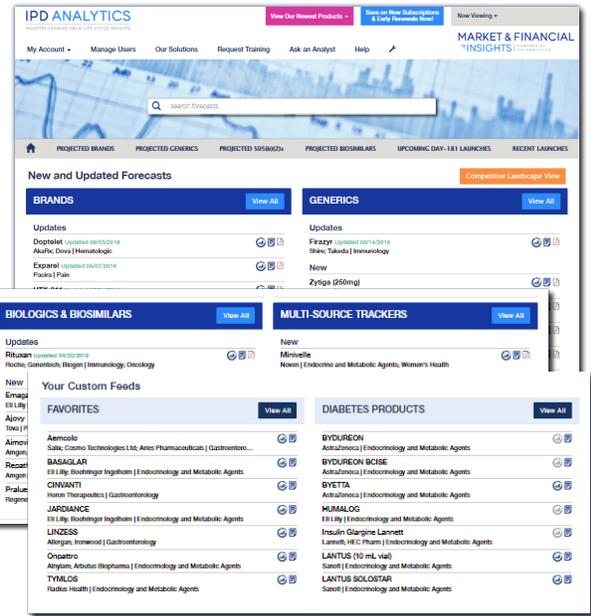


Look beyond the numbers for better forecasts.

The strongest forecasts are based on more than models and trends - they're built on a deep understanding of qualitative catalysts that drive financial performance throughout the entire product life cycle. Staying competitive requires not just knowing these key drivers, but staying on top of them as they shift in a complex, ever-changing marketplace.

Now, you can improve your forecasting process with IPD's new Market and Financial Insights platform, which includes continually updated, independent, and fully transparent forecasts, as well as input data, analogs, and incisive expert commentary.



METHODOLOGY & INPUTS

Forecasted values for Gaspres are based on a patient based model with use as a third line agent, moving to second line by 2020. 2018 Reported Net sales were ~\$10 million. Based on our initial calculations, we estimate that ~\$3 million of that was inventory stocking.

| INPUT NAME | SOURCE TYPE | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 |
|---|--------------------|---------|---------|---------|--------|------|------|
| RECENT POPULATION | | | | | | | |
| Distinctive Stock Patients (in thousands) | Publicly Available | 800 | 800 | 800 | 800 | 800 | 800 |
| Patients receiving first line therapy | Publicly Available | 745 | 745 | 745 | 745 | 745 | 745 |
| Patients remaining second line therapy | Publicly Available | 260 | 260 | 260 | 260 | 260 | 260 |
| Non-responders to second line therapy | IPD Prediction | 91 | 91 | 91 | 91 | 91 | 91 |
| GAZPESZA - THIRD LINE THERAPY | | | | | | | |
| Gaspres Penetration | IPD Prediction | 8% | 21% | 31% | 34% | | |
| Gaspres Patients | IPD Prediction | 7.7 | 19.3 | 28.2 | 31.1 | | |
| Average Cost Per Patient | IPD Prediction | \$3,710 | \$3,928 | \$4,534 | \$4,34 | | |
| Gross Sales (\$-millions) | IPD Prediction | \$29 | \$76 | \$116 | \$135 | | |
| GAZPESZA - SECOND LINE THERAPY | | | | | | | |
| Gaspres Penetration | IPD Prediction | 0% | 0.4% | 2% | 9% | | |
| Gaspres Patients | IPD Prediction | 0 | 0.7 | 4.3 | 15.2 | | |
| Gross Sales (\$-millions) | IPD Prediction | 0 | \$3 | \$18 | \$57 | | |
| TOTAL BRAND POTENTIAL | | | | | | | |
| Gaspres Patients | IPD Prediction | 7.7 | 20 | 32.4 | 46.4 | | |
| Pharmaceutical Sales | IPD Prediction | 9% | 9% | 7.9% | 10.9% | | |

BRAND/BIOSIMILAR SCORECARD

| BRAND FORECAST DRIVER | DESCRIPTION | ADDITIONAL COMMENTS |
|---|---|---------------------|
| COMPETITIVE LANDSCAPE | Unique Patient Population Characteristics | None |
| Order of Entry in Class | Third or Later | Gaspres is the |
| Pending FDA Approval/Competitive Launches in Class | None | |
| Off Label Utilization | Limited/No Off Label Use | |
| Manufacture Established | No | |
| Compounded Competitor | No | |
| CLINICAL AND REGULATORY COMPLEXITY | Acute, Intermittent, or Chronic Therapy | Inpatient |
| Administration Setting | Inpatient | |
| Clinically Meaningful Differentiation | Limited Differentiation | |
| Manufacturing Challenges | No | |
| FDA Production Restrictions | None | |
| REMS/DEA Scheduling | None | |
| COMMERCIALIZATION, DISTRIBUTION, AND OTHER GO-TO-MARKET FACTORS | Relative Pricing | Above Market |
| Applicable Payer Line of Business | Commercial/Medicare/Medicaid | |
| Likely Payer Management of Brand Therapy | Non-Formulary | Many hospitals |
| Likely Brand Discount | <25% Discount | |
| Patient Assistance/Copay Coaspen/Advocacy | N/A | |
| Manufacturer Sales Strategies Identified | N/A | |

