HCV in the United States

12.2. Total Diagnosed cases of HCV in the United States

12.3. Gender-specific cases of HCV in the United States

12.4. Age-specific Diagnosed Cases of HCV in the United States

12.5. Genotype-specific Diagnosed Cases of HCV in the United States

12.6. Diagnosed Cases of HCV by Impact on Liver in the United States

12.7. Treated cases of HCV in the United States

13. EU-5 EPIDEMIOLOGY

13.1. Germany

13.1.1. Total Prevalent Cases of HCV in Germany

13.1.2. Total Diagnosed cases of HCV in Germany

13.1.3. Gender-specific cases of HCV in Germany

- 13.1.4. Age-specific Diagnosed Cases of HCV in Germany
- 13.1.5. Genotype-specific Diagnosed Cases of HCV in Germany
- 13.1.6. Diagnosed Cases of HCV by Impact on Liver in Germany
- 13.1.7. Treated cases of HCV in Germany
- 13.2. France
 - 13.2.1. Total Prevalent Cases of HCV in France
 - 13.2.2. Total Diagnosed cases of HCV in France
 - 13.2.3. Gender-specific cases of HCV in France
 - 13.2.4. Age-specific Diagnosed Cases of HCV in France
 - 13.2.5. Genotype-specific Diagnosed Cases of HCV in France
 - 13.2.6. Diagnosed Cases of HCV by Impact on Liver in France
 - 13.2.7. Treated cases of HCV in France
- 13.3. Italy
 - 13.3.1. Total Prevalent Cases of HCV in Italy
 - 13.3.2. Total Diagnosed cases of HCV in Italy
 - 13.3.3. Gender-specific cases of HCV in Italy
 - 13.3.4. Age-specific Diagnosed Cases of HCV in Italy
 - 13.3.5. Genotype-specific Diagnosed Cases of HCV in Italy
 - 13.3.6. Diagnosed Cases of HCV by Impact on Liver in Italy
 - 13.3.7. Treated cases of HCV in Italy
- 13.4. Spain
 - 13.4.1. Total Prevalent Cases of HCV in Spain
 - 13.4.2. Total Diagnosed cases of HCV in Spain
 - 13.4.3. Gender-specific cases of HCV in Spain
 - 13.4.4. Age-specific Diagnosed Cases of HCV in Spain
 - 13.4.5. Genotype-specific Diagnosed Cases of HCV in Spain
 - 13.4.6. Diagnosed Cases of HCV by Impact on Liver in Spain
 - 13.4.7. Treated cases of HCV in Spain
- 13.5. The United Kingdom
 - 13.5.1. Total Prevalent Cases of HCV in the United Kingdom
 - 13.5.2. Total Diagnosed cases of HCV in the United Kingdom
 - 13.5.3. Gender-specific cases of HCV in the United Kingdom
 - 13.5.4. Age-specific Diagnosed Cases of HCV in the United Kingdom
 - 13.5.5. Genotype-specific Diagnosed Cases of HCV in the United Kingdom
 - 13.5.6. Diagnosed Cases of HCV by Impact on Liver in the United Kingdom
 - 13.5.7. Treated cases of HCV in the United Kingdom

14. JAPAN EPIDEMIOLOGY

- 14.1. Total Prevalent Cases of HCV in Japan
- 14.2. Total Diagnosed cases of HCV in Japan
- 14.3. Gender-specific cases of HCV in Japan
- 14.4. Age-specific Diagnosed Cases of HCV in Japan
- 14.5. Genotype-specific Diagnosed Cases of HCV in Japan
- 14.6. Diagnosed Cases of HCV by Impact on Liver in Japan
- 14.7. Treated cases of HCV in Japan

15. CURRENT TREATMENT PRACTICES: HCV

- 15.1. Treatment Algorithm of HCV
- 15.2. Direct-acting Antiviral Agents (DAA)
 - 15.2.1. Classes of DAAs
- 15.3. Pangenotypic treatments
- 15.4. Liver Transplant

16. TREATMENT GUIDELINES OF HCV

- 16.1. American Association for the Study of Liver Diseases (AASLD) Treatment Guidelines
- 16.2. World Health Organization (WHO) Treatment Guidelines
- 16.3. EASL recommendations on treatment of hepatitis C 2020

