

Innovative drugs: Mapping the pricing, reimbursement and HTA landscape

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Abstracts

Widespread patient access to innovative new products is being frustrated in non-US markets by Health Technology Assessments (HTA). Between January 2016 and June 2017, 58 innovative medicines were approved and launched in the US - but what of their status elsewhere? For example, only 35 of the 58 have been approved in the EU and of these many are tied up in HTA reviews. The commercial impact cannot be underestimated: with no predictable outcome, companies cannot plan effectively or understand the competitive environment in which they will operate. Which companies are being impacted? What products have made the grade? When – and where – will new competitive threats emerge?

Delivering a detailed report and usable data set, this ground breaking analysis exposes the pricing, reimbursement and HTA review status of innovative drugs in Australia, Canada, France, Germany and the UK for a clear picture of the competitive landscape.

DISCOVER ON THIS PAGE

Why this report is important to you

Key facts about this report and data

This report will enable you

The deliverables: market analysis and data set

Table of contents



WHY THIS REPORT IS IMPORTANT TO YOU

Pharma prides itself on being an innovative industry. It spends US\$ billions on R&D and negotiates the regulatory regimes to gets its products approved. But overcoming the HTA hurdle is neither a standardised nor predictable process with commercially-acceptable pricing and reimbursement decisions far from guaranteed.

The burden of HTA assessment grows heavier as each national - or even sub-national - authority sets its own standards for evidence. Smaller companies and biotechs may not have either the finance or resources to engage. Knowing which companies are currently engaged and the impact on the products is critical competitive intelligence.

KEY FACTS ABOUT THIS REPORT AND DATA

Products: 58 innovative products covered, including ixekizumab (Eli Lilly), nusinersen (Biogen), palbociclib (Pfizer), selexipag (Actelion) and sofosbuvir/velpatasir (Gilead)

Therapy areas: The 58 products cover 13 therapy areas – mainly oncology and neurology but also respiratory, anti-infectives, musculoskeletal and gastrointestinal

Indications: Conditions indicated for the 58 products include cancer (various), dry eye, muscular dystrophy , hepatitis C, IBS, Parkinson's disease and diabetes

Companies: The products of 47 companies are covered including Actelion, Bristol-Myers Squibb, Eli Lilly, Genentech and Gilead

Markets: Detailed information is provided for HTA status in Australia, Canada, France, Germany and the UK

THIS REPORT WILL ENABLE YOU TO

Review the pricing, reimbursement and HTA status of each product at the national level

Profile the therapy areas that are being targeted by innovative drugs



Estimate likely HTA decisions using average timeframes

Identify products that have been approved but not referred for HTA assessment

Assess the impact of HTA systems on smaller companies and biotechs in the innovative drug space

Profile the emerging innovative therapies in key therapy areas

Delivering market analysis and data

This report delivers two competitive analysis resources!

1. Analysis report

Rich in charts and tables, this detailed analytical report provides:

At a glance overview of the approved drugs, therapy areas, routes of administration, company and latest sales performance

Pricing, reimbursement and HTA policies and practices in Canada, France, Germany and the UK

Product-level analysis providing overviews of regulatory approvals, HTA status/market launch and sales (including first half 2017 sales where available)

1. Data Set

Delivered in Microsoft Excel™, all the data used to drive this report can be used for further analysis or to incorporate into competitive intelligence systems. For each product the data covers:

Generic name, brand name, developer company, condition targeted and therapy area

US FDA/EMA/Health Canada approval dates and days to approve



Sales performance, where relevant, in local currency and US\$ **Summary Contents** Overview Approved drugs By therapy area By Route of Administration By company Sales Data Latest Sales Revenues by Therapy Area (\$m) P&R/HTA Activity Canada France Germany UK