BRAND LAUNCH - ANALOGS

MAKENA (AUTO-INJECTOR)

| GENERIC SALES | 2018 | 2019 |
|---------------|--------|--------|
| GENERIC SALES | \$117M | \$136M |

- Makena subcutaneous auto-injector is also a proinsulin-admixed product that launched with enhanced convenience of administration following an original product with more complex administration.
- Like Clevers, and brand, the Makena subcutaneous auto-injector launched prior to generic entry of the original intramuscular formulation.
- Makena is proinsulin-admixed and labeled on the medical benefits, which suggests a high level of prescriber (as opposed to payer) influence in specific product selection.
- Due to Makena auto-injector's launch in 2018, its most recent year of sales is a year-to-date total.

AMATEKA

| BRAND LAUNCH YEAR | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 |
|-------------------|-------|-------|--------|--------|--------|--------|
| GENERIC SALES | \$28M | \$28M | \$148M | \$218M | \$288M | \$288M |

- Fiascure is also a proinsulin-admixed product.
- Admixedness in an oral solid dose setting with organization type impact between independent clinical and clinical owned by a larger organization or health system.
- Due to Fiascure's launch in 2016, its most recent year of sales is a year-to-date total.

AMATEKA

| BRAND LAUNCH YEAR | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 |
|-------------------|-------|-------|--------|--------|--------|--------|
| GENERIC SALES | \$28M | \$28M | \$148M | \$218M | \$288M | \$288M |

- Also approved on the 505(b)(2) pathway.
- Also an intrinsically administered tripartite product given in a clinic setting.
- Like Clevers, typically prescribed by a specialist.

CELEBREX (100, 200, 400 MG)

| GENERIC LAUNCH YEAR | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 |
|---------------------|--------|---------|---------|---------|---------|---------|
| GENERIC SALES | \$3.9B | \$7.27B | \$9.24B | \$9.02B | \$9.32B | \$9.13B |

- Like Jadem, Celebra is an oral solid formulation of a small molecule.
- Like we expect for Jadem, several manufacturers launched generic Celebrex, with additional launches in the following months.

GENERIC EVENT SCORECARD

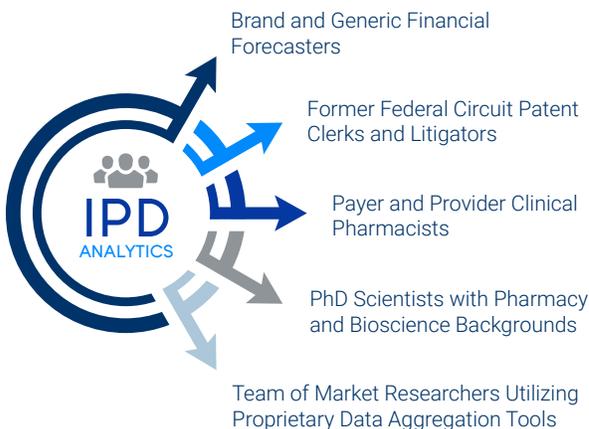
| GENERIC FORECAST DRIVER | DESCRIPTION | ADDITIONAL COMMENTS |
|---|--|---|
| COMPETITIVE LANDSCAPE | 100 Day Exclusivity/First to File | None |
| Settlements | None | |
| Authorized Generics | Confirmed | AMAG used Franco to launch an AG. |
| Pending FDA Approval/Competitive Launches | Brand launch confirmed Generic launch confirmed | Makena Auto-Injector launched March 2018. Amgen (Sant and Franco) AG launched an AP generic version of Makena July 2018. Sanofi AG was granted FDA effective approval 1/23/2019. |
| Competing 505(b)(2)s | Confirmed | Makena is a 505(b)(2) of Diabetes which has been discontinued. On 07/25/2018, FDA granted effective approval to AMAG 505(b)(2) for 200 mg/ml biosimilar/intermediate strength injection to the top 100 highest revenue for- and off-injectable insulin analogs. AMAG received FDA approval for its 200 mg/ml intermediate strength and its non-therapeutic equivalent (NTE) to Makena. AMAG launched the product in June 2018. Amgen (Sant and Franco) AG launched its 200 mg/ml intermediate strength injection to Makena in October 2018. In this case, the 2018 reported presentation, Amgen (Sant and Franco) AG is a generic presentation of the 200 mg/ml intermediate strength injection which is receiving AMAG's 505(b)(2) approval. AMAG's 505(b)(2) approval is expected to launch in 1Q 2019. |
| Competing OTCs | None | |
| GENERIC LAUNCH COMPLEXITY | Formulation Complexity | Simple |
| API Supply Chain | API Supply Not Limited | 5 API Manufacturers, 4 with completed DMFs |
| FDA Production Restrictions | None | |
| REMS/DEA Scheduling | None | |
| Unique Patient Population Characteristics | Vulnerable/Protected Class | Makena is indicated for a vulnerable condition, the prevention of gestosis both, which may limit willingness of patients and providers to switch products if they are stable on therapy. |
| COMMERCIALIZATION, DISTRIBUTION, AND OTHER GO-TO-MARKET FACTORS | Likely Brand Discount | 25 to 50% Discount |
| Brand Patient Assistance | Copay Assistance Program | AMAG offers robust financial support and controls a significant portion of the supply chain through its Makena Care Hub: https://makenanag.com/makena-care-connection/ |
| Generic Patient Assistance | None | |
| Applicable Payer Line of Business | Commercial/Medicare | |

