Type 2 Diabetes Therapeutics Market to 2019
A Shifting Treatment Algorithm and Intensified Competition Expected to Drive Growth by 2019
GBI Research Report Guidance

- The second chapter provides an introduction to type 2 diabetes, including symptoms, etiology, pathophysiology, methods of initial diagnosis and determination of disease severity, and treatment algorithms.
- The third chapter provides an overview of the type 2 diabetes market landscape, including product profiles for sixteen key marketed products.
- The fourth chapter analyses the type 2 diabetes pipeline, detailing, among other parameters, drug distribution by phase, molecule type and mechanism of action. The clinical trial landscape is also analyzed, with an emphasis on failure rates across phases in addition to trends in clinical trial size and duration.
- The market forecast to 2019 for eight major markets (US, UK, France, Germany, Italy, Spain, and Japan) is displayed in chapter five, and includes prevalence rates, annual cost of treatment and a market size forecast.
- A strategic consolidation analysis is provided in chapter six, including major co-development and licensing deals.
Executive Summary

A Highly Competitive and Growing Market

The market for type 2 diabetes contains a wide range of drugs that are used to treat patients at different points in the treatment algorithm. The market landscape is dense, with a number of drugs competing with one another for different market segments. Although the first-line therapy is usually metformin, a generic drug, it is often unable to bring the disease under control. The second-line therapy involves the use of other drugs in combination with metformin, and at this stage of the treatment algorithm competition between products is very strong. The established second-line therapy involves the use of sulfonylureas, a highly genericized class of drugs, in combination with metformin. The usage of this class of drug is likely to decline in future due to the recent approval of superior products and the anticipated approval of stronger products over the forecast period (2012–2019).

The market for type 2 diabetes is expected to grow from $XX billion in 2012 to $XX billion in 2019 at a Compound Annual Growth Rate (CAGR) of XX%. This strong growth is due to the anticipated approval of products in relatively novel treatment classes, such as GLP-1 agonists, DPP-4 inhibitors and SGLT-2 inhibitors. Should these expensive drug classes capture substantial market shares, this would be expected to result in an even more robust level of market growth.
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Introduction

2.1 Epidemiology

Type 2 diabetes is the most prevalent type of diabetes, accounting for XX% of all cases (Srinivasan et al., 2008). The prevalence in the population has been shown to increase with age, although incidence is increasing in younger sections of the population. It is currently estimated to be present in XX% of adults aged 20 years and older, and XX% of persons aged 65 and older (CDC, 2011).

2.2 Symptoms

The most common symptoms of this disease are listed below:

- Regular thirst
- Frequent urination
- Blurred vision
- Irritability
- Tingling or numbness in the hands or feet
- Frequent skin, bladder or gum infections
- Slow wound healing
- Extreme, unexplained fatigue- particularly following meals

Although these symptoms are usually apparent in type 2 diabetes sufferers, the disease can also remain asymptomatic for months or even years. These symptoms can be controlled with appropriate disease management, but may grow increasingly worse as the disease progresses.
When sales following marketing approval are compared, Januvia emerges as the fastest-growing product following its launch. While Lantus generates the largest annual revenues, its growth was slower, and it took over a decade to reach the sales peak Januvia reached after five years.

**Figure 12: Type 2 Diabetes Market, Global, Sales of Novel Products (\$m, Years after Approval), 1998–2012**

Source: Company Annual Reports, 10-K and 20-F Filings, 1998–2012
5.3 Top Five Countries of Europe

5.3.1 Treatment Usage Patterns

The general trend in the EU is one of increasing prevalence of type 2 diabetes, caused by worsening diets and increasingly sedentary lifestyles. Additionally, no significant changes are expected to the proportion of patients who are treated with pharmaceutical products.

Figure 30: Type 2 Diabetes Market, Top Five Countries of Europe, Treatment Usage Patterns, 2012–2019

Source: GBI Research
6 Deals and Strategic Consolidations

6.1 Licensing Deals

Licensing deals involving products for the treatment of Type 2 diabetes were mostly situated in North America, with the remainder being largely situated in Europe or the Asia-Pacific region, in terms of the licensor headquarters.

