Drugs to Watch-2018
The year of blockbuster drugs

Dr. Mandakini Goel
Solution Consultant
Featured Speaker

Dr. Mandakini Goel
Solution Consultant, South Asia
Clarivate Analytics
Formerly the **IP&S Business of Thomson Reuters**, we’ve been providing pharmaceutical & scientific, intellectual property and scholarly intelligence to our customers for over 60 years.

Now as an independent company with over 4,000 employees, operating in more than 100 countries around the world, we remain expert, objective and agile.
Table of Content

1. Look back at 2017.. .......................................................... 5
2. Methodology ........................................................................... 6
3. Top 12 drugs to watch .............................................................. 8
4. Individual drug: Deep Dive .................................................... 10
5. Few more Drugs to Watch ....................................................... 25
Look Back at 2017....

46

17

8

7
Methodology (1/2)

Data is compiled from Cortellis from Clarivate Analytics

Cortellis is the premier source of life sciences competitive intelligence information and analytics. It covers and includes data gathered from diverse sources, including annual fillings, drug pipelines, clinical trials, patents, chemistry, deals, conferences, and company announcements.

Using the advanced search functions, drugs in phase 2 and phase 3 trials, at prelaunch or registration stage, or already launched in 2018 were selected.

Drugs launched prior to 2018 were excluded.

Drugs that had total forecast sales of > 1 billion were filtered.

Manual review of 28 drugs to determine likelihood of market entry in 2018 based on factors such as company’s expected approval or launch date.

Each of the 12 drugs selected were subsequently searched and evaluated in individual context.
Methodology (2/2)

Each of the 12 drugs were researched and evaluated on multiple parameters such as:
- Clinical trial results
- Regulatory status
- The market for each drug (including analysis of competitor drugs)
- Regulatory designations (orphan drug, priority review, etc.)

Sources for these data included:
- SWOT analysis compiled by Cortellis editors
- Pharmaceutical company press releases and other publications covered in Cortellis
- Peer-reviewed publications
- Competitor sales obtained via the Cortellis database
<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug</th>
<th>Disease</th>
<th>Company (HQ)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Hemlibra (emicizumab)</td>
<td>Hemophilia A with factor VIII inhibitors</td>
<td>Roche/Chugai</td>
</tr>
<tr>
<td>2</td>
<td>Biktarvy (tenofovir alafenamide + emtricitabine+bictegravir)</td>
<td>HIV Infection</td>
<td>Gilead (US)</td>
</tr>
<tr>
<td>3</td>
<td>Ozempic (semaglutide)</td>
<td>Type 2 Diabetes</td>
<td>Novo Nordisk (Denmark)</td>
</tr>
<tr>
<td>4</td>
<td>Erleada (apalutamide)</td>
<td>Non-metastatic CRPC</td>
<td>Johnson &amp; Johnson (US)</td>
</tr>
<tr>
<td>5</td>
<td>Shingrix (zoster vaccine recombinant, adjuvanted)</td>
<td>Shingles</td>
<td>GlaxoSmithKline (UK)</td>
</tr>
<tr>
<td>6</td>
<td>Patisiran</td>
<td>Hereditary TTR Amyloidosis</td>
<td>Alnylam/Genzyme (US)</td>
</tr>
<tr>
<td>7</td>
<td>Epidiolex (plant-derived cannabidiol)</td>
<td>Dravet and L-G Syndrome</td>
<td>GW Pharmaceuticals (UK)</td>
</tr>
<tr>
<td>8</td>
<td>Aimovig (erenumab)</td>
<td>Migraine</td>
<td>Amgen (US)/Novartis (Switzerland)</td>
</tr>
<tr>
<td>9</td>
<td>Lanadelumab</td>
<td>Hereditary angioedema</td>
<td>Shire (Ireland)</td>
</tr>
<tr>
<td>10</td>
<td>Elagolix</td>
<td>Endometriosis</td>
<td>Abbvie (US)</td>
</tr>
<tr>
<td>11</td>
<td>Steglatro (ertugliflozin)</td>
<td>Type 2 Diabetes</td>
<td>Pfizer/Merck (US)</td>
</tr>
<tr>
<td>12</td>
<td>Sublocade (once monthly buprenorphine)</td>
<td>Opioid dependence</td>
<td>Indivior (UK)</td>
</tr>
</tbody>
</table>
### Top 12 drugs to achieve blockbuster sales of over USD 1 billion by 2022

