OPTUMRx®

OptumRx Drug Pipeline Insights Report

Q1 2021

Looking Ahead: 2021 Pipeline

By Sumit Dutta, Chief Medical Officer at OptumRx

OptumRx is pleased to once again provide a summary of notable new drug approvals expected for the early part of 2021.

While COVID-19 and associated vaccines continue to dominate the news, the broader drug development pipeline continues to be robust. We anticipate that in 2021 the number of novel FDA approvals could approach a new record high. This would be similar to 2020, which saw 53 new approvals, the second highest ever.

In this report we will discuss five new drugs expected to come to market this spring and significantly impact a range of conditions. These include treatments for Alzheimer's disease to an ultra-rare condition, paroxysmal nocturnal hemoglobinuria. We will also feature treatments for a common chronic condition that affects 10% of children and adults in the U.S. — atopic dermatitis, also commonly known as eczema.

Our **Industry Trend to Watch** will also focus on atopic dermatitis as this category is experiencing a significant increase in new therapies. We expect development activity to yield new treatments throughout the year and even the decade.

Here are five drugs with FDA approval dates that fall within the second quarter. Please refer here for additional technical background and supplemental sources.

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Drug overview

Aducanumab (Brand name: To be determined). Expected FDA decision date: June 7, 2021.

Aducanumab is a human monoclonal antibody that is in development for the treatment for Alzheimer's disease. Aducanumab acts by reducing amyloid plaques in the brain.[1]

Alzheimer's disease is an irreversible, progressive brain disorder that slowly destroys memory and cognition. An estimated 5.7 million Americans were living with the disease in 2018. It is the most common cause of dementia and the fifth leading cause of death for adults aged 65 years and older and is the sixth leading cause of death for all adults.[2]

Several prescription drugs are currently approved to treat the symptoms of Alzheimer's such as memory loss. If approved, aducanumab would be the first disease modifying therapy for Alzheimer's disease. About 1.4 million people would be eligible for therapy based on mild disease status and confirmed presence of amyloid beta.[3]

Aducanumab was evaluated in two trials in patients with mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease.[4] Then we saw a series of related events:

- In March 2019, Biogen announced that the trials were stopped by an independent data monitoring committee. They found that the trials were unlikely to meet their primary endpoint upon completion.[5]
- In October 2019, Biogen announced that they would still pursue an FDA filing based on a new analysis that included additional data.[6]
- In November 2020, an FDA Advisory Committee met to discuss the safety and efficacy of aducanumab. The Committee voted not to endorse the treatment.[7]
- In January 2021 the FDA extended the review period for aducanumab by three months. A decision is now expected on June 7, 2021.[8]

The FDA is not bound by the Advisory Committee's vote. It is still possible that they may accept the aducanumab application despite questions:

- Aducanumab only demonstrated a statistically significant improvement in one of the two pivotal trials.[9]
- The improvements demonstrated in the positive trial were small and questions remain about the clinical significance.[10]
- These and other trial results with other similar investigational drugs have raised questions about whether amyloid is the correct target for Alzheimer's disease treatments.[11]

In addition to the questions on drug efficacy, aducanumab was also associated with side effects, including brain swelling. The possibility of side effects will require additional provider monitoring and potentially genetic testing to identify patients at higher risk.[12]

While price has not been announced by the manufacturer, one dementia care resource center (Dementia Care Central) projects the annual cost for aducanumab to be around $50,000 for the recommended dosage (once per month).[13] On that basis, U.S. sales for aducanumab could reach over $7 billion by 2025, which could make aducanumab the fourth best-selling drug in the country on a revenue basis.[14]

For a more extensive look at aducanumab and the long struggle to find effective Alzheimer's treatments, see here.

Drug overview

Pegcetacoplan (Brand Name: To be determined). Expected FDA decision: May 14, 2021.