IPD's fully independent forecasts feature:

- Robust and transparent reviews of forecast inputs and methodologies
- Clear and concise forecast scorecards for brand, generic and biosimilar launches
- Expert-curated brand and generic analogs
- Focused qualitative insights on the competitive landscape

IPD's inputs, methodologies, analogs, and expert-driven insights, cover:

- Brands
- Generics
- Biologics
- Biosimilars
- 505(b)(2)s
- Multi-source drugs



Our unique team of brand and generic financial forecasters, clinical pharmacists, and patent attorneys, use IPD's proprietary data and purpose-built technology platform to continually collect, track, evaluate, and provide the most relevant key forecast drivers.

With IPD's team behind you, you can ensure your strategy always incorporates critical market events across multiple dimensions, including:

- Products that create new therapeutic classes
- New products that disrupt established therapeutic areas
- Products impacted by generic and biosimilar launches
- Additional generics intensifying market competition

Leverage **timely alerts** and fully-transparent **version tracking** to stay informed and understand how forecasts have evolved over time.



From: IPD Analytics <healthcare@ipdanalytics.com>
Sent: Monday, January 28, 2019 7:39 AM

Subject: IPD Analytics Market Forecast Update: Giapreza - IPD Tweaks 2019 Outlook From \$22M to \$27M; Consensus Estimates Reduced Significantly Since Launch

CONFIDENTIAL

From: IPD Analytics <healthcare@ipdanalytics.com>
Sent: Thursday, October 18, 2018 8:09 AM

Subject: IPD Analytics Market Forecast Update: Tymlos (Radius) Continues to Gain Medicare Access Against Market-leading Forteo (Eli Lilly)

CONFIDENTIAL

From: IPD Analytics <healthcare@ipdanalytics.com>
Sent: Wednesday, November 07, 2018 7:33 AM

Subject: IPD Analytics Market Forecast Update: Rhopressa (Aerie) and Vyzulta (Bausch) - Late-Cycle 2019 Medicare Formulary Wins Offer Opportunity for Uptake for Novel Glaucoma Agents

CONFIDENTIAL

From: IPD Analytics <healthcare@ipdanalytics.com>
Sent: Wednesday, June 19, 2019 9:48 AM

Subject: IPD Analytics Market Forecast Update: Revatio (Oral Suspension) - Generic Price Contingent on Pfizer's Authorized Generic Strategy

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RECENT DEVELOPMENTS

On 5/31/19, FDA granted effective approval to Novitium's ANDA 212260, and Novitium launched its generic version of Pfizer's Revatio for oral suspension. On 6/4/19, Novitium confirmed that it had launched its generic powder and stated that it had received a Competitive Generic Therapy (CGT) designation. The CGT designation includes a period of exclusivity (180-days) that will expire on or about 11/27/19. During that time, only an authorized generic of Revatio would be permitted to launch.

We anticipate that Pfizer will launch an authorized generic priced at parity with Novitium through their generic arm, Greenstone. Considering Greenstone's consistent pattern of launching soon after exclusivity expires, it is noteworthy that Greenstone has not yet launched an AG for Revatio. This may be due to the reported shortage of sildenafil, which Pfizer has indicated will be resolved by August 2019. Although Greenstone has a history of achieving considerable market share with an AG, this delay could limit its long-term potential.

We note in the recent launch of generic Delcoid, Greenstone launched the AG at 80% of brand WAC following Teva's launch at 88%. If Greenstone were to pursue a similar strategy for Revatio, we believe it would stand to gain a higher proportion of the generic market, and the average generic price would fall more rapidly as payors apply more aggressive and earlier MAC rates.

Incorporate IPD's **continually-updated forecast inputs** into your own models for an efficient, comprehensive look at the drug landscape ahead.