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug</th>
<th>2018*</th>
<th>2019*</th>
<th>2020*</th>
<th>2021*</th>
<th>2022*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Hemlibra (emicizumab)</td>
<td>496</td>
<td>1,457</td>
<td>2,356</td>
<td>3,362</td>
<td>4,002</td>
</tr>
<tr>
<td>2</td>
<td>Biktarvy (tenofoviralafenamide + emtricitabine+bictegravir)</td>
<td>896</td>
<td>2,282</td>
<td>3,387</td>
<td>4,296</td>
<td>3,716</td>
</tr>
<tr>
<td>3</td>
<td>Ozempic (semaglutide)</td>
<td>260</td>
<td>862</td>
<td>1,576</td>
<td>2,583</td>
<td>3,469</td>
</tr>
<tr>
<td>4</td>
<td>Erleada (apalutamide)</td>
<td>25</td>
<td>500</td>
<td>1,200</td>
<td>1,600</td>
<td>2,000</td>
</tr>
<tr>
<td>5</td>
<td>Shingrix (zoster vaccine recombinant, adjuvanted)</td>
<td>242</td>
<td>537</td>
<td>879</td>
<td>1,202</td>
<td>1,368</td>
</tr>
<tr>
<td>6</td>
<td>Patisiran</td>
<td>83</td>
<td>373</td>
<td>726</td>
<td>1,104</td>
<td>1,212</td>
</tr>
<tr>
<td>7</td>
<td>Epidiolex (plant-derived cannabidiol)</td>
<td>19</td>
<td>266</td>
<td>645</td>
<td>936</td>
<td>1,191</td>
</tr>
<tr>
<td>8</td>
<td>Aimovig (erenumab)</td>
<td>115</td>
<td>361</td>
<td>685</td>
<td>941</td>
<td>1,170</td>
</tr>
<tr>
<td>9</td>
<td>Lanadelumab</td>
<td>74</td>
<td>350</td>
<td>629</td>
<td>902</td>
<td>1,153</td>
</tr>
<tr>
<td>10</td>
<td>Elagolix</td>
<td>57</td>
<td>268</td>
<td>549</td>
<td>896</td>
<td>1,152</td>
</tr>
<tr>
<td>11</td>
<td>Steglatro (ertugliflozin)</td>
<td>220</td>
<td>482</td>
<td>769</td>
<td>1,024</td>
<td>1,087</td>
</tr>
<tr>
<td>12</td>
<td>Sublocade (once monthly buprenorphine)</td>
<td>121</td>
<td>308</td>
<td>439</td>
<td>634</td>
<td>1,072</td>
</tr>
</tbody>
</table>

* Forecast sales in $ Million
Individual Drug: Deep Dive
01. Hemlibra for Hemophilia A with factor VIII inhibitors (1/2)

**Overview**

A novel approach to treat Hemophilia A, Roche/Chugai’s once weekly Hemlibra (emicizumab) is a bispecific antibody that simultaneously binds to both factor IX and factor X, bringing them into spatially appropriate position to mimic the function of factor VIII.

**Hemlibra Expected sales**

- $496 M
  - In 2018
- $1.457B
  - In 2019
- $4.002 B
  - In 2022

In the Phase 3 HAVEN 1 study, people aged ≥12 y, who received Hemlibra prophylaxis achieved an 87% reduction in bleed rate compared with those who received no prophylaxis.

In the HAVEN 2 study, 94.7% of pediatric patients with inhibitors receiving prophylactic Hemlibra experienced zero bleed.

**Cortellis**

*Powering Life Sciences Innovation*
01. Hemlibra for Hemophilia A with factor VIII inhibitors (2/2)

The Hemophilia market

- **ELOCTATE (BIOVERATIV)**
  - $1.153B
  - Expected sales in 2018

- **ADVATE (SHIRE)**
  - $1.795B
  - Expected sales in 2018

- **ADYNOVATE (SHIRE)**
  - $600M
  - Sales over next 5 years not expected to exceed this number

First long-acting recombinant factor VIII replacement therapy

Key features of Hemlibra:
- Novel mechanism of action
- Impressive efficacy
- Potential monthly dosing
**02. Biktarvy for HIV infection**

*Overview*

Gilead’s new single-tablet HIV treatment, once-daily dosing contains the new integrase inhibitor bictegravir, plus the nucleoside reverse transcriptase inhibitors tenofovir alafenamide and emtricitabine.

**Biktarvy expected sales**

- $896 M in 2018
- $2.282B in 2019
- $3.716 B in 2022

In previously untreated patients infected with HIV-1 and in virologically suppressed adults who switched to Biktarvy, the drug has demonstrated high rates of virological suppression (~93%). No treatment emergent resistance has been associated through 48 weeks in phase 3 trials.