Pegcetacoplan is in development for the treatment of adults with paroxysmal nocturnal hemoglobinuria. Paroxysmal nocturnal hemoglobinuria causes the immune system to attack and break down healthy red bloods cells ("hemolysis) leading to anemia. Patients can experience symptoms such as fatigue, jaundice, hemoglobin in the urine and difficulty breathing. Thrombosis (blood clots), occurs in 15% to 30% of patients with paroxysmal nocturnal hemoglobinuria and it is the leading cause of death.[15]

Between 400 and 500 cases of paroxysmal nocturnal hemoglobinuria are diagnosed in the U.S. each year, principally among people in their 30s and 40s.[16]

Pegcetacoplan is designed to regulate excessive activation of the complement cascade.[17]

The efficacy of pegcetacoplan was evaluated against Soliris® (eculizumab), a comparable type of inhibitor currently used for PNH, in a Phase 3 trial (PEGASUS). Pegcetacoplan was superior to Soliris and met the study's primary endpoint for efficacy, which tracked changes in hemoglobin level from baseline. Pegcetacoplan showed a difference of 3.8 grams/deciliter (g/dL) vs. Soliris. In addition, 85% of pegcetacoplan-treated patients were transfusion-free over 16 weeks vs. 15% of Soliris-treated patients.[18]

For detailed trial results please see here (p.9).

Competitive environment

The only curative treatment for paroxysmal nocturnal hemoglobinuria is bone marrow transplantation, but this is generally reserved for patients with severe complications associated with paroxysmal nocturnal hemoglobinuria.[19]

Since 2007, Alexion's Soliris has been the standard of care for the treatment of paroxysmal nocturnal hemoglobinuria. In 2018, the same manufacturer's next-generation inhibitor, Ultomiris® (ravulizumab), was also approved for paroxysmal nocturnal hemoglobinuria based on non-inferiority data to Soliris. While these drugs are effective in most patients, some will still require blood transfusions and both Soliris and Ultomiris require IV administration.[20]

If approved, pegcetacoplan would be the first paroxysmal nocturnal hemoglobinuria therapy to target a different portion of the complement cascade. There are several differences among these drugs some of which could lead to pegcetacoplan becoming a new market leader for the treatment of PNH:[21]

- Pegcetacoplan is administered via SC injection; both Soliris and Ultomiris require IV administration.
- Pegcetacoplan is dosed twice a week. (Compare to Ultomiris, given every 8 weeks and Soliris given every 2 weeks.)
- In the head-to-head trial vs. Soliris, pegcetacoplan showed greater improvements in hemoglobin and significant reductions in transfusion dependence.
- However, pegcetacoplan was associated with higher rates of adverse events such as diarrhea and injection site reactions. There were also 3 discontinuations due to adverse events with pegcetacoplan vs. none with Soliris.
- Pegcetacoplan would be a late market entry and its use would be initially limited to PNH, which is an ultra-rare condition.
- Alexion's inhibitors have been available for nearly 15 years. They are approved for additional indications, including atypical hemolytic uremic syndrome, generalized myasthenia gravis, and neuromyelitis optica spectrum disorder.

For reference, the WAC for Ultomiris is approximately $458,000 per year and the WAC for Soliris is approximately $500,000.[22]

Drug overview

Abrocitinib (Brand Name: To be determined). Expected FDA decision: Q3 2021.

Abrocitinib is in development to treat moderate-to-severe atopic dermatitis in patients aged 12 years and older. The most common symptoms of atopic dermatitis are skin dryness and extreme itchiness. These symptoms can lead to repeated scratching which can cause thickening and hardening of the skin and can also make the skin vulnerable to infection. Atopic dermatitis is characterized by unpredictable flare-ups that disrupt the daily life of patients and their families, which makes managing the disease complex and frustrating.[23]

Abrocitinib is one of a class of drugs called Janus kinase (JAK) inhibitors. JAK inhibitors inhibit the autoimmune process and help ease inflammation and other related symptoms. In particular, abrocitinib selectively inhibits JAK1, which is thought to be specifically involved in causing symptoms of AD.[24]

Results from a randomized Phase 3 clinical trial were published in November 2020. Patients received either 100 mg or 200 mg of abrocitinib, or a placebo. Both doses met the study co-primary endpoints. A significantly higher proportion of patients treated with abrocitinib achieved an Investigators Global Assessment (IGA) score of "clear" or "almost clear." Additionally, a significantly higher proportion had at least a 75% change from baseline in an eczema severity score.[25]

For detailed trial results please see here (p.1).