17. UNMET NEEDS

18. PATIENT JOURNEY OF HCV

19. KEY ENDPOINTS IN HCV CLINICAL TRIALS

20. MARKETED THERAPY

- 20.1. Mavyret (Glecaprevir and Pibrentasvir): AbbVie
 - 20.1.1. Product Description
 - 20.1.2. Regulatory Milestones
 - 20.1.3. Other Developmental Activities
 - 20.1.4. Pivotal Clinical Trial
- 20.2. Vosevi (sofosbuvir, velpatasvir, and voxilaprevir): Gilead Sciences
 - 20.2.1. Product Description
 - 20.2.2. Regulatory Milestones

- 20.2.3. Other Developmental Activities
- 20.2.4. Pivotal Clinical Trial
- 20.3. Viekira Pak/ Viekirax (ombitasvir, paritaprevir and ritonavir; dasabuvir): AbbVie
 - 20.3.1. Product Description
 - 20.3.2. Regulatory Milestones
 - 20.3.3. Other Developmental Activities
 - 20.3.4. Pivotal Clinical Trial
 - 20.3.5. Ongoing Current Pipeline Activity
- 20.4. Epclusa (sofosbuvir/velpatasvir): Gilead Sciences
 - 20.4.1. Product Description
 - 20.4.2. Regulatory Milestones
 - 20.4.3. Other Developmental Activities
 - 20.4.4. Pivotal Clinical Trial
 - 20.4.5. Ongoing Current Pipeline Activity
- 20.5. Zepatier (Elbasvir and Grazoprevir): Merck
 - 20.5.1. Product Description
 - 20.5.2. Regulatory Milestones
 - 20.5.3. Other Developmental Activities
 - 20.5.4. Pivotal Clinical Trial
- 20.6. Harvoni (ledipasvir and sofosbuvir): Gilead Sciences
 - 20.6.1. Product Description
 - 20.6.2. Regulatory Milestones
 - 20.6.3. Other Developmental Activities
 - 20.6.4. Pivotal Clinical Trial
 - 20.6.5. Ongoing Current Pipeline Activity

21. EMERGING THERAPIES

- 21.1. CC-31244 (CDI-31244): Cocrystal Pharma
 - 21.1.1. Product Description
 - 21.1.2. Other Developmental Activities
 - 21.1.3. Clinical Development
 - 21.1.4. Safety and Efficacy
- 21.2. AT-527: Atea Pharmaceuticals
 - 21.2.1. Product Description
 - 21.2.2. Clinical Development
 - 21.2.3. Safety and Efficacy
- 21.3. PRI-724 (OP-724): PRISM Pharma and Ohara Pharmaceuticals
 - 21.3.1. Product Description

- 21.3.2. Other Developmental Activities
- 21.3.3. Clinical Development
- 21.3.4. Safety and Efficacy
- 21.4. AT-777: Atea Pharmaceuticals
 - 21.4.1. Product Description
 - 21.4.2. Clinical Development
- 21.5. HCVax (Therapeutic HCV vaccine): GeneCure Biotechnologies
 - 21.5.1. Product Description
 - 21.5.2. Clinical Development

22. HEPATITIS C VIRUS (HCV): SEVEN MAJOR MARKET ANALYSIS

- 22.1. Key Findings
- 22.2. Market Outlook: 7MM

23. 7MM MARKET SIZE

- 23.1. Total Market Size of HCV in the 7MM
- 23.2. Total Market size of HCV by Therapies in the 7MM

24. THE UNITED STATES MARKET SIZE

- 24.1. Total Market size of HCV in the United States

25. EU-5 MARKET SIZE

- 25.1. Germany Market Size
 - 25.1.1. Total Market size of HCV in Germany
- 25.2. France Market Size
 - 25.2.1. Total Market size of HCV in France
- 25.3. Italy Market Size
 - 25.3.1. Total Market size of HCV in Italy
- 25.4. Spain Market Size
 - 25.4.1. Total Market size of HCV in Spain
- 25.5. The United Kingdom Market Size
 - 25.5.1. Total Market size of HCV in the United Kingdom

26. JAPAN MARKET SIZE

26.1. Total Market size of HCV in Japan

27. MARKET ACCESS AND REIMBURSEMENT OF HCV THERAPIES

27.1. Restricted Access to Costly HCV DAA Medications

27.2. Reimbursement Management

27.2.1. Insurance and Medicaid Approval

27.2.2. Pharmaceutical Patient Assistance Programs

28. MARKET DRIVERS

29. MARKET BARRIERS

30. APPENDIX

30.1. Bibliography

30.2. Report Methodology

31. DELVEINSIGHT CAPABILITIES

32. DISCLAIMER

33. ABOUT DELVEINSIGHT

List Of Tables

LIST OF TABLES

Table 1: Summary of the Hepatitis C Virus (HCV) Market, Epidemiology, and Key Events (2017–2030)