**Key feature of Biktarvy:**
- True Once-daily dosing
- Combination of best-in-class tenofovir alafenamide and an integrase inhibitor non-inferior to Tivicay
03. Ozempic for Type 2 diabetes

Overview

Novo Nordisk’s Ozempic is a weekly glucagon-like peptide-1 (GLP-1) analog, which help stimulate the body’s own insulin release, limits how much sugar gets into the blood from the liver and slow down how quickly food leaves the stomach.

Ozempic expected sales

- $260 M
  - In 2018
- $3.469B
  - In 2022

MYOCARDIAL INFARCTION RISK REDUCED BY 39%

STROKE RISK REDUCED BY 26%

Cortellis
Powering Life Sciences Innovation
# 03. Ozempic for Type 2 diabetes

*GLP-1 Market*

<table>
<thead>
<tr>
<th></th>
<th>OZEMPIC</th>
<th>TRULICITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.5</td>
<td>1.5</td>
<td>1.1</td>
</tr>
<tr>
<td>4.6</td>
<td>2.3</td>
<td>2.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>HBA1c reductions, percentage points at the lowest dosed tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>2022 Expected sales</td>
<td></td>
</tr>
<tr>
<td>OZEMPIC</td>
<td>$3.469B</td>
</tr>
<tr>
<td>TRULICITY</td>
<td>$4.090B</td>
</tr>
<tr>
<td>VICTOZA</td>
<td>$3.912B</td>
</tr>
</tbody>
</table>

Weight loss kg, SUSTAIN 7
04. Erleada for prostate cancer

J&J’s Erleada is first approved drug for treatment with non-metastatic castration resistant prostate cancer until the spread of cancer could be confirmed by radiographic assessment.

**Erleada expected sales**

- $25 M In 2018
- $2.000B In 2022

**Phase 3 SPARTAN TRIAL**

- **24.3 months**
  - Metastasis-free survival extension, compared with placebo

- **72%**
  - Reduction in risk of distant metastasis or death

**Key features of Erleada:**

- First mover advantage
- Potential applications in other clinical settings, including metastatic hormone-sensitive prostate cancer, in high-risk localized/locally advanced prostate cancer, and in combination with Zytiga for treatment of metastatic CRPC in men who have not yet received chemotherapy.
05. Shingrix for herpes zoster (shingles) infection

GSK’s Shingrix (Zoster vaccine recombinant, adjuvanted) will be the first new shingles vaccine in more than a decade and offers long lasting protection from herpes zoster.

Shingrix expected sales

- $242M In 2018
- $1.368B In 2022

97.2%
Risk reduction in adult aged 50 years or older versus placebo in the phase 3 ZOE-50 trial

89.8%
Risk reduction in adult aged 70 years or older versus placebo in the ZOE-70 trial

Key features of Shingrix:
- Offers long lasting protection
- Also provides protection for those who have already received Zostavax
- Based on superior efficacy, recommended by US Centers for Disease Control and Prevention over Zostavax in adults aged ≥ 50 years
Alnylam/Genzyme’s Patisiran, an intravenously administered RNA interference (i-RNA) therapeutic targeting the transthyretin gene is filed for treatment of patients with debilitating hereditary transthyretin-mediated amyloidosis, with a potential to be a best-in class treatment.

**06. Patisiran for hereditary transthyretin-mediated amyloidosis**

Patisiran expected sales

- **$83M**
  - In 2018
- **$373M**
  - In 2019
- **$1.212B**
  - In 2022

APOLLO Phase 3 trial

34-point difference

In the mNIS+7 scale (a composite measure of neurological impairment) at 18 months

Competitor Drugs, expected sales

- **INOTERSEN**
  - **$533M**
    - In 2022
- **VYNDAQEL**
  - **$170M**
    - In 2022

Key feature of Patisiran:

- Superior efficacy and safety profile
GW Pharmaceuticals’ Epidiolex (plant-derived cannabidiol) is the first cannabinoid-based anti-epileptic medication and has the potential to become market leader based on its efficacy in clinical trial settings.

Epidiolex expected sales

<table>
<thead>
<tr>
<th></th>
<th>EPIDIOLEX</th>
<th>PLACEBO</th>
<th>Decrease in the frequency of seizures at 14 weeks in patients with Dravet syndrome</th>
<th>Decrease in the frequency of seizures at 14 weeks in patients with Lennox-Gastaut syndrome</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>39%</td>
<td>13%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2022</td>
<td>44%</td>
<td>22%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Key features of Epidiolex:
- Superior efficacy
- However, if approved, might face barriers and hurdles associated with cannabis-derived medicines
Amgen/Novartis’ Aimovig (erenumab), a once-monthly subcutaneously administered monoclonal antibody, is a calcitonin gene-related peptide (CGRP) receptor inhibitor, for the prevention of episodic migraine.