Competitive environment
Current atopic dermatitis treatment options include corticosteroids, calcineurin inhibitors, Eucrisa® (crisaborole) and Dupixent® (dupilumab). Dupixent, the current market leader, is a biologic drug (a monoclonal antibody).[26]

Since each of the new atopic dermatitis drugs featured in this report may be competing with Dupixent, we will briefly describe how it works.

Dupixent, similar to JAK inhibitors, works to regulate allergic inflammation and keep the immune system from overreacting. Dupixent blocks the signaling molecule called interleukin-4 (IL-4). In this respect, Dupixent is similar to tralokinumab (reviewed below).[27]

Dupixent is administered via subcutaneous injection, whereas abrocitinib provides an oral and once daily treatment option for moderate-to-severe atopic dermatitis.

The efficacy of abrocitinib appears similar to Dupixent, however the use of oral JAK inhibitors for atopic dermatitis may be limited by their safety profile. Currently approved JAK inhibitors have boxed warnings for serious infections, malignancy, and thrombosis. These warnings are likely to apply to abrocitinib as well.[28]

In addition to abrocitinib, Eli Lilly's oral JAK inhibitor Olumiant® (baricitinib), and AbbVie's Rinvoq® (upadacitinib), are also being reviewed by the FDA for atopic dermatitis. A decision for Olumiant is expected in the second quarter of 2021 and for Rinvoq a decision is expected in August 2021.[29]

Analysts from SVB Leerink expect that the boxed warnings will limit abrocitinib to second-line status behind Dupixent until physicians gain experience with its use. Still, Leerink predicts abrocitinib to generate approximately $2 billion in sales by 2027. Since any drug with $1 billion in sales is considered a blockbuster, abrocitinib could have a strong market presence.[30]

For reference, the Wholesale Acquisition Cost (WAC) for Dupixent is approximately $41,000 per year.[31]

Drug overview

Tralokinumab (Brand Name: To be determined). Expected FDA decision: April 2021.

Tralokinumab, intended to treat adults with moderate-to-severe atopic dermatitis, acts on interleukin (IL)-13. IL-13 plays a key role in driving the underlying chronic inflammation in atopic dermatitis.[32]

In Phase 3 trials, patients were treated with tralokinumab administered subcutaneously every two weeks or every four weeks, and with or without a topical corticosteroid. The results demonstrated efficacy and safety at each interval, with or without the use of a topical corticosteroid.[33]

For detailed trial results please see here (p.3).

Competitive environment

If approved, tralokinumab would offer a novel mechanism of action (MOA) for moderate-to-severe atopic dermatitis. However, as mentioned above, tralokinumab will compete not only with existing treatment options like Dupixent, but also, potentially, several JAK inhibitors as well.[34]

There is a lack of data comparing tralokinumab head-to-head against any of its potential competitors. Measured indirectly, its efficacy does appear more modest than other treatment options. The proposed initial indication will be limited to adult patients which will reduce its use, as atopic dermatitis is common among children and adolescents. In contrast to JAK inhibitors, tralokinumab requires administration via SC injection like Dupixent.[35]

For reference, the WAC for Dupixent is approximately $41,000 per year.[36]

Drug overview

Ruxolitinib topical cream (Brand Name: To be determined). Expected FDA decision: June 21, 2021.

Ruxolitinib topical cream, is intended to treat mild-to-moderate atopic dermatitis in patients aged 12 years and older. [**NOTE:** Ruxolitinib is currently available as an oral brand (Jakafi®) for the treatment of myelofibrosis, polycythemia vera, and graft vs. host disease.][37]

Applied topically, ruxolitinib, a selective JAK inhibitor directly targets two chemical pathways that underlie atopic dermatitis. By disrupting two of the four cytokine networks (JAK1 and JAK2), ruxolitinib helps to limit atopic dermatitis symptoms.[38]

Phase 3 trial researchers randomly assigned three patient groups eight weeks of treatment. One group had ruxolitinib cream 0.75% administered twice daily, the second group had ruxolitinib cream 1.5% twice daily. A control group received an inactive vehicle cream.[39]

Similar to the drugs above, topline results show that significantly more patients treated with both strengths of ruxolitinib cream achieved a Treatment Success score of "clear" or "almost clear". [40]

For detailed trial results please see here (p.5).