Figure 35: Type 2 Diabetes Market, Global, Licensing Deals by Country, 2006–2013

Source: GBI Research
Figure 37: Type 2 Diabetes Market, Global, Licensing Deals, 2006–2013

A) Licensing deals by Phase and Value

B) Licensing Deals by Stage and Molecule Type

C) Deal Values by Molecule Type

D) Licensing Deals by Mechanism of Action

Source: GBI Research
7 Appendix

7.1 All Pipeline Drugs by Stage of Development

7.1.1 Discovery

Table 2: Pipeline Drugs (Discovery)

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Source: GBI Research Proprietary Database
7.1.2 Preclinical and IND-filed

<p>| Table 3: Pipeline Drugs (Preclinical and IND-filed) |
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Source: GBI Research Proprietary Database
### 7.1.3 Phase I

Table 4: Pipeline Drugs (Phase I)

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Source: GBI Research Proprietary Database
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Source: GBI Research Proprietary Database
### 7.1.5 Phase III and Pre-registration

Table 6: Pipeline Drugs (Phase III)

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Source: GBI Research Proprietary Database
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### 7.2.2 US

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### 7.2.3 UK

**Table 10: Type 2 Diabetes Market, UK, Market Forecast, 2012–2019**

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Source: GBI Research

### 7.2.4 France

**Table 11: Type 2 Diabetes Market, France, Market Forecast, 2012–2019**

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Source: GBI Research

### 7.2.5 Germany

**Table 12: Type 2 Diabetes Market, Germany, Market Forecast, 2012–2019**

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Source: GBI Research
7.3 **Market Definitions**

The global type 2 diabetes therapeutics market covers type 2 diabetes in the top seven markets: the US, the UK, Germany, France, Spain, Italy and Japan.

- The top five European countries comprise the UK, Germany, France, Spain and Italy.
- The prevalence population is the estimated number of people at any given point of time who are affected by type 2 diabetes.
- The prescription rate is the percentage of the diabetes-suffering population that has been prescribed pharmacological therapeutics for type 2 diabetes.
- The prescription population refers to the number of people using pharmacological products for type 2 diabetes.