HTA referral, review, decision dates and outcomes where known

Drug status reports

For each of the products covered



Product overview	
Regulatory approvals	
HTA and market launch	
Sales	
Products covered	
Abaloparatide	
Alectinib	
Atezolizumab	
Avelumab	
Betrixaban	
Bezlotoxumab	
Brigatinib	
Brivaracetam	
Brodalumab	
Cerliponase Alfa	
Crisaborole	
Daclizumab	
Daratumumab	
Defibrotide	



Deflazacort
Delafloxacin
Dupilumab
Durvalumab
Edaravone
Elbasvir/Grazoprevir
Elotuzumab
Eluxadoline
Enasidenib
Etelcalcetide
Eteplirsen
Glecaprevir/Pibrentasvir
Guselkumab
Ixazomib
Ixekizumab
Lenvatinib
Lifitegrast Ophthalmic Solution
Lixisenatide
Midostaurin
Naldemedine



Necitumumab
Neratinib Maleate
Niraparib
Nusinersen
Obeticholic Acid
Ocrelizumab
Olaratumab
Osimertinib
Palbociclib
Pimavanserin
Plecanatide
Reslizumab
Ribociclib
Rolapitant
Rucaparib
Safinamide
Sarilumab
Selexipag
Sofosbuvir/Velpatasvir



Telotristat Ethyl

Valbenazine

Venetoclax

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FirstWord Reports deliver timely, need-to-know intelligence about your products, your competitors and your markets. Covering biosimilars, market access, medical affairs, sales & marketing, technology and therapy areas, FirstWord Reports provide expert views and intelligence on the challenges facing pharma today.



Contents

1. EXECUTIVE SUMMARY

2. RESEARCH METHODOLOGY AND OBJECTIVES

3. OVERVIEW

- 3.1 Approved drugs
- 3.2 Sales Data
- 3.3 P&R/HTA Activity

4. DRUG STATUS REPORTS

- 4.1 Abaloparatide
- 4.2 Alectinib
- 4.3 Atezolizuma
- 4.4 Avelumab
- 4.5 Betrixaban
- 4.6 Bezlotoxumab
- 4.7 Brigatinib
- 4.8 Brivaracetam
- 4.9 Brodalumab
- 4.10 Cerliponase Alfa
- 4.11 Crisaborole
- 4.12 Daclizumab
- 4.13 Daratumumab
- 4.14 Defibrotide
- 4.15 Deflazacort
- 4.16 Delafloxacin
- 4.17 Dupilumab
- 4.18 Durvalumab
- 4.19 Edaravone
- 4.20 Elbasvir/Grazoprevir
- 4.21 Elotuzumab
- 4.22 Eluxadoline
- 4.23 Enasidenib
- 4.24 Etelcalcetide
- 4.25 Eteplirsen



- 4.26 Glecaprevir/Pibrentasvir
- 4.27 Guselkumab
- 4.28 Ixazomib
- 4.29 Ixekizumab
- 4.30 Lenvatinib
- 4.31 Lifitegrast Ophthalmic Solution
- 4.32 Lixisenatide
- 4.33 Midostaurin
- 4.34 Naldemedine
- 4.35 Necitumumab
- 4.36 Neratinib Maleate
- 4.37 Niraparib
- 4.38 Nusinersen
- 4.39 Obeticholic Acid
- 4.40 Ocrelizumab
- 4.41 Olaratumab
- 4.42 Osimertinib
- 4.43 Palbociclib
- 4.44 Pimavanserin
- 4.45 Plecanatide
- 4.46 Reslizumab
- 4.47 Ribociclib
- 4.48 Rolapitant
- 4.49 Rucaparib
- 4.50 Safinamide
- 4.51 Sarilumab
- 4.52 Selexipag
- 4.53 Sofosbuvir/Velpatasvir
- 4.54 Sofosbuvir/Velpatasvir/Voxilaprevir
- 4.55 Telotristat Ethyl
- 4.56 Valbenazine
- 4.57 Venetoclax

5. ACRONYMS USED IN THIS REPORT



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