



PIPELINE INSIGHTS REPORT DRUGS TO WATCH



Bimekizumab (*brand name to be determined*). FDA delayed.

Bimekizumab is for adults with moderate-to-severe plaque psoriasis. In trials, it demonstrated superior results in standardized assessments against comparator drugs and placebo.

Despite successful trials, bimekizumab is entering a crowded market with well-established competitors. Other biologic agents are dosed less frequently or can be used in pediatric populations. Biosimilars may enter the market in 2023 with lower prices.

No price has been set.



Plinabulin (*brand name to be determined*). Expected FDA decision: November 30, 2021.

Plinabulin is in development for the prevention of neutropenia, a common side-effect of chemotherapy involving damage to neutrophils, a type of infection-fighting white blood cell.

In trials, adding plinabulin to the standard treatment seems to help patients remain on their existing chemotherapy regimens.

Initially plinabulin is expected to be limited to patients at high risk for neutropenia.

No price has been set.



Dextromethorphan/bupropion (AXS-05) **(*brand name to be determined*).** FDA decision delayed.

AXS-05 is in development for treatment of adult patients with major depressive disorder. It combines the over-the-counter cough medicine dextromethorphan with bupropion, one of the most widely prescribed antidepressant medications in the world.

In trials, this combination appears to work faster vs. some of the commonly used treatments for major depressive disorder.

AXS-05 would compete with well-established, inexpensive generics. Also, the FDA review of its application is still ongoing.



Efgartigimod (*brand name