IPD's analyses go beyond simple, standard projections (MOA, disease class, etc.) to incorporate a wide range of complex, nuanced catalysts driven by players across the market. **Access the latest information at-a-glance, including difficult-to-access data points such as:**

- Sales and Utilization
- Pricing Strategy
- Patient Population Characteristics
- Market Basket/Competition
- Clinical Pipeline/Pending Approvals in Class
- Loss-of-Exclusivity Outlook
- Likely Order of Competitor Entry
- Off-Label Utilization
- Compounded Competitors
- Therapy Characteristics (Acute, Chronic, Intermittent, etc.)
- Administration Setting Considerations
- Clinical Differentiation
- Regulatory Actions
- Manufacturing Challenges/FDA Production Restrictions
- Formulation Complexity
- REMS/DEA Scheduling
- Formulary Coverage (by Relevant Line of Business)
- Payer Management Scenarios
- Projected Supply Chain Discounts
- Rebate Agreements, Copay Assistance, and Other Programs
- Clinical Guidelines and Economic Evaluations
- Manufacturer Sales Strategy and Capabilities
- Manufacturer Life-cycle Management Strategies
- Prescriber Type Considerations
- Benefit Type Considerations (Medical vs. Pharmacy)
- Distribution Channel Impact
- Provider Usage Patterns
- 180-day Exclusivity
- Settlement Agreements
- Authorized Generic Strategies

Brand Forecasts

View complete forecasts, including sales, utilization, pricing, patient population, and therapy-cost for new brands, established brands, and those facing upcoming generic competition.

Ajovy (Fremanezumab-vfrm)
Teva | Calcitonin gene-related peptide (CGRP) inhibitor

More Information >

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ACTUALS **FORECAST**

2018: \$32M 2019: \$189M 2020: \$432M 2021: \$693M 2022: \$837M 2023: \$962M

■ ANNUAL SALES ■ NET SALES

FORECAST SUMMARY **KEY FORECAST DRIVERS**

PAYOR STRATEGY & FORMULARY ACCESS
Since all products in this class have similar clinical profiles, formulary access and sales and marketing strategy will determine market share among the competitors.

FORECAST OVERVIEW
Forecast Summary
Methodology & Inputs
Brand/Biosimilar Scorecard

CLINICAL & REGULATORY
Clinical Efficacy & Regulatory Actions

PRODUCT LIFE-CYCLE MANAGEMENT
BRAND/BIOSIMILAR SCORECARD

| BRAND FORECAST DRIVER | DESCRIPTION | ADDITIONAL COMMENTS |
|---|--|--|
| COMPETITIVE LANDSCAPE | Unique Patient Population Characteristics | None |
| Order of Entry in Class | Second | Already approved in May 2018, was the first of four injectable calcitonin gene-related peptide (CGRP) inhibitors in line for approval over the next 18 months. Ajovy launched in September 2018. |
| Pending FDA Approvals/Competitive Launches in Class | Brand launch confirmed Brand launch suspected | The third product in the same class launched within a month after Ajovy. Emgality by Eli Lilly launched in October 2018. Additional competitors are in late-stage development. (eptinezumab/Aidev) |
| OT Label Utilization | Limited/No Off Label Use | |
| Manufacturer Established | Overall | |
| Compounded Competitor | No | |
| CLINICAL AND REGULATORY COMPLEXITY | Acute, Intermittent, or Chronic Therapy | Chronic |
| Administration Setting | Outpatient | Self |
| Clinically Meaningful Differentiation | Limited Differentiation | Similar efficacy and safety across the four CGRP inhibitors. The Ajovy pre-filled syringe results might be less painful than competing products auto-injectors, which could aid in adoption. Ajovy is also the only CGRP available as a subcutaneous monthly and quarterly dose. |
| Manufacturing Challenges | No | |
| FDA Production Restrictions | None | |
| REMS/DEA Scheduling | None | |
| COMMERCIALIZATION, DISTRIBUTION, AND OTHER GO-TO-MARKET FACTORS | Relative Pricing | At Parity |
| Applicable Payer Line of Business | Commercial Medicare Medicaid | Already set the entry point for products in this class at \$6,900/year, which was at the low end of the predicted entry point of \$8,000-12,000/year. |
| Likely Payer Management of Brand Therapy | Prior Authorization | Payers are implementing criteria that may limit sales. Implementation of prior authorization criteria was expected, and doctors are now starting to understand what information is expected by payers. As competition |

Focus on the key drivers that matter most.

Each forecast features a **summary** and **key forecast drivers**, providing a streamlined view of the most relevant information. **Dig deeper with quick links**, each diving deeper into the story behind the numbers.

Bolster your current forecasting efforts with efficient model inputs, derived from complex, qualitative analysis.

From clinical efficacy to payer strategy, every forecast considers every angle.

Designed to deliver data and analysis in a structured and efficient way, IPD's **methodology, inputs, and proprietary brand and generic scorecards** efficiently summarize all of the key qualitative drivers of the projections.

Brands Facing First-Time Generic Competition

PRODUCT LIFE-CYCLE MANAGEMENT

★ GENERIC EVENT - FORECAST DATA/TRACKING

NO. OF GENERICS

Month 1: 1 Month 2: 1 Month 3: 1 Month 4: 2 Month 5: 2 Month 6: 2 Month 7: 2 Month 8: 2 Month 9: 2 Month 10: 2 Month 11: 2 Month 12: 2