Table 2: HCV Antibody and HCV RNA Test Result Interpretations

Table 3: Summary of Recommendations

Table 4: Summary of Recommendations

Table 5: Summary of Recommendations

Table 6: Summary of Recommendations

Table 7: Summary of Recommendations

Table 8: Summary of Recommendations

Table 9: Summary of Recommendations

Table 10: Summary of Recommendations

Table 11: Summary of Recommendations

Table 12: Summary of Recommendations

Table 13: Summary of Recommendations

Table 14: Total Prevalent Cases of HCV in the 7MM (2017–2030)

Table 15: Total Diagnosed cases of HCV in the 7MM (2017–2030)

Table 16: Gender-specific cases of HCV in the 7MM (2017–2030)

Table 17: Age-specific Diagnosed Cases of HCV in the 7MM (2017–2030)

Table 18: Genotype-specific Diagnosed Cases of HCV in the 7MM (2017–2030)

Table 19: Diagnosed Cases of HCV by Impact on Liver in the 7MM (2017–2030)

Table 20: Total Treated cases of HCV in the 7MM (2017–2030)

Table 21: Total Prevalent Cases of HCV in the United States (2017–2030)

Table 22: Total Diagnosed cases of HCV in the United States (2017–2030)

Table 23: Gender-specific cases of HCV in the United States (2017–2030)

Table 24: Age-specific Diagnosed Cases of HCV in the United States (2017–2030)

Table 25: Genotype-specific Diagnosed Cases of HCV in the United States (2017–2030)

Table 26: Diagnosed Cases of HCV by Impact on Liver in the United States (2017–2030)

Table 27: Total Treated cases of HCV in the United States (2017–2030)

Table 28: Total Prevalent Cases of HCV in Germany (2017–2030)

Table 29: Total Diagnosed cases of HCV in Germany (2017–2030)

Table 30: Gender-specific cases of HCV in Germany (2017–2030)

Table 31: Age-specific Diagnosed Cases of HCV in Germany (2017–2030)

Table 32: Genotype-specific Diagnosed Cases of HCV in Germany (2017–2030)

- Table 33: Diagnosed Cases of HCV by Impact on Liver in Germany (2017–2030)
- Table 34: Total Treated cases of HCV in Germany (2017–2030)
- Table 35: Total Prevalent Cases of HCV in France (2017–2030)
- Table 36: Total Diagnosed cases of HCV in France (2017–2030)
- Table 37: Gender-specific cases of HCV in France (2017–2030)
- Table 38: Age-specific Diagnosed Cases of HCV in France (2017–2030)
- Table 39: Genotype-specific Diagnosed Cases of HCV in France (2017–2030)
- Table 40: Diagnosed Cases of HCV by Impact on Liver in France (2017–2030)
- Table 41: Total Treated cases of HCV in France (2017–2030)
- Table 42: Total Prevalent Cases of HCV in Italy (2017–2030)
- Table 43: Total Diagnosed cases of HCV in Italy (2017–2030)
- Table 44: Gender-specific cases of HCV in Italy (2017–2030)
- Table 45: Age-specific Diagnosed Cases of HCV in Italy (2017–2030)
- Table 46: Genotype-specific Diagnosed Cases of HCV in Italy (2017–2030)
- Table 47: Diagnosed Cases of HCV by Impact on Liver in Italy (2017–2030)
- Table 48: Total Treated cases of HCV in Italy (2017–2030)
- Table 49: Total Prevalent Cases of HCV in Spain (2017–2030)
- Table 50: Total Diagnosed cases of HCV in Spain (2017–2030)
- Table 51: Gender-specific cases of HCV in Spain (2017–2030)
- Table 52: Age-specific Diagnosed Cases of HCV in Spain (2017–2030)
- Table 53: Genotype-specific Diagnosed Cases of HCV in Spain (2017–2030)
- Table 54: Diagnosed Cases of HCV by Impact on Liver in Spain (2017–2030)
- Table 55: Total Treated cases of HCV in Spain (2017–2030)
- Table 56: Total Prevalent Cases of HCV in the United Kingdom (2017–2030)
- Table 57: Total Diagnosed cases of HCV in the United Kingdom (2017–2030)
- Table 58: Gender-specific cases of HCV in the United Kingdom (2017–2030)
- Table 59: Age-specific Diagnosed Cases of HCV in the United Kingdom (2017–2030)
- Table 60: Genotype-specific Diagnosed Cases of HCV in the United Kingdom (2017–2030)
- Table 61: Diagnosed Cases of HCV by Impact on Liver in the United Kingdom (2017–2030)
- Table 62: Total Treated cases of HCV in the United Kingdom (2017–2030)
- Table 63: Total Prevalent Cases of HCV in Japan (2017–2030)
- Table 64: Total Diagnosed cases of HCV in Japan (2017–2030)
- Table 65: Gender-specific cases of HCV in Japan (2017–2030)
- Table 66: Age-specific Diagnosed Cases of HCV in Japan (2017–2030)
- Table 67: Genotype-specific Diagnosed Cases of HCV in Japan (2017–2030)
- Table 68: Diagnosed Cases of HCV by Impact on Liver in Japan (2017–2030)
- Table 69: Total Treated cases of HCV in Japan (2017–2030)