7.4 **Abbreviations**

- 11βHSD: 11β-Hydroxysteroid Dehydrogenase
- ACoT: Annual Cost of Therapy
- ADP: Adenosine Diphosphate
- AGTR2: Angiotensin II Receptor Type 2
- AMP: Adenosine Monophosphate
- AMPK: Adenosine Monophosphate-activated Protein Kinase
- AMPK beta: Adenosine Monophosphate-activated Protein Kinase beta
- ASBT: Apical Sodium-dependent Bile Acid Transporter
- AWARD: Assessment of Weekly Administration (A Clinical trial for Insulin Glargine)
- BMI: Body Mass Index
- CAGR: Compound Annual Growth Rate
- CB1: Cannabinoid receptor type 1
- CB2: Cannabinoid receptor type 2
- CCR2: C-C Chemokine Receptor Type 2
- COX: Cyclooxygenase
- CPT 1: Carnitine Palmitoyltransferase I
- CRADA: Cooperative Research and Development Agreement
- CTA: Clinical Trial Authorization
- CMC: Chemistry, Manufacturing and Controls
- DGAT-1: Diglyceride Acyltransferase-1
- DPP-4: Dipeptidyl-Peptidase Four
- DRI: Dopamine Reuptake Inhibitor
- ECG: Electrocardiogram
- EGFR: Epidermal Growth Factor Receptor
- EMA: European Medicines Agency
- EU: European Union
- FBPase: Fructose-2,6-Biphosphatase
- Fc: Fragment crystallizable
- FDA: Food and Drug Administration
- FGFR: Fibroblast Growth Factor Receptor
- FGFR-1: Fibroblast Growth Factor Receptor 1
- FPG: Fasting Plasma Glucose
- FXR: Farnesoid X Receptor
- GABA: Gamma-Aminobutyric Acid
- GI: Gastrointestinal
- GIP: Gastric Inhibitory Polypeptide
- GIPR: Gastric Inhibitory Polypeptide Receptor
- GKA: Glucokinase Activator
- GLP-1: Glucagon-Like Peptide One
- GPBAR-1: G Protein-coupled Bile Acid Receptor 1
- GPCR: G-Protein Coupled Receptor
- GPR40: G Protein-Coupled Receptor 40
- GPR120: G-Protein Coupled Receptor 120
- GR: Glucocorticoid Receptor
- GSK3β: Glycogen Synthase Kinase 3β
- HbA1c: Glycated Hemoglobin level
- IL-2: Interleukin 2
- IMC: Intramyocellular
- IND: Investigational New Drug
- IR: Immediate Release
- LPS: Lipopolysaccharide-binding Protein
- mAChR: muscarinic Acetylcholine Receptor
- MAOI: Monoamine Oxidase Inhibitor
- mg: milligrams
- mg/dl: milligrams per deciliter
- mmol/mol: millimoles per mole
- MR: Modified Release
- MTP: Microsomal Triglyceride Transfer Protein
- nAChR: nicotinic Acetylcholine Receptor
- NAFLD: Non-Alcoholic Fatty Liver Disease
- NF-κB: Nuclear Factor Kappa-light-chain-enhancer of activated B cells
- NIDDK: National Institute of Diabetes and Digestive and Kidney Diseases
- NIDDM: Non-Insulin Dependent Diabetes Mellitus
- NPH: Neutral Protamine Hagedorn
- NPYR2: Neuropeptide Y receptor Y2
- NRI: Norepinephrine Reuptake Inhibitor
- OCA: Obeticholic Acid
- OGTT: Oral Glucose Tolerance Test
- PARP: Poly-Adenosine diphosphate Ribose Polymerase
- PKC: Protein Kinase C
- PPAR: Peroxisome Proliferator-Activated Receptor
- PPAR-alpha: Peroxisome Proliferator-Activated Receptor alpha
- PPAR-beta/delta: Peroxisome Proliferator-Activated Receptor beta/delta
- PPAR-gamma: Peroxisome Proliferator-Activated Receptor gamma
- PPRE: Peroxisome Proliferator Responsive Elements
- PTP: Protein Tyrosine Phosphatase
- PTP1B: Protein Tyrosine Phosphatase 1B
- Scr: Serum Creatine
- SGLT: Sodium-dependent Glucose Co-transporter
- SGLT-1: Sodium-dependent Glucose Co-transporter 1
- SGLT-2: Sodium-dependent Glucose Co-transporter 2
- SIRT-1: Siruin-1
- SIR2: Silent Information Regulator 2 Protein
- STAT4: Signal Transducer and Activator of Transcription 4
- TNF-α: Tumor Necrosis Factor-alpha
- TPK1: Thiamin Pyrophosphokinase 1
- µg: micrograms
- VEGF-B: Vascular Endothelial Growth Factor B
- WHO: World Health Organization
# 7.5 References for Heat Maps

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27. Seino Y et al., (2012). Randomized, double-blind, placebo-controlled trial of the once-daily GLP-1 receptor agonist lixisenatide in Asian patients with type 2 diabetes insufficiently controlled on basal insulin with or without a sulfonylurea (GetGoal-L-Asia). Diabetes, Obesity and Metabolism; 14(10): 910–917.


Source: GBI Research
7.6 References

7.7 Research Methodology

GBI Research’s dedicated research and analysis teams consist of experienced professionals with marketing, market research and consulting backgrounds in the pharmaceutical industry as well as advanced statistical expertise.

GBI Research adheres to the codes of practice of the Market Research Society (www.mrs.org.uk) and the Strategic and Competitive Intelligence Professionals (www.scip.org).

All GBI Research databases are continuously updated and revised.

7.7.1 Coverage

The objective of updating GBI Research coverage is to ensure that it represents the most up to date vision of the industry possible.