★ GENERIC EVENT SCORECARD

| GENERIC EVENT DRIVER | DESCRIPTION | ADDITIONAL COMMENTS |
|---|---|---|
| COMPETITIVE LANDSCAPE | 180-Day Exclusivity/First to File | Potential |
| Settlements | Confirmed | Teva and Apotex have settlements with Lilly. |
| Authorized Generics | Potential | Lilly likely offers a significant discount to payors on Forteo through rebate agreements for preferred formulary position. With recent pressure and scrutiny on drug pricing, a authorized generic would allow Lilly to offer a product with a lower list price while maintaining the net revenue it currently has on the rebated brand. |
| Pending FDA Approvals/Competitive Launches | Brand launch confirmed Brand launch suspected | Brand launch confirmed Generic launch suspected |
| Competing 505(b)(2)s | Confirmed | Plasma is developing a generic in partnership with Amgen called PFT07. Plasma completed Phase 3 trial in osteoporosis patients in May 2018 (NCT03064228). On 12/10/18, Plasma announced that it had filed a 505(b)(2) NDA seeking FDA approval for PFT07 for the treatment of osteoporosis and preventing fractures. On 3/15/19, Plasma announced that FDA had accepted its 505(b)(2) NDA and set a PDUFA target date of 10/7/19. Plasma also announced that PFT07 remains on track to enter the U.S. market as early as the fourth quarter of 2019, subject to FDA approval and other factors. |
| Competing OTCs | None | |
| GENERIC LAUNCH COMPLEXITY | Formulation Complexity API Supply Chain FDA Production Restrictions | Highly Complex API Supply Limited None |
| REMS/DEA Scheduling | None | The REMS for Forteo was originally approved on July 22, 2009, and the most recent modification was approved on August 05, 2011. A REMS is no longer required for Forteo. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/021138Orig1s011.pdf |
| Unique Patient Population Characteristics | None | |
| COMMERCIALIZATION, DISTRIBUTION, AND OTHER GO-TO-MARKET FACTORS | Likely Brand Discount | 25 to 50% Discount |
| | | Even with a lower list price for competitor Tysabri, some leading Medicare plans continue to prefer Forteo, suggesting that Forteo may be highly rebated, resulting in a lower net cost. |

COMPETITIVE LANDSCAPE

| MARKET BASKET | Name | Manufacturer | Route of Administration | Mechanism of Action | Generic / Biosimilar | Probability | Loss of Exclusivity | Brand Sales (2018) | Status | Submission Type | Therapy Class | Therapy Code |
|-----------------------|--------------|--------------|-------------------------|-------------------------------|----------------------|-------------|---------------------|--------------------|----------|-----------------|---------------|--------------|
| TYSABRI (alemtuzumab) | TYSABRI | Genentech | Subcutaneous | Parathyroid hormone or analog | No | 60% | 04/29/2031 | \$116M | Approved | NDA | 521,860 | |
| | Emgality | Angen | Subcutaneous | Sclerostin inhibitor | N/A | N/A | 2031 or 2033 | TBD | Approved | BLA | | |
| FORTEO (teriparatide) | FORTEO | Eli Lilly | Subcutaneous | Parathyroid hormone or analog | No | 50% | 29/19/2019 | \$94M | Approved | NDA | \$41,115 | |
| | Teriparatide | Amgen | Subcutaneous | Parathyroid hormone or analog | No | 50% | 29/19/2019 | \$94M | Approved | NDA | \$41,115 | |

PIPELINE & NEW INDICATIONS

| PIPELINE & NEW INDICATIONS | Name | Manufacturer | Route of Administration | Mechanism of Action | Status | Submission Type | Indications |
|----------------------------|--------|--------------|-------------------------|-------------------------------|----------------------|-----------------|---|
| FORTEO (teriparatide) | FORTEO | Eli Lilly | Subcutaneous | Parathyroid hormone or analog | Approved | NDA | No Current Pending Indications |
| PFT07 (teriparatide) | PFT07 | Plasma | Subcutaneous | Parathyroid hormone or analog | Pending (10/07/2019) | 505(b)2 NDA | Osteoporosis; Osteoporosis (Pending) 505(b)2 NDA - 15077... |

Gain a deeper understanding of all current and potential market players.

In our **Market Basket** and **Pipeline and New Indications** sections, you will find everything you need to know about the competitive landscape. Starting with drugs still in clinical development, IPD considers each competitor carefully to gauge potential financial impact.

Biologics & Biosimilars

Benchmark our projections with yours.

With up-to-date, continually tracked data, our forecasts can serve as a point of reference for your own model projections. **Speak to the analysts directly responsible for building the forecasts** for a clearer understanding of the outputs and applicable insights.

REIMBURSEMENT & CODING

J9312: Injection, rituximab, 10 mg

Do not use for dates of service prior to 11/1/2019 see J9310

Active 01/01/2019

Rituxan/rituximab

Antineoplastic Agents | Antineoplastics And Adjunctive Therapies | Antineoplastic - Antibodies

Price is per 10 MG

Related Administration Codes

96413: Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug

96415: each additional hour (List separately in addition to code for primary procedure)

MANUFACTURER & PAYOR STRATEGY

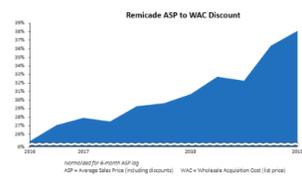
PRICING Key Driver

Prior Biosimilar Launches in the U.S.