Table 70: Trade and Generic Names for First Line HCV DAA Medications

Table 71: Summary of Recommendations

Table 72: Summary of Recommendations

Table 73: Summary of Recommendations

Table 74: Summary of Recommendations

Table 75: Summary of Recommendations

Table 76: Summary of Recommendations

Table 77: Summary of Recommendations

Table 78: Summary of Recommendations

Table 79: Summary of Recommendations

Table 80: Summary of Recommendations

Table 81: Summary of Recommendations

Table 82: Recommended Duration for Treatment-Na?ve Patients

Table 83: Recommended Duration for Treatment-Experienced Patients

Table 84: Recommended Treatment Regimen and Duration in Adults Without Cirrhosis or With Compensated Cirrhosis (Child-Pugh A)

Table 85: Trials Conducted With VOSEVI in DAA-Experienced Subjects With HCV Infection

Table 86: Treatment Regimen and Duration by Patient Population (Treatment-Na?ve or Interferon-Experienced)

Table 87: Clinical Trials Conducted with Viekira Pak With or Without Ribavirin (RBV) in Subjects with Chronic HCV GT1 Infection

Table 88: Clinical Trial Description, 2020

Table 89: Recommended Treatment Regimen and Duration in Patients 6 Years of Age and Older or Weighing at Least 17 kg with Genotype 1, 2, 3, 4, 5, or 6 HCV

Table 90: Dosing for Pediatric Patients 6 Years and Older or Weighing at Least 17 kg with Genotype 1, 2, 3, 4, 5, or 6 HCV

Table 91: Recommended Dosing for Ribavirin in Combination Therapy with Epclusa for Pediatric Patients 6 Years and Older

Table 92: Trials Conducted with EPCLUSA in Subjects with Genotype 1, 2, 3, 4, 5, or 6 HCV Infection

Table 93: Epclusa (sofosbuvir/velpatasvir), Clinical Trial Description, 2020

Table 94: Recommended dosage regimens and durations for Zepatier for treatment of HCV genotype 1 or 4 in patients with or without cirrhosis

Table 95: Trials Conducted with Zepatier

Table 96: Recommended treatment regimen and duration for Harvoni in patients three years of age and older with genotype 1, 4, 5, or 6 HCV

Table 97: Dosing for pediatric patients three years and older using Harvoni tablets or oral pellets

Table 98: Recommended Dosing for Ribavirin in Combination Therapy with Harvoni for Pediatric Patients 3 Years and Older

Table 99: Trials Conducted with Harvoni with or without Ribavirin in Subjects with Chronic HCV Genotype 1, 4, 5, or 6 Infection

Table 100: Harvoni (ledipasvir and sofosbuvir), Clinical Trial Description, 2020

Table 101: CC-31244, Clinical Trial Description, 2020

Table 102: AT-527, Clinical Trial Description, 2020

Table 103: PRI-724, Clinical Trial Description, 2020

Table 104: AT-777, Clinical Trial Description, 2020

Table 105: HCVax, Clinical Trial Description, 2020

Table 106: 7MM Market Size of HCV, in USD Million (2017–2030)

Table 107: 7MM Market Size of HCV by Therapies, in USD Million (2017–2030)

Table 108: Total United States Market Size of HCV, in USD Million (2017–2030)

Table 109: The United States Market Size of HCV by Therapies, in USD Million (2017–2030)

Table 110: Germany Market Size of HCV, in USD Million (2017–2030)

