OPTUMRx®

RxOutlook®

1st Quarter 2018

Pending drug approvals

Drug Name	Manufacturer	Indication/Use	Expected FDA Decision Date
avatrombopag	Dova/Eisai	Thrombocytopenia	5/21/2018
binimetinib/encorafenib	Array/Ono	Melanoma	6/30/2018
burosumab	Ultragenyx/Kyowa Hakko Kirin	X-linked hypophosphatemia	4/17/2018
cannabidiol (Epidiolex)	GW Pharmaceuticals	Lennox-Gastaut syndrome, Dravet syndrome	6/27/2018
elagolix	AbbVie/Neurocrine Biosciences	Endometriosis	2Q 2018
erenumab (Aimovig)	Amgen/Novartis	Migraine prophylaxis	5/17/2018
fremanezumab	Teva/Otsuka/Pfizer	Migraine prophylaxis	Mid-2018
fostamatinib (Tavalisse)	Rigel	Thrombocytopenia	4/17/2018
mogamulizumab (Poteligeo)	Kyowa Hakko Kirin	Cutaneous T-cell lymphoma	6/4/2018

avatrombopag

Manufacturers: Dova/Eisai

Therapeutic use

Avatrombopag is in development for the treatment of thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure.

Thrombocytopenia is a state of low platelet count and is a common occurrence among patients with chronic liver disease. These patients may be at an elevated risk for bleeding during medical procedures.

- Treatment of thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure

Clinical profile

Avatrombopag is a second-generation thrombopoietin (TPO) receptor agonist similar to Promacta® (eltrombopag).

Promacta is indicated for the treatment of thrombocytopenia in adult and pediatric patients ≥ 1 year old with chronic immune (idiopathic) thrombocytopenia who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. In addition, Promacta is also indicated for the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy; and for the treatment of severe aplastic anemia in patients who have had an insufficient response to immunosuppressive therapy.

In two pivotal trials, patients with thrombocytopenia who were scheduled to undergo a procedure were given either avatrombopag or placebo. In both trials, a greater number of patients in the avatrombopag group did not require platelet transfusions or any rescue procedure for bleeding vs. placebo. Among those with low baseline platelet count, 66% – 69% of patients in the avatrombopag group met the endpoint vs. 23% – 35% for placebo ($p < 0.0001$ and $p < 0.0006$, respectively). Similarly, among those with high baseline platelet count (defined as 40 x109 – 50 x 109 per liter), 88% vs. 33% – 38% ($p < 0.0001$) achieved the endpoint with avatrombopag vs. placebo, respectively.

Common adverse events reported in the trials included fever, abdominal pain, nausea, headache, diarrhea, and fatigue. In addition, one treatment-emergent, non-serious thrombotic event occurred with avatrombopag. In one of the trials, two deaths occurred in the avatrombopag arm; however, these were not deemed to be treatment-related.

Based on the trials, the anticipated dosage of avatrombopag is 40 mg to 60 mg orally once daily for one to five days prior to the scheduled procedure.

- TPO receptor agonist
- Oral formulation
- Greater number of patients did not require platelet transfusions or any rescue procedure for bleeding vs. placebo
- Common adverse events: fever, abdominal pain, nausea, headache, diarrhea, or fatigue
- Dose: 40 mg – 60 mg once daily for 1 to 5 days prior to procedure

Continued…

avatrombopag (continued...)

Competitive environment

If approved, avatrombopag will be the first treatment for thrombocytopenia in the procedural setting. Avatrombopag has also demonstrated high efficacy in clinical trials and is an oral agent, requiring short, once daily therapy.

However, Promacta, a related TPO receptor agonist, is also currently available. While Promacta does not share the same indication as avatrombopag, an off-label potential does exist with Promacta.

For reference, the average monthly wholesale acquisition cost (WAC) for Promacta is approximately $8,000.

- Advantages: first drug for thrombocytopenia in procedural setting, high efficacy, oral, once daily dosing
- Disadvantage: related product is available (ie, Promacta)
- Average WAC for Promacta = $8,000 per month

Expected FDA decision date

An FDA decision regarding the approval of avatrombopag is expected by May 21, 2018.