Previous biosimilars and brand biologic competitors have typically entered the market at a modest discount to the brand (~30% off brand wholesale acquisition cost [WAC]). This discount alone has proven insufficient for most payors to drastically modify formulary design in order to prefer a biosimilar over the innovator product, particularly when the brand responds with increased discounts in the face of biosimilar competition. Thus, an additional ~10-15% rebate has often been required for biosimilar products to gain significant uptake.

Remicade

Janessen responded to competition from lower-priced biosimilars of Remicade (infliximab) by gradually increasing its discount to ensure continued formulary access.



did not yet launch. Will be based

Rituxan (Rituximab)

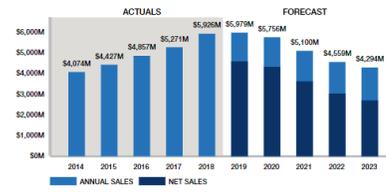
Roche; Genentech; Biogen | Anti-CD20 antibody

More Information >

View Publications

Forecast Updates

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FORECAST SUMMARY

Rituxan (rituximab)/Genentech/Biogen is a CD20-directed cytotoxic antibody indicated for the treatment of adult patients with Non-Hodgkin's Lymphoma, Chronic Lymphocytic Leukemia, Rheumatoid Arthritis, Granulomatosis with polyangiitis and Microscopic Polyangiitis, and Pemphigus Vulgaris.

Teva and its partner Celltrion are likely to launch Truxima (rituximab-ctx), the first biosimilar version of Rituxan, in the second half of 2019. Truxima's entry to the market will be followed closely by a Pfizer biosimilar by the end of 2019, and as many as three additional biosimilar competitors may enter the market in 2020. Teva may have an opportunity to leverage Truxima's brief period as the only Rituxan biosimilar to gain early uptake, before increased discounts on the brand from Genentech and additional biosimilars vying for formulary position result in a substantially more competitive market.

See More

FORECAST OVERVIEW

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Forecast Detail

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Clinical Efficacy & Regulatory Actions

PRODUCT LIFE-CYCLE MANAGEMENT

Loss of Exclusivity Outlook

Manufacturer Life-Cycle Management Strategies

COMPETITIVE LANDSCAPE

Relevant Patient Population

Market Basket

Pipeline & New Indications

MANUFACTURER & PAYOR STRATEGY

Pricing Key Driver

Payor Strategy & Formulary Access Key Driver

Manufacturer Sales Strategy Key Driver

OTHER

Reimbursement & Coding

Additional Commentary

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Consider every driver affecting the forecast.

Utilizing our wide range of experts in various fields, **IPD reaches beyond typical considerations**, taking into account some of the less traditional market characteristics, such as **coding and reimbursement, payer strategy, formulary access, and manufacturer sales strategy.**

Multi-Source Drug Trackers

Gleevec (Imatinib Mesylate)

Novartis | Tyrosine kinase inhibitor

More Information >

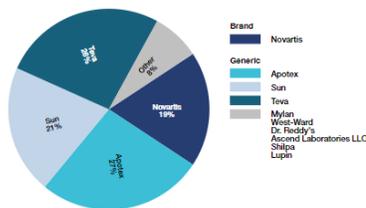
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GLEEVEC MULTI-SOURCE TRACKER

MARKET SHARE

By Units

Gross Sales - Trailing Twelve Months (TTM)



Gleevec (imatinib mesylate) is a tyrosine kinase inhibitor indicated for the treatment certain forms of cancer, including chronic myeloid leukemia, acute lymphoblastic leukemia, myelodysplastic/myeloproliferative diseases, aggressive systemic mastocytosis, hypereosinophilic syndrome and/or chronic eosinophilic leukemia, metastatic dermatofibrosarcoma protuberans, and gastrointestinal stromal tumors. In late 2015, the FDA approved the first generic formulation of imatinib, leading to multi-source competition in the years that followed. Currently, Gleevec has a large number of generic manufacturers, with Apotex leading the market, followed closely by Teva.

Track the progression of multi-source drug markets, viewing up-to-date market-share and pricing information by manufacturer.

Understand market share, pricing, generic outlook, and a complete list of competing manufacturers all within each of IPD's Multi-Source Tracker pages.

Updated monthly, allow for a full view of the market for multi-source drugs and how they are unfolding.