Table 111: Germany Market Size of HCV by Therapies, in USD Million (2017–2030)

Table 112: France Market Size of HCV, in USD Million (2017–2030)

Table 113: France Market Size of HCV by Therapies, in USD Million (2017–2030)

Table 114: Italy Market Size of HCV, in USD Million (2017–2030)

Table 115: Italy Market Size of HCV by Therapies, in USD Million (2017–2030)

Table 116: Spain Market Size of HCV, in USD Million (2017–2030)

Table 117: Spain Market Size of HCV by Therapies, in USD Million (2017–2030)

Table 118: The United Kingdom Market Size of HCV, in USD Million (2017–2030)

Table 119: The United Kingdom Market Size of HCV by Therapies, in USD Million (2017–2030)

Table 120: Japan Market Size of HCV, in USD Million (2017–2030)

Table 121: Japan Market Size of HCV by Therapies, in USD Million (2017–2030)

Table 122: NICE Recommendations for Sofosbuvir

Table 123: NICE Recommendations for Elbasvir–grazoprevir

Table 124: NICE Recommendations for Sofosbuvir–velpatasvir–voxilaprevir

Table 125: NICE Recommendations for Ledipasvir–sofosbuvir

Table 126: NICE Recommendations Ombitasvir–paritaprevir–ritonavir with or without dasabuvir

Table 127: NICE Recommendations for Sofosbuvir–velpatasvir

Table 128: Recommendations for HCV Therapies by NICE

Table 129: Recommendations for HCV Therapies by IQWiG

Table 130: Recommendations for HCV Therapies by HAS

Table 131: Availability of reimbursed interferon-free DAA drugs for HCV infection in

Europe

List Of Figures

LIST OF FIGURES

- Figure 1: Hepatitis C Virus (HCV) SWOT Analysis
- Figure 2: Epidemiology and Market Methodology
- Figure 3: Progression of HCV Infection
- Figure 4: Signs and symptoms of HCV
- Figure 5: Causes of HCV
- Figure 6: HCV Viral Cycle
- Figure 7: Complications of HCV Infection
- Figure 8: Diagnostic Algorithm of HCV
- Figure 9: OraQuick HCV Rapid Antibody Test
- Figure 10: Ultrasound
- Figure 11: Total Prevalent Cases of HCV in the 7MM (2017–2030)
- Figure 12: Total Diagnosed cases of HCV in the 7MM (2017–2030)
- Figure 13: Gender-specific cases of HCV in the 7MM (2017–2030)
- Figure 14: Age-specific Diagnosed Cases of HCV in the 7MM (2017–2030)
- Figure 15: Genotype-specific Diagnosed Cases of HCV in the 7MM (2017–2030)
- Figure 16: Diagnosed Cases of HCV by Impact on Liver in the 7MM (2017–2030)
- Figure 17: Treated cases of HCV in the 7MM (2017–2030)
- Figure 18: Total Prevalent Cases of HCV in the United States (2017–2030)
- Figure 19: Total Diagnosed cases of HCV in the United States (2017–2030)
- Figure 20: Gender-specific cases of HCV in the United States (2017–2030)
- Figure 21: Age-specific Diagnosed Cases of HCV in the United States (2017–2030)
- Figure 22: Genotype-specific Diagnosed Cases of HCV in the United States (2017–2030)
- Figure 23: Diagnosed Cases of HCV by Impact on Liver in the United States (2017–2030)
- Figure 24: Treated cases of HCV in the United States (2017–2030)
- Figure 25: Total Prevalent Cases of HCV in Germany (2017–2030)
- Figure 26: Total Diagnosed cases of HCV in Germany (2017–2030)
- Figure 27: Gender-specific cases of HCV in Germany (2017–2030)
- Figure 28: Age-specific Diagnosed Cases of HCV in Germany (2017–2030)
- Figure 29: Genotype-specific Diagnosed Cases of HCV in Germany (2017–2030)
- Figure 30: Diagnosed Cases of HCV by Impact on Liver in Germany (2017–2030)
- Figure 31: Treated cases of HCV in Germany (2017–2030)
- Figure 32: Total Prevalent Cases of HCV in France (2017–2030)
- Figure 33: Total Diagnosed cases of HCV in France (2017–2030)