Changes to the industry taxonomy are built on the basis of extensive research of company, association and competitor sources.

Company coverage is based on three key factors: market capitalization, revenues and media attention/innovation/market potential.

An exhaustive search of 56 member exchanges is conducted and companies are prioritized on the basis of their market capitalization.

The estimated revenues of all major companies, including private and governmental, are gathered and used to prioritize coverage.

Companies which are making the news, or which are of particular interest due to their innovative approach, are prioritized.

GBI Research aims to cover all major news events and deals in the pharmaceutical industry, updated on a daily basis.

The coverage is further streamlined and strengthened with additional inputs from GBI Research’s expert panel (see below).

7.7.2 Secondary Research

The research process begins with exhaustive secondary research on internal and external sources being carried out to source qualitative and quantitative information relating to each market.

The secondary research sources that are typically referred to include, but are not limited to:

- Company websites, annual reports, financial reports, broker reports, investor presentations and US Securities and Exchanges Commission (SEC) filings
- Industry trade journals, scientific journals and other technical literature
- Internal and external proprietary databases
- Relevant patent and regulatory databases
- National government documents, statistical databases and market reports;
- Procedure registries
- News articles, press releases and web-casts specific to the companies operating in the market

7.7.3 Primary Research

GBI Research conducts hundreds of primary interviews a year with industry participants and commentators in order to validate its data and analysis. A typical research interview fulfills the following functions:

- It provides first-hand information on the market size, market trends, growth trends, competitive landscape and future outlook.
- It helps in validating and strengthening the secondary research findings.
- It further develops the analysis team’s expertise and market understanding.
Primary research involves email and telephone interviews as well as face-to-face interviews for each market, category, segment and sub-segment across geographies.

The participants who typically take part in such a process include, but are not limited to:

- **Industry participants**: CEOs, VPs, marketing/product managers, market intelligence managers and national sales managers
- **Hospital stores**, laboratories, pharmacies, distributors and paramedics
- **Outside experts**: Investment bankers, valuation experts, research analysts specializing in specific medical equipment markets
- **Key opinion leaders**: Physicians and surgeons specializing in different therapeutic areas corresponding to different kinds of medical equipment

### 7.7.4 Therapeutic Landscape

Revenues for each indication, by geography, are arrived at by utilizing the GBI Research market forecasting model. The global revenue for each indication is the sum value of revenues of all seven regions.

The annual cost of therapy for each indication is arrived at by considering the cost of the drugs, dosage of the drugs and the duration of the therapy.

The generic share of the market for each indication is obtained by calculating the prescription share for generic drugs and the respective cost of treatment.

The treatment usage pattern which includes quantitative data on the diseased population, treatment-seeking population, diagnosed population and treated population for an indication, is arrived at by referring to various sources as mentioned below.

GBI Research uses an epidemiology-based treatment flow model to forecast market size for therapeutic indications.

### 7.7.5 Epidemiology-based Forecasting

The forecasting model used at GBI Research makes use of epidemiology data gathered from research publications and primary interviews with physicians to represent the treatment flow patterns for individual diseases and therapies. The market for any disease segment is directly proportional to the volume of units sold and the price per unit.

\[
\text{Sales} = \text{Volume of Units sold} \times \text{Price per Unit}
\]

The volume of units sold is calculated on the average dosage regimen for that disease, duration of treatment and number of patients who are prescribed drug treatment (prescription population). Prescription population is calculated as the percentage of population diagnosed with a disease (diagnosis population). The diagnosis population is the population diagnosed with a disease expressed as a percentage of the population that is seeking treatment (treatment-seeking population). The prevalence of a disease (diseased population) is the percentage of the total population that suffers from a disease/condition.

Data on the treatment-seeking rate, diagnosis rate and prescription rate, if unavailable from research publications, are gathered from interviews with physicians and are used to estimate the patient volumes for the disease under consideration. Therapy uptake and compliance data are fitted into the forecasting model to account for patient switching and compliance behavior.

To account for differences in the affordability of drugs for patients across various geographies, macroeconomic data such as inflation and GDP and healthcare indicators such as healthcare spending, insurance coverage and average income per individual are used.