PRODUCT LIFE-CYCLE MANAGEMENT

LOSS OF EXCLUSIVITY OUTLOOK

Estimated LOE: Already Occurred

Expected Outlook for Generic Entry: Apotex (Launched); Dr. Reddy's (Launched); Mylan (Launched); Natco Pharma/Lupin (Launched); Shipla/Ascend Laboratories LLC (Launched); Sun (Launched); Teva (Launched); West-Ward (Launched); Amneal (Approved); Breckenridge (Approved); Wockhardt (Approved); Ranbaxy/Sun (TBD)

Comments on Generic Entry: On 5/16/06, Sun filed ANDA 07540 seeking FDA approval for generic 100 mg and 400 mg tablets. Sometime thereafter, Sun amended ANDA 07540 to include Paragraph IV certifications challenging some of the patents on Gleevec. We speculate that Sun did not challenge the '184 patent, "carved out" the GST indication from the proposed labeling of its generic 100 mg and 400 mg tablets in order to avoid the '335 patent, and filed Paragraph IV certifications challenging only the '051 and '799 patents. Novartis received formal notification of Sun's Paragraph IV certifications on 8/25/07, but initially did not sue Sun for patent infringement. FDA granted tentative approval to Sun's ANDA on 11/13/09. After Sun sued Novartis on 6/7/12, Novartis counter-sued Sun for infringement of the '051 patent. Novartis and Sun later reached a settlement agreement. On 12/3/15, FDA granted effective approval to Sun's ANDA and confirmed that Sun was eligible for 180-day exclusivity. Under the terms of the settlement agreement, Sun launched its generic 100 mg and 400 mg tablets on 2/1/16. Sun's 180-day exclusivity expired on 7/30/16.

Apotex (07/9179), Mylan (02/0444), and Teva (20/4285) also filed ANDAs seeking FDA approval for generic 100 mg and 400 mg tablets. Like Sun, we speculate that Apotex, Mylan, and Teva did not challenge the '184 patent, "carved out" the GST indication from the proposed labeling of its generic 100 mg and 400 mg tablets in order to avoid the '335 patent, and filed Paragraph IV certifications challenging only the '051 and '799 patents. Novartis did not sue Apotex, Mylan, or Teva for patent infringement. After Sun's 180-day exclusivity expired, Apotex and Teva announced that they had launched their generic 100 mg and 400 mg tablets on 8/5/16. FDA granted effective approval to Mylan's ANDA on 6/21/17. Mylan launched its generic tablets on 9/29/17.

Annual (02/0748), Breckenridge (02/0590), Dr. Reddy's (02/0647), Natco (02/0748), Roxane (02/0758), Shipla (02/0820), and Wockhardt (02/0842) also filed ANDAs with Paragraph IV certifications seeking FDA approval for generic 100 mg and 400 mg tablets. Novartis sued Amneal, Breckenridge, Dr. Reddy's, Natco, Roxane, Shipla, and Wockhardt for patent infringement, and the companies later reached settlement agreements. Roxane changed its name to Hikma in June 2018. Hikma's subsidiary West-Ward now controls ANDA 207586. FDA has granted effective approval to ANDAs held by Dr. Reddy's, Natco, Shipla, West-Ward, and Wockhardt, and at least Dr. Reddy's and West-Ward have launched their generic tablets. Ascend apparently launched Shipla's generic tablets. Lupin launched Natco's generic tablets. Although we do not know when Amneal and Breckenridge will be permitted to launch their generic 100 mg and 400 mg tablets under the terms of their settlement agreements, we speculate that Amneal and Breckenridge may be permitted to launch their generic 100 mg and 400 mg tablets now that they have received FDA effective approval.

Sometime in mid-2014, Ranbaxy filed ANDA 206723 with a Paragraph IV certification seeking FDA approval for generic 100 mg and 400 mg tablets. Novartis appears to have sued Ranbaxy for patent infringement in a timely manner. Sun acquired Ranbaxy on 3/25/15. Novartis, Ranbaxy, and Sun apparently reached a settlement agreement in October 2015. Now that Ranbaxy is a subsidiary of Sun, it is unclear whether Ranbaxy/Sun plans to launch its generic 100 and 400 mg tablets manufactured under ANDA 206723.

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New products that create classes



New products that launch into established classes



Products with upcoming first-time generic events



Additional generics entering established, competitive markets

How will likely payer restrictions and a strong pipeline impact the emerging CGRP class?

How will a pricey new entrant like Giapreza, with murky clinical benefits, perform in the critical care space?

How will Gilead's efforts to move patients to Descovy shape the PrEP market with generic Truvada on the horizon?

How will pricing, rebates, and market share shift as other entrants follow Mylan into the Advair Diskus space?