Aimovig expected sales

- $115M in 2018
- $1.170B in 2022

STRIVE trial

<table>
<thead>
<tr>
<th></th>
<th>AIMOVIG</th>
<th>PLACEBO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day reduction in monthly migraine days (at 140 mg)</td>
<td>3.7</td>
<td>1.8</td>
</tr>
</tbody>
</table>

Competitor Drugs, expected sales in 2022

- FREMANEZUMAB: $999M
- GALCANEZUMAB: $546M
- EPTINEZUMAB: $368M

Key features of Aimovig:
- First-to-market advantage
- Once-monthly subcutaneous dosing
09. Lanadelumab for hereditary angioedema

Shire’s Lanadelumab (a fully human monoclonal antibody which inhibits plasma kallikrein), is a novel drug that prevents hereditary angioedema.

<table>
<thead>
<tr>
<th>Phase 3 HELP trial</th>
<th>LANADELUMAB</th>
<th>HAEGARDA</th>
<th>CINRYZE</th>
<th>Reduction in the mean frequency of angioedema attacks in patients with hereditary angioedema versus placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>87%</td>
<td>84%</td>
<td>54%</td>
<td></td>
</tr>
</tbody>
</table>

Key features of Lanadelumab:
- Once every two-weeks dosing with a potential for once-monthly dosing
- Smaller injection volume, allowing for more rapid injection

Lanadelumab expected sales
- $74M in 2018
- $1.153B in 2022
10. Elagolix for endometriosis

Abbvie’s Elagolix is a first-in-class oral gonadotropin-releasing hormone (GnRH) antagonist, which acts to reduce levels of estrogen as well as other sex hormones such as progesterone, for the management of endometriosis associated pain.

<table>
<thead>
<tr>
<th>Elagolix expected sales</th>
</tr>
</thead>
</table>
| **$57M**  
In 2018 |
| **$1.152B**  
In 2022 |

<table>
<thead>
<tr>
<th>Reduction in the proportion of women complaining of menstrual pain at six months</th>
</tr>
</thead>
<tbody>
<tr>
<td>ELAGOLIX</td>
</tr>
<tr>
<td>76.9%</td>
</tr>
<tr>
<td>62.2%</td>
</tr>
</tbody>
</table>

| Reduction in the proportion of women complaining of non-menstrual pain at six months |

Key features of Elagolix:
- Superior efficacy
- Reduced proliferation of endometrial tissue
- Fewer menopause-like side effects
- Acceptable effect on bone density relative to Lupron
11. Steglatro for type 2 diabetes

Pfizer/Merck’s Steglatro (ertugliflozin) is a SGLT-2 inhibitor, which effectively reduce HBA1C levels in diabetes patients and has also showcased cardiovascular benefits.

<table>
<thead>
<tr>
<th>Steglatro expected sales</th>
<th>VERTIS SITA trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>$220M In 2018</td>
<td>STEGLATRO+ JANUVIA</td>
</tr>
<tr>
<td>$1.087B In 2022</td>
<td>PLACEBO</td>
</tr>
<tr>
<td></td>
<td>1.7</td>
</tr>
<tr>
<td></td>
<td>0.4</td>
</tr>
</tbody>
</table>

HBA1C reductions in first-line setting

Competitor Drugs, expected sales in 2022
- FARXIGA $2.025B
- JARDIANCE $1.713B
- SOTAGLIFLOZIN $1.193B
- INVOKANA $652M

Key features of Steglatro:
- SGLT-2 inhibitor efficacious in combination therapy as well as monotherapy
- Positive cardiovascular data
12. Sublocade for Opioid dependence

Sublocade (once-monthly subcutaneous buprenorphine) is the first once-monthly formulation for medication-assisted treatment options to overcome opioid use.

Sublocade expected sales

- $121M in 2018
- $1.072B in 2022

Phase 3 trial

<table>
<thead>
<tr>
<th></th>
<th>SUBLOCADE</th>
<th>PLACEBO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstinence rate</td>
<td>42.7%</td>
<td>5.0%</td>
</tr>
</tbody>
</table>

Significantly higher abstinence rates in patients with opioid use disorder

Key features of Sublocade:
- Once-monthly dosing
- Subcutaneous administration
- Treatment doesn’t require detox period
Few more Drugs to Watch

- Juno Therapeutics’ CAR T-cell therapy, lisocabtagene maraleucel, is expected to be filed for diffuse large B-cell lymphoma in the second half of 2018 and has 2022 sales forecast of $2.221 billion.

- Alexion’s next-generation Soliris treatment, ravulizumab, for paroxysmal nocturnal hemoglobinuria, is expected to file for approval in the third quarter of 2018. This drug is forecast to generate $2.199 billion of sales by 2022.