- PDUFA: 5/21/2018

binimetinib/encorafenib

Manufacturers: Array/Ono

Therapeutic use

Binimetinib (BINI) and encorafenib (ENCO) are two medications in development for combination treatment in patients with BRAF-mutant advanced, unresectable, or metastatic melanoma.

As many as 50% of melanoma patients may have BRAF mutations.

- In combination for the treatment of BRAF-mutant advanced, unresectable, or metastatic melanoma

Clinical profile

BINI is a mitogen-activated kinase (MEK) inhibitor similar to agents such as Mekinist® (trametinib) and Cotellic® (cobimetinib).

ENCO is a RAF inhibitor similar to agents such as Zelboraf® (vemurafenib) and Tafinlar® (dabrafenib).

In a pivotal trial, the combination of BINI plus ENCO was compared against two separate comparator groups – Zelboraf alone and ENCO alone. The purpose of the ENCO arm was to determine the effect of adding BINI to the ENCO regimen in the combination arm. Relative to the comparators, the combination group achieved a greater progression-free survival (PFS) of 14.9 months vs. 7.3 months for Zelboraf alone and 9.6 months for ENCO alone. In addition, the median overall survival was 33.6 months for patients treated with the combination vs. 16.9 months for patients treated with Zelboraf as monotherapy.

The notable safety concerns identified in the trial included reports of increased gamma glutamyltransferase levels, increased creatinine phosphokinase, and hypertension. Other concerns of interest included rash (23% of subjects), pyrexia (18% of subjects), retinal pigment epithelial detachment (13% of subjects), and photosensitivity (5% of subjects).

In the trials, ENCO was given orally once daily and BINI was given orally twice daily.

- BINI = MEK inhibitor
- ENCO = RAF inhibitor
- Oral formulation
- Greater PFS and ORR vs. Zelboraf alone or ENCO alone
- Common adverse events: rash, pyrexia, retinal pigment epithelial detachment, and photosensitivity
- Dose: ENCO once daily and BINI twice daily

Competitive environment

Currently, there are limited treatment options for patients with advanced melanoma. Moreover, because the BINI and ENCO combination employs two separate mechanisms of action (MOA) to achieve a clinical effect, this oral regimen may offer a benefit over single drug treatments.

However, the regimen will require frequent dosing (twice daily), and other similar alternatives are available (eg, Mekinist, Cotellic, Zelboraf, and Tafinlar), which can be used in combination for BRAF melanomas.

The monthly WAC for related combination regimens range from $17,855 to $20,713.

- Advantages: limited options for advanced melanoma, targets different MOAs, oral
- Disadvantages: frequent dosing, alternatives are available
- Monthly WAC for related combination regimens = $17,855 - $20,713

Expected FDA decision date

An FDA decision regarding the approval of the BINI and ENCO combination regimen is expected by June 30, 2018.

- PDUFA: 6/30/2018

burosumab

Manufacturers: Ultragenyx/Kyowa Hakko Kirin

Therapeutic use

Burosumab is in development for the treatment of pediatric and adult patients with X-linked hypophosphatemia (XLH).

XLH is a rare genetic condition. Also referred to as vitamin D-resistant rickets, XLH is associated with bone deformity, short stature, bow leggedness, and hypophosphatemia.

- Treatment of pediatric and adult patients with XLH

Clinical profile

Burosumab is a fibroblast growth factor 23 (FGF23) antagonist.

FGF23 is involved in phosphate metabolism and is secreted by osteocytes when calcitriol levels become elevated. In the kidneys, FGF23 lowers expression of a key sodium-phosphate co-transporter, thereby decreasing re-absorption of phosphate and increasing its excretion. Thus, blockade of the FGF23 pathway is thought to improve phosphate levels in patients with XLH.

Burosumab was evaluated in one main trial against placebo. The primary endpoint was the proportion of subjects who achieved a mean serum phosphate level above the lower limit of normal. At the end of 24 weeks, a significantly larger percentage of patients in the burosumab group achieved the endpoint vs. placebo (94% vs. 8%, $p < 0.0001$).

Common adverse events reported in the trial included back pain, nasopharyngitis, tooth abscess, injection site reactions, headache, restless leg syndrome, dizziness, nausea, arthralgia, pain in the extremity, vitamin D deficiency, musculoskeletal pain, and oropharyngeal pain.