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Therapeutic Areas

- Behavioral Health: Attention Deficit Hyperactivity Disorder (ADHD), Depression, Schizophrenia, Substance Dependence or Overdose
- Cardiovascular: Antiplatelet Therapies, Direct-acting Oral Anticoagulant (DOAC/NOAC), Dyslipidemia, Glycoprotein Inhibitors, Heart Failure, Hypertension, Hypotension
- CNS: Alzheimer's Disease, Duchenne Muscular Dystrophy (DMD), Epilepsy / Seizure Disorder, Lambert-Eaton myasthenic syndrome (LEMS), Multiple Sclerosis (MS), Neurodegenerative Disorders, Parkinson's Disease
- Dermatology: Acne Vulgaris, Botulinum Toxins, Dermatitis or Eczema, Head Lice and other parasitic disease, Hypertrophic Scar, Onychomycosis (nail infection), Plaque Psoriasis, Rosacea
- Endocrine and Metabolic Agents: Fabry Disease, Familial amyloid polyneuropathy, Gaucher's Disease, Gout, Growth Hormone, Hypothyroidism, Osteoporosis and other bone disease, Phenyletonuria, Testosterone
- Hematologic: Anemia, Erythropoietic Protoporphyrin, Hemophilia, Neutropenia, Sickle cell disease, Thrombocytopenia, Thrombotic Thrombocytopenic Purpura, Treatment of Paroxysmal Nocturnal Hemoglobinuria
- Oncology: Multiple Myeloma, Myelodysplastic Syndromes, Neuroendocrine Tumors (NET), Non-Hodgkin's Lymphoma, Non-Small Cell Lung Cancer, Ovarian Cancer, Prostate Cancer, Skin Cancer (not otherwise classified), Small Cell Lung Cancer, Solid Tumors
- Renal and Urology Agents: Erectile Conditions, Kidney Disease, Kidney Disease, Overactive Bladder
- Immunology: Allergic Reactions (other), Angioedema, Immune Globulin (IVIG) Management, Interleukin Antagonists (IL antagonist), Janus Kinase Inhibitors (JAK inhibitor), Lipids, Otezla, Otezla, Entyvio, Tysabri, Rituxan and other, Other Immunology Disease, Thrombocytopenia
- Ophthalmics: Cataract, Conjunctivitis, Dry Eye, Glaucoma or Ocular Hypertension, Macular Degeneration, Neurotrophic keratopathy
- Respiratory: Asthma, Chronic Obstructive Pulmonary Disease (COPD), Cystic Fibrosis, Pulmonary Hypertension, Severe Asthma
- Infectious Disease: Abdominal Infections, Acute Bacterial Skin and Infections (ABSSSI), Antibiotics/Antiviral, Clostridium difficile infection, Complicated Urinary Tract Infections, Hepatitis B (HBV), Hepatitis C (HCV), HIV or AIDS, Infectious Disease, Fungal
- Pain: Exparel - Post-operative Pain, Fibromyalgia, Migraine or Headache, Non-Opoid Pain Relievers, Opioid Pain Relievers, Osteoarthritis
- Women's Health: Contraception, Hormone Replacement Therapy (HRT), Infertility, Pregnancy, Uterine Fibroids and Endometriosis

Oncology: Prostate Cancer

| ORAL ANTI-ANDROGEN | ANDROGEN DE... | TARGETED THE... | VACCINE THER... | BONE-MODIFY... | OTHER MOA | IN DEVELOPE... | IN DEVELOPE... | | | |
|--|-------------------------|-----------------|-----------------|----------------|------------------|----------------|-----------------------|-----|-----------|----------|
| ZYTIGA (250 mg) Abiraterone Acetate | Janssen | Androgen bi... | Oral | Yes (R) | Already Occurred | \$1,241M | Approved (04/29/2011) | NDA | \$132,499 | ↓ 6.40 % |
| XTANDI Enzalutamide | Astellas Pfizer | Antiandrogens | Oral | No | 3Q 2027 | \$966M | Approved (09/19/2014) | NDA | \$140,508 | ↑ 5.90 % |
| NILANDRON Nilotinib | Novartis | Antiandrogens | Oral | Yes (T) | Already Occurred | < \$10M | Approved (09/19/1998) | NDA | \$85,271 | → 0.00 % |
| Erleada Apalutamide | Janssen Aragon Pharm... | Androgen re... | | | | | | | | |
| Nubeqa Enzalutamide | Bayer | Androgen re... | | | | | | | | |
| Galitone galeterone | Novus Therapeu... | Androgen re... | | | | | | | | |
| ZYTIGA (500 mg) Abiraterone Acetate | Janssen | Androgen bi... | | | | | | | | |
| YONSA Abiraterone Acetate (9500g) or ZYTIGA (250 mg) (9500g) or ZYTIGA (250 mg) | Sun | Androgen bi... | | | | | | | | |

Projected Annual U.S. Sales (millions)

| | 2018 | 2019 | 2020 | 2021 |
|------------------------------|---------|---------|---------|---------|
| Zytiga (Janssen) | \$1,540 | \$1,708 | \$305 | \$265 |
| Xtandi (Pfizer/Astellas) | \$1,552 | \$1,923 | \$2,150 | \$2,409 |
| Erleada (Janssen) | \$116 | \$190 | \$806 | \$1,377 |
| Doralutamide/ODM-201 (Bayer) | - | \$64 | \$214 | \$319 |

Prostate Cancer Market +11% Annual Growth Rate 2018-2021

| Year | Doralutamide | Erleada | Xtandi | Zytiga |
|------|---------------|------------|------------|------------|
| 2018 | \$3,209 (48%) | \$385 (5%) | \$347 (5%) | \$385 (5%) |
| 2019 | \$3,885 (49%) | \$426 (5%) | \$376 (5%) | \$385 (5%) |
| 2020 | \$3,476 (62%) | \$476 (7%) | \$376 (5%) | \$385 (5%) |
| 2021 | \$4,370 (82%) | \$476 (7%) | \$376 (5%) | \$385 (5%) |

Note: Zytiga sales lost due to generic competition.

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