Competitive environment
If approved, ruxolitinib would be the first **topical** JAK inhibitor for atopic dermatitis. While oral JAK inhibitors have been associated with serious side effects, the topical form may potentially reduce some of the safety concerns associated with the class. According to the data available, topical ruxolitinib appears to be well tolerated with no major safety issues.[41]

Notably, ruxolitinib was studied in **mild-to-moderate patients.** This is a significantly larger subpopulation than moderate-to-severe, but one that is also easier to treat with topical corticosteroids and calcineurin inhibitors. In this population, ruxolitinib would also compete with Pfizer's topical Eucrisa. The efficacy data for topical ruxolitinib appears to be more promising vs. Eucrisa when compared indirectly, but Eucrisa is already approved for adult and pediatric patients aged three months and older.[42]

Like the products discussed earlier in this report, there are a lack of data comparing ruxolitinib against alternative agents used for atopic dermatitis.[43]

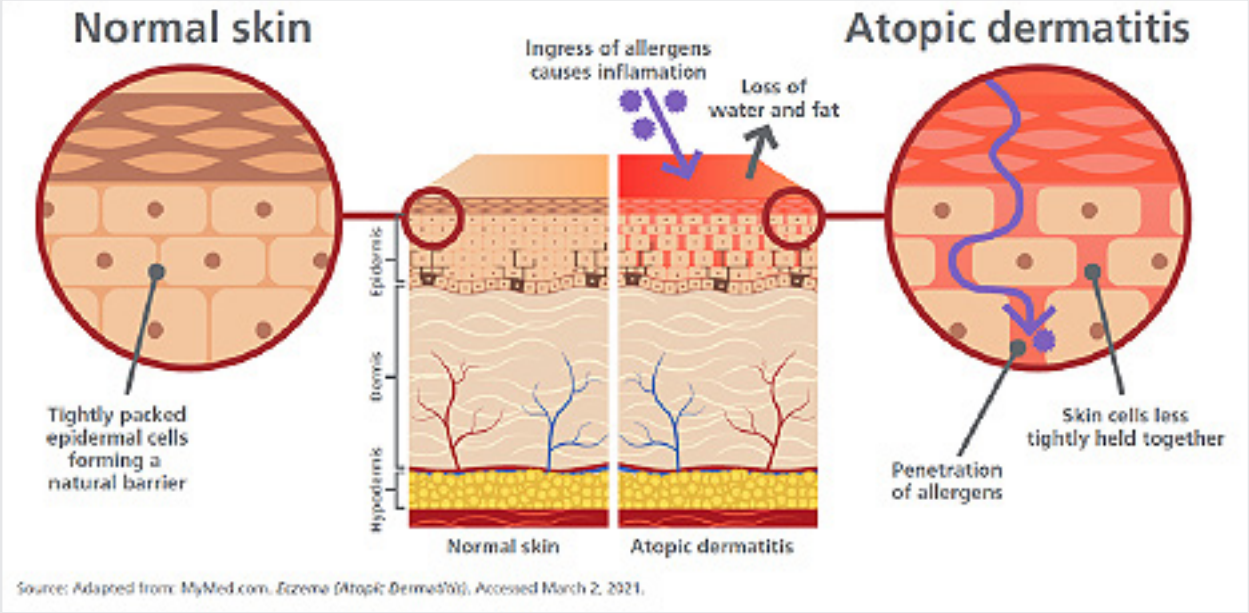
For reference, the WAC for Eucrisa is approximately $8,000 per year.[44]

Industry trend to watch

Atopic dermatitis

There is a surge of emphasis on atopic dermatitis drug development due in part to the high frequency of the condition. Nearly 32 million people in the U.S. have some form of atopic dermatitis, and nearly 10 million Americans experience moderate to severe atopic dermatitis.[45]

In the illustration below we can see how atopic dermatitis is more than a simple surface irritation. Atopic dermatitis affects the underlying structure of the skin, which helps account for its severe and lasting effects:



Source: Adapted from MyMed.com. *Eczema (Atopic Dermatitis)*. Accessed March 2, 2021.