In trials, burosumab was dosed based on weight and given subcutaneously (SC) every 4 weeks.

- FGF23 antagonist
- SC formulation
- More patients achieved normal phosphate levels vs. placebo (94% vs. 8%)
- Common adverse events: back pain, nasopharyngitis, tooth abscess, injection site reactions, headache, restless leg syndrome, dizziness, nausea, arthralgia, pain in the extremity, vitamin D deficiency, musculoskeletal pain, and oropharyngeal pain
- Dose: weight-based every 4 weeks

Competitive environment

Burosumab offers the patient a novel MOA to manage a difficult condition. Moreover, it only requires once monthly dosing, and demonstrated high efficacy in raising phosphate levels vs. placebo.

Despite these advantages, burosumab requires SC injections, and because therapy is not curative, patients may require ongoing therapy. However, there are no long-term safety data available.

The estimated U.S. prevalence for XLH is 1 in 20,000 newborns.

- Advantages: novel MOA, infrequent dosing, high efficacy
- Disadvantages: SC injections, no long-term safety data
- XLH prevalence in the U.S. is 1 in 20,000 newborns

Expected FDA decision date

The FDA granted burosumab an orphan drug designation, breakthrough status, and fast track status.

An FDA decision regarding the approval of burosumab is expected by April 17, 2018.

- Orphan drug
- Breakthrough status
- Fast track status
- PDUFA: 4/17/2018

cannabidiol (Epidiolex)

Manufacturer: GW Pharmaceuticals

Therapeutic use

Cannabidiol is in development for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) and Dravet syndrome.

LGS is a rare condition that typically occurs between 3 to 5 years of age. LGS may be caused by various conditions; however, up to 30% of cases have no known cause. While treatments for LGS are available, the options are limited.

Dravet syndrome is a rare, severe infantile-onset disease that often manifests in the first year of life. Patients suffer from prolonged or frequent seizures. Dravet syndrome is associated with mutations in the SCN1A sodium channels. While existing antiepileptic medications are used to manage this condition, there are no FDA-approved drugs for Dravet syndrome.

- Adjunctive treatment of seizures associated with LGS and Dravet syndrome

Clinical profile

Cannabidiol is a non-psychoactive, cannabinoid receptor antagonist.

In the LGS and Dravet syndrome trials, patients inadequately managed on existing antiepileptic therapy were given either cannabidiol or placebo, along with stable doses of their current antiepileptic regimens. In the LGS trials, a greater proportion of patients taking cannabidiol achieved a reduction in the number of monthly drop seizures vs. placebo (37% – 44% vs. 17% – 22%).

In the Dravet syndrome trial, a greater proportion of patients experienced a decrease in the frequency of convulsive seizures vs. placebo ($p = 0.01$). However, there was no difference in the frequency of non-convulsive seizures, the percentage of patients who became seizure-free, or the percentage of patients who experienced ≥ 50% reduction in convulsive seizure frequency.

Common adverse events reported in the trials included diarrhea, somnolence, decreased appetite, pyrexia, vomiting, and upper respiratory tract infection.

In the trials, cannabidiol was given twice daily based on weight. Cannabidiol is expected to be formulated as an oral solution.

- Cannabinoid receptor antagonist
- Oral formulation
- LGS trials: greater improvement in drop seizures vs. placebo
- Dravet syndrome trial: greater improvement in convulsive seizure frequency vs. placebo
- Common adverse events: diarrhea, somnolence, decreased appetite, pyrexia, vomiting, and upper respiratory tract infection
- Dose: weight-based twice daily

Continued…

cannabidiol (Epidiolex) (continued...)

Competitive environment

While treatments exist for LGS, the options are limited, and currently, there are no FDA-approved treatments available for Dravet syndrome. Thus, cannabidiol offers a novel alternative for treatment-resistant patients with these rare diseases. In addition, there are no known psychoactive effects associated with cannabidiol.

However, cannabidiol is not intended to be used as monotherapy. Therefore, the addition of cannabidiol will increase the overall pill burden for patients with LGS or Dravet syndrome. Cannabidiol also requires multiple dosing per day and may carry a controlled substance designation in its final label, which may impact the ease of patient access to this medication.

- Advantages: limited novel treatment options for LGS and Dravet syndrome, effective in treatment-resistant cases, no known psychoactive effects
- Disadvantages: only for adjunctive use, frequent dosing, and possible controlled substance

Expected FDA decision date

The FDA granted cannabidiol an orphan drug designation.

An FDA decision regarding the approval of cannabidiol is expected by June 27, 2018.

- Orphan drug
- PDUFA: 6/27/2018

elagolix

Manufacturers: AbbVie/Neurocrine Biosciences

Therapeutic use

Elagolix is in development for the management of endometriosis with associated pain.

Endometriosis affects approximately 6% – 10% of women of reproductive age with peak prevalence between 25 – 35 years of age.

- Management of endometriosis with associated pain

Clinical profile

Elagolix is an orally active, second-generation gonadotropin releasing hormone (GnRH) antagonist.

Elagolix was evaluated in two similarly designed, placebo-controlled trials. At both 3 and 6 months, a greater percentage of patients achieved an improvement in dysmenorrhea and non-menstrual pelvic pain vs. placebo. Moreover, improvements were dose-dependent with greater improvement observed for the high dose regimen (200 mg twice daily) than the low dose regimen (150 mg once daily).

Common adverse events reported in the trials included hot flush, headache, and nausea.

Partial estradiol suppression occurs with the low dose (150 mg once daily) and complete suppression with the high dose (200 mg twice daily).

- GnRH antagonist
- Oral formulation
- Greater improvement in dysmenorrhea and non-menstrual pelvic pain vs. placebo
- Dose: 150 mg once daily up to 200 mg twice daily

Competitive environment

If approved, elagolix will be the first in-class, orally active GnRH antagonist on the market.

In addition, there may be less bone loss with elagolix than presently available GnRH products. Thus, AbbVie is pursuing elagolix for long-term therapeutic use. Furthermore, there is no known suppression of ovulation with elagolix, possibly making it a preferred option for women of reproductive age.

Despite these benefits, there are limited long-term data available at this time, and currently, there are several related options available (eg, Zoladex® [goserelin], Synarel® [nafarelin], and Lupron Depot® [leuprolide acetate]). Zoladex and Lupron Depot are available as injections. Synarel is available as a nasal spray.

The projected U.S. sales of elagolix are $564 million by 2020.

- Advantages: first in-class, orally active GnRH antagonist, may avoid significant bone loss, no ovulation suppression
- Disadvantages: limited long-term safety data, alternatives are available
- Projected peak U.S. sales are $564 million by 2020

Expected FDA decision date

An FDA decision regarding the approval of elagolix is expected by early second quarter of 2018.

- PDUFA: 2Q 2018

erenumab (Aimovig)

Manufacturers: Amgen/Novartis

Therapeutic use

Erenumab is in development for the prevention of migraine headaches in patients experiencing ≥ 4 migraines per month.

- Prevention of migraine in patients experiencing ≥ 4 migraines per month

Clinical profile

Erenumab is a monoclonal antibody and represents a new class of emerging medications known as calcitonin gene-related peptide (CGRP) antagonists. Erenumab works by targeting the CGRP receptor, thereby disrupting a key pathway in the pathophysiology of migraine headaches.

Erenumab was evaluated in studies for both episodic migraines and chronic migraines. In the episodic migraine trials, greater reductions in mean monthly migraine days were achieved with erenumab vs. placebo (-2.9 to -3.7 days vs. -1.8 days, $p < 0.001$). Comparable results were achieved with erenumab in its chronic migraine trial (-6.63 days vs. -4.18 days, $p < 0.001$).

Common adverse events reported in the trials included infections, injection site pain, and nasopharyngitis. Overall, erenumab was well tolerated.

In the trials, erenumab was administered by SC injection once monthly.

- CGRP antagonist
- SC formulation
- Greater reduction in mean monthly migraine days vs. placebo in episodic and chronic migraine patients
- Common adverse events: infections, injection site pain, and nasopharyngitis
- Dose: once monthly

Competitive environment

Erenumab represents a new class of medication for the prevention of migraine headaches, and may offer a beneficial option for treatment-resistant patients. Furthermore, erenumab only requires once monthly dosing.