The annual cost of treatment is calculated using product purchase frequency and the average price of the therapy. Product purchase frequency is calculated from the dosage data available for the therapies and drug prices are gathered from public sources. The sources for the price of drugs are RxUSA, ZenRx and the British National Formulary.

The epidemiology-based forecasting model uses a bottom-up methodology and it makes use of estimations in the absence of data from research publications. Such estimations may result in a final market value which is different from the actual value. To correct this ‘gap’ the forecasting model uses ‘triangulation’ with the...
help of base year sales data (from company annual reports, internal and external databases) and sales estimations.

**Analogous Forecasting Methodology**

Analogous forecasting methodology is used to account for the introduction of new products, patent expiries of branded products and subsequent introduction of generics. Historic data for new product launches and generics penetration are used to arrive at robust forecasts. Increase or decrease of prevalence rates, treatment seeking rate, diagnosis rate and prescription rate are fitted into the forecasting model to estimate market growth rate.

The proprietary model enables GBI Research to account for the impact of individual drivers and restraints in the growth of the market. The year of impact and the extent of impact are quantified in the forecasting model to provide close-to-accurate data sets.

**Diseased Population**

The diseased population for any indication is the prevalence. The prevalence population for this report is taken from articles published in various journals including the Annals of the Rheumatic Diseases, British Medical Journal and Rheumatology.

**Prescription Population**

RA has multiple treatment options depending upon the stage of the disease and the previous effectiveness of other similar treatments. Options for the treatment of type 2 diabetes include lifestyle modification, non-biologic drug therapy and biologic drug therapy. The prescription population is defined as the number of patients who are prescribed biologic drug therapy. This is calculated as a percentage of the diagnosis population. The prescription population proportion is taken from articles published in various journals including the Annals of the Rheumatic Diseases, British Medical Journal and Rheumatology.

7.7.5.1 **Market Size by Geography**

The treatment usage pattern and annual cost of treatment in each country has been factored in while deriving the individual country market size.

**Forecasting Model for Therapeutic Areas**
The above figure represents a typical forecasting model followed in GBI Research. As discussed previously, the model is built on the treatment flow patterns. The model starts with the general population, then diseased population as a percentage of the general population and then follows the treatment-seeking population as a percentage of the diseased population and diagnosed population as a percentage of the treatment-seeking population. Finally, the total volume of units sold is calculated by multiplying the treated population by the average dosage per year per patient.

7.7.5.2 Geographical Landscape

GBI Research analyzes seven major geographies: the US, the top five countries in Europe (the UK, Germany, France, Spain and Italy) and Japan. The total market size for each country is provided which is the sum value of the market sizes of all the indications for that particular country. The maximum and minimum estimated market sizes are then provided by adjusting all variables expected to impact upon the market during the forecast period in order to provide the best- and worst-case scenarios.

7.7.6 Pipeline Analysis

This section provides a list of molecules at various stages in the pipeline for various indications. The list is sourced from internal database and validated for the accuracy of phase and mechanism of action at ClinicalTrials.gov and company websites. The section also includes a list of promising molecules which is narrowed down based on the results of the clinical trials at various stages and the novelty of mechanism of
action. A heat map, sourced from relevant clinical trials, is provided in order to compare these products to one another in addition to currently marketed products. The latest press releases issued by the company and news reports are also the source of information for the status of the molecule in the pipeline. This list of pipeline molecules, in conjunction with a list of ongoing and completed clinical trials, is analyzed in this section, and a full breakdown of pipeline molecules and clinical trials by Phase, molecule type and molecular target is provided.

7.7.7  Expert Panel Validation

GBI Research uses a panel of experts to cross verify its databases and forecasts.

GBI Research expert panel comprises marketing managers, product specialists, international sales managers from pharmaceutical companies; academics from research universities and key opinion leaders from hospitals.

Historic data and forecasts are relayed to GBI Research’s expert panel for feedback and are adjusted in accordance with their feedback.

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