- Figure 34: Gender-specific cases of HCV in France (2017–2030)
- Figure 35: Age-specific Diagnosed Cases of HCV in France (2017–2030)
- Figure 36: Genotype-specific Diagnosed Cases of HCV in France (2017–2030)
- Figure 37: Diagnosed Cases of HCV by Impact on Liver in France (2017–2030)
- Figure 38: Treated cases of HCV in France (2017–2030)
- Figure 39: Total Prevalent Cases of HCV in Italy (2017–2030)
- Figure 40: Total Diagnosed cases of HCV in Italy (2017–2030)
- Figure 41: Gender-specific cases of HCV in Italy (2017–2030)
- Figure 42: Age-specific Diagnosed Cases of HCV in Italy (2017–2030)
- Figure 43: Genotype-specific Diagnosed Cases of HCV in Italy (2017–2030)
- Figure 44: Diagnosed Cases of HCV by Impact on Liver in Italy (2017–2030)
- Figure 45: Treated cases of HCV in Italy (2017–2030)
- Figure 46: Total Prevalent Cases of HCV in Spain (2017–2030)
- Figure 47: Total Diagnosed cases of HCV in Spain (2017–2030)
- Figure 48: Gender-specific cases of HCV in Spain (2017–2030)
- Figure 49: Age-specific Diagnosed Cases of HCV in Spain (2017–2030)
- Figure 50: Genotype-specific Diagnosed Cases of HCV in Spain (2017–2030)
- Figure 51: Diagnosed Cases of HCV by Impact on Liver in Spain (2017–2030)
- Figure 52: Treated cases of HCV in Spain (2017–2030)
- Figure 53: Total Prevalent Cases of HCV in the United Kingdom (2017–2030)
- Figure 54: Total Diagnosed cases of HCV in the United Kingdom (2017–2030)
- Figure 55: Gender-specific cases of HCV in the United Kingdom (2017–2030)
- Figure 56: Age-specific Diagnosed Cases of HCV in the United Kingdom (2017–2030)
- Figure 57: Genotype-specific Diagnosed Cases of HCV in the United Kingdom (2017–2030)
- Figure 58: Diagnosed Cases of HCV by Impact on Liver in the United Kingdom (2017–2030)
- Figure 59: Treated cases of HCV in the United Kingdom (2017–2030)
- Figure 60: Total Prevalent Cases of HCV in Japan (2017–2030)
- Figure 61: Total Diagnosed cases of HCV in Japan (2017–2030)
- Figure 62: Gender-specific cases of HCV in Japan (2017–2030)
- Figure 63: Age-specific Diagnosed Cases of HCV in Japan (2017–2030)
- Figure 64: Genotype-specific Diagnosed Cases of HCV in Japan (2017–2030)
- Figure 65: Diagnosed Cases of HCV by Impact on Liver in Japan (2017–2030)
- Figure 66: Treated cases of HCV in Japan (2017–2030)
- Figure 67: Treatment Algorithm
- Figure 68: Targets of DAAs
- Figure 69: Unmet Needs
- Figure 70: Atea Pharmaceuticals' purine nucleotide prodrug platform against RNA

viruses

Figure 71: Gene Transfer Technology

Figure 72: Market Size of HCV in the 7MM, in USD Million (2017–2030)

Figure 73: Market Size of HCV in the 7MM by Therapies, in USD Million (2017–2030)

Figure 74: Total Market Size of HCV in the United States, in USD Million (2017–2030)

Figure 75: Market Size of HCV in the United States by Therapies, in USD Million (2017–2030)

Figure 76: Total Market Size of HCV in Germany, in USD Million (2017–2030)

Figure 77: Market Size of HCV in Germany by Therapies, in USD Million (2017–2030)

Figure 78: Total Market Size of HCV in France, in USD Million (2017–2030)

Figure 79: Market Size of HCV in France by therapies, in USD Million (2017–2030)

Figure 80: Total Market Size of HCV in Italy, in USD Million (2017–2030)

Figure 81: Market Size of HCV in Italy by Therapies, in USD Million (2017–2030)

Figure 82: Total Market Size of HCV in Spain, in USD Million (2017–2030)

Figure 83: Market Size of HCV in Spain by therapies, in USD Million (2017–2030)

Figure 84: Total Market Size of HCV in the United Kingdom, in USD Million (2017–2030)

Figure 85: Market Size of HCV in the United Kingdom by Therapies, in USD Million (2017–2030)

Figure 86: Total Market Size of HCV in Japan, in USD Million (2017–2030)

Figure 87: Market Size of HCV in Japan by Therapies, in USD Million (2017–2030)

Figure 88: Market Drivers

Figure 89: Market Barriers

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