The wide prevalence of atopic dermatitis means that there are numerous measurable impacts, including lost workdays and increased health care costs. Overall, the economic burden of atopic dermatitis is estimated to be over $5 billion per year. These include direct medical costs, indirect costs from lost productivity, and quality of life impacts.[46]

The economic impact numbers may not adequately convey how many moderate to severe atopic dermatitis patients have poorly controlled disease. The resulting effects include skin trauma, intense itching, sleep disturbances, secondary effects, like anxiety and depression and significantly diminished quality of life. [47, 48]

Mild cases of atopic dermatitis are frequently treated with a topical corticosteroid or emollient skin creams. But long-term use of topical steroids can cause skin thinning, atrophy, acne and changes in skin pigmentation, which can be disfiguring.[49]

Moderate to severe atopic dermatitis may need to be treated with medications that affect the immune system. Historically these have included off-label use of drugs like methotrexate, azathioprine, and cyclosporine. These have the potential for serious side effects and are only recommended for short-term use.[50]

Industry trend to watch

More recently Dupixent has replaced the other immunosuppressants for moderate-to-severe patients, mainly because of its good safety profile, especially for chronic use. It does have the drawback of being injectable though.[51]

Let's review some of the activity in this dynamic space.

Broadly speaking, most of the newest drugs to treat atopic dermatitis are attempting to influence the same basic immune system signaling process (called the JAK-STAT pathway). They just act on different parts of the pathway. But from a pharmacology perspective, the drugs are quite different.[52]

We can sort the next-gen options into two basic buckets. One bucket would contain the biologic interleukin inhibitors (like Dupixent). The other would contain the small molecule JAK inhibitors.[53]

There are at least three new biologic interleukin inhibitors under development for atopic dermatitis. They include tralokinumab (reviewed above), lebrikizumab (whose Phase 3 trial was suspended in 2020 due to COVID-19) and nemolizumab.[54]

We have discussed the four JAK inhibitors that are expected this year (abrocitinib, ruxolitinib, baricitinib, upadacitinib). Researchers count at least four additional JAK inhibitors that are expected to be evaluated by the FDA within the next five years.[55]

There is other development activity, including non JAK small molecules and monoclonal antibodies. However, the main activity seems to be concentrated in the two buckets shown above.[56, 57]

Dermatologists must weigh the choice of biologics versus JAK inhibitors for each patient. There are some clear differences in mode of action, safety, route of administration and price that all will be important. Consequently, we probably are not looking at a winner-take-all scenario in favor of either the biologics or the JAK inhibitors. Rather we may see a blend of products designed to address different levels of disease severity and utilizing multiple approaches in order to care for a diverse and growing patient population.[58]

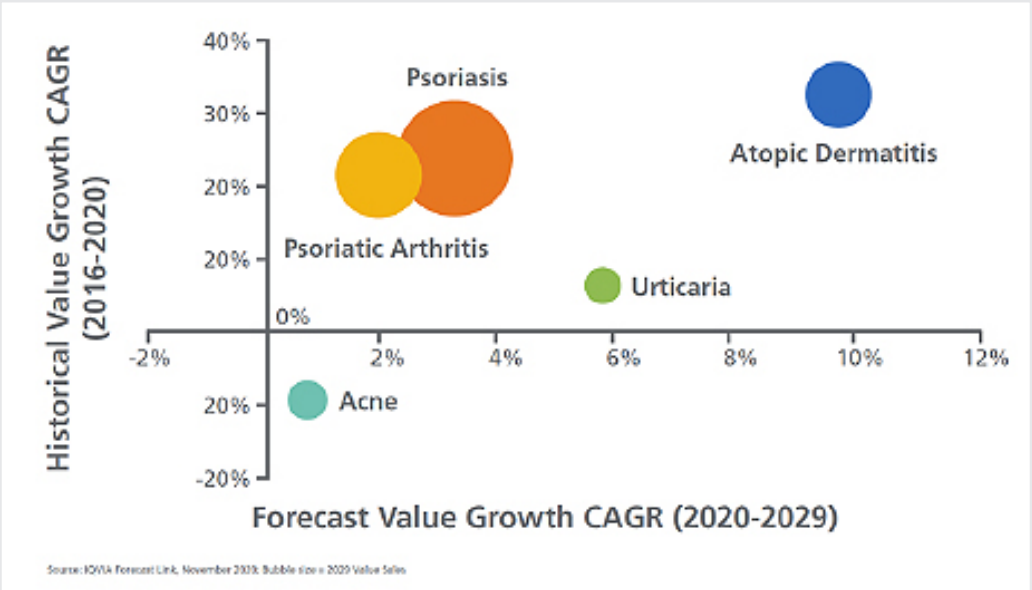
There are still many important questions about the place in therapy for the next wave of atopic dermatitis agents. For example, despite the improvements in the latest generation of JAK inhibitors, it's still not clear exactly how they work. Concerns about JAK inhibitor safety, like off-target effects, plague the entire class and remain for atopic dermatitis as well.[59]