However, erenumab requires injection, which is not the preferred route of administration by patients. Moreover, long-term safety data remain unknown. Like other monoclonal antibodies, erenumab carries a potential high drug cost and is expected to be a specialty medication.

Analysts expect the annual WAC for erenumab to fall between $8,500 – $20,000.

- Advantage: first in-class, useful offering for treatment-resistant patients, infrequent dosing
- Disadvantages: SC injection, long-term safety unknown, potential high cost
- Projected annual WAC = $8,500 – $20,000

Expected FDA decision date

An FDA decision regarding the approval of erenumab is expected by May 17, 2018.

- PDUFA: 5/17/2018

fremanezumab

Manufacturers: Teva/Otsuka/Pfizer

Therapeutic use

Fremanezumab is in development for the prevention of migraines in adult patients.

- Prevention of migraines in adult patients

Clinical profile

Similar to erenumab, fremanezumab is a monoclonal antibody and represents a new class of medication known as calcitonin gene-related peptide (CGRP) antagonists. However, unlike erenumab, which targets the CGRP receptor, fremanezumab is a CGRP ligand antagonist.

Because of subtle differences in their mechanisms, headache specialists could consider concomitant use of fremanezumab and erenumab in select patients with severe, treatment-resistant migraines.

In trials, fremanezumab was evaluated in both episodic migraines and chronic migraine patients. In the episodic migraine trials, greater reductions in mean monthly migraine days were achieved with erenumab vs. placebo (-3.7 days vs. -2.2 days, $p < 0.0001$). In a chronic migraine trial, similar reductions were achieved vs. placebo (-4.6 days vs. -2.5 days, $p < 0.001$).

Notable adverse events reported in the trials included injection site reactions and increased liver function tests.

Fremanezumab is being evaluated for SC injection for once monthly and once quarterly administration.

- CGRP antagonist
- SC formulation
- Greater reduction in mean monthly migraine days vs. placebo in episodic and chronic migraine patients
- Common adverse events: injection site pain and increased liver function test
- Dose: once monthly and/or once quarterly

Competitive environment

Like erenumab, fremanezumab represents a new class of medication for the prevention of migraine headaches, and may offer a beneficial option for treatment-resistant patients. Furthermore, fremanezumab is being studied for once quarterly administration, which if approved, would offer an advantage over erenumab's once monthly regimen.

Nonetheless, fremanezumab will still require SC administration, and long-term safety data remain unknown. Like other monoclonal antibodies, fremanezumab carries a potential high drug cost and is expected to be a specialty medication.

Analysts expect the annual WAC for erenumab to fall between $8,500 – $20,000.

- Advantage: first in-class, useful option for treatment-resistant patients, infrequent dosing
- Disadvantages: SC injection, long-term safety unknown, potential high cost
- Projected annual WAC = $8,500 – $20,000

Expected FDA decision date

An FDA decision regarding the approval of fremanezumab is expected by the middle of 2018.

- PDUFA: Mid-2018

fostamatinib (Tavalisse)

Manufacturer: Rigel

Therapeutic use

Fostamatinib is in development for the treatment of patients with chronic or persistent immune thrombocytopenia (ITP).

ITP is a potentially serious and life-threatening condition in which the body's own immune system attacks the platelet cells, interfering with one's normal blood clotting mechanism. As a result, patients are at increased risk of bruising and bleeding.

- Treatment of chronic or persistent ITP

Clinical profile

Fostamatinib is a spleen tyrosine kinase (syk) inhibitor. Syk inhibitors block the activation of mast cells and B-cells, thereby reducing the body's inflammatory response. Syk inhibitors may also block tumor necrosis factor and suppress the immune system through various interleukin pathways.

Fostamatinib was compared against placebo in two trials, which evaluated fostamatinib's ability to stabilize the platelet response, defined as a platelet count ≥ 50,000 per microliter on at least 4 out of 6 visits between weeks 14 through 24. In one of the trials, more patients achieved a stable response with fostamatinib vs. placebo (18% vs. 0%). In contrast, the second trial failed to demonstrate a significant difference ($p = 0.152$). However, the combined analysis from both trials did meet the threshold for statistical significance ($p = 0.007$).

Common adverse events reported in trials included nausea, diarrhea, infection, hypertension, and elevated liver function test.

In the trials, fostamatinib was administered orally twice daily.

- Syk inhibitor
- Oral formulation
- Mixed trial results
- Common adverse events: nausea, diarrhea, infection, hypertension, and elevated liver function test
- Dose: twice daily

Competitive environment

Fostamatinib is an oral drug and represents a novel MOA. In addition, fostamatinib offers patients another therapeutic option for treating their condition.

Unfortunately, the trial results were mixed with one of the trials failing to achieve statistical significance. Furthermore, alternative treatments are available for ITP, including Promacta and Nplate®.

It's estimated that between 60,000 to 125,000 Americans have ITP.

- Advantages: oral, novel mechanism
- Disadvantages: mixed trial results, alternatives available
- ITP prevalence in the U.S. is 60,000 to 125,000

Expected FDA decision date

The FDA granted fostamatinib an orphan drug designation.

An FDA decision regarding the approval of fostamatinib is expected by April 17, 2018.

- Orphan drug
- PDUFA: 4/17/2018

mogamulizumab (Poteligeo)

Manufacturer: Kyowa Hakko Kirin

Therapeutic use

Mogamulizumab is in development for the treatment of cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy.

- Treatment of CTCL in patients who have received ≥ 1 prior systemic therapy

Clinical profile

Mogamulizumab is a CC chemokine receptor 4 (CCR4) antagonist. CCR4 is selectively expressed in T-helper 2 cells.

In a pivotal trial evaluating mogamulizumab against Zolinza® (vorinostat), mogamulizumab met the primary endpoint of PFS ($p < 0.05$). However, the efficacy and safety details from the trial have not been disclosed at this time.

Mogamulizumab was studied for weight-based dosing and administered intravenously (IV) once weekly for 4 doses in cycle 1, followed by doses every other week until disease progression.

- CCR4 antagonist
- IV formulation
- Met endpoint vs. Zolinza
- Dose: weight-based every other week, after cycle 1

Competitive environment

If approved, mogamulizumab will be the first CCR4 antagonist for CTCL and will offer another treatment option for patients.

However, mogamulizumab requires IV administration and frequent dosing. Moreover, due to the unavailable trial results, mogamulizumab's efficacy and safety profile cannot be reviewed.

The estimated incidence of CTCL in the U.S. is 6.4 cases per 1 million.

- Advantages: first CCR4 antagonist for CTCL, another treatment option
- Disadvantages: IV administration, frequent dosing, lack of trial results
- CTCL incidence is 6.4 cases per 1 million in the U.S.

Expected FDA decision date

The FDA granted mogamulizumab orphan drug designation and breakthrough status.

An FDA decision regarding the approval of mogamulizumab is expected by June 4, 2018.

- Orphan drug
- Breakthrough status
- PDUFA: 6/4/2018

OptumRx brand pipeline forecast

OptumRx closely monitors and evaluates the pipeline landscape for upcoming brand drug approvals, including both traditional and specialty medications. This report provides a summary of developmental drugs that may be approved in the upcoming two years.

Read more

OptumRx generic pipeline forecast

OptumRx closely monitors and evaluates the pipeline landscape for upcoming first-time generics and biosimilars. This report provides a summary of upcoming first-time generic drugs and biosimilars that may be approved in the upcoming two years.

Read more

Getting acquainted with pipeline forecast terms

Clinical trial phases

Phase I trials	Researchers test an experimental drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
Phase II trials	The experimental study drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
Phase III trials	The experimental study drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.
Phase IV trials	Post marketing studies delineate additional information including the drug's risks, benefits, and optimal use.

Pipeline acronyms

ANDA	Abbreviated New Drug Application
BLA	Biologic License Application
CRL	Complete Response Letter
FDA	Food and Drug Administration
NME	New Molecular Entity
NDA	New Drug Application
sBLA	Supplemental Biologic License Application
sNDA	Supplemental New Drug Application
OTC Drugs	Over-the-Counter Drugs
PDUFA	Prescription Drug User Fee Act
REMS	Risk Evaluation and Mitigation Strategy

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