Industry trend to watch

Cost concerns

We cannot say for sure that a developmental drug will come to market, including the ones mentioned in this report. But the atopic dermatitis market is projected to grow faster than other leading dermatological conditions such as psoriasis and psoriatic arthritis in the coming decade. In dollar terms the global atopic dermatitis market is expected to grow by 130% to approximately $11bn by 2029.[60]

This graph shows the historical vs forecast value growth of leading dermatology markets:



While the overall size of the atopic dermatitis market will grow, the exact mix of utilization between the biologic and small molecule atopic dermatitis drugs will matter a lot, although perhaps not immediately.[61]

As we have seen, the next wave of new atopic dermatitis drugs will include both small molecules, like JAK inhibitors, and large molecules like tralokinumab.

In general, small molecule drugs are much less expensive than biologic drugs.[62] But that does not necessarily mean that the small molecule JAK inhibitors will be less costly than an existing biologic like Dupixent, at least at first. In fact, the JAK inhibitors currently approved for other conditions such as rheumatoid arthritis are actually **more expensive** than Dupixent.[63]

Ultimately, the atopic dermatitis market for JAK inhibitors may evolve to look very different, due to the far larger patient population and multiple entries into the class. Analysts have forecast 11 new product launches for atopic dermatitis globally between 2020 and 2029.[64] (These include the drugs listed in this report.)

Industry trend to watch

Challenges remain

There is still more work ahead. One broad unmet need is treatments for children. Approximately 10 million people in the U.S. have moderate to severe atopic dermatitis; of these, fully one in three are children.[65]

Until Dupixent was approved in 2017, there were no systemic drugs, other than corticosteroids, approved for pediatric and adolescent atopic dermatitis. However, it is indicated only for those age 6 and older. Studies are currently underway to evaluate Dupixent for younger children.[66]

Additional studies are underway to learn about treatments that may prove useful for younger patients.[67] This is desirable in human terms, but of course if effective treatments are found, the resulting expansion of therapy to more utilizers could add to anticipated cost expansion.

Of course, the biggest remaining challenge in atopic dermatitis is to move beyond just treating symptoms and into disease modification. That is, therapeutic strategies aimed to break, stop, or reverse the natural course of a chronic disease.

Theoretically the biologics have the potential to act as disease modifying drugs. Researchers are investigating various combinations of the IL-4/IL-13 and IL-31 elements (found in tralokinumab, lebrikizumab and nemolizumab). These have the advantage of blocking multiple steps of the inflammation cycle that causes atopic dermatitis. The hope is that drugs in this class may offer both a rapid and durable therapeutic response.[68]

What remains is to build up our experience and our understanding of how all these molecules work and gather the data to determine which approaches work best for patients. Only then can we determine whether they can do the job of switching off the disease.[69]

Healthcare providers are excited by the possibilities that a more diversified atopic dermatitis drug class may hold for their patients. However, it is reasonable to expect overall spending in the class to rise as multiple new drugs enter the market and as the atopic dermatitis population grows.

Final Thought

The five drugs discussed here are just some of the important drugs we are watching. We look forward to providing plan sponsors ongoing updates throughout the year as new drugs make their way through the development pipeline. And as always, you can count on OptumRx for the resources, programs and clinical assistance you may need to manage these new medications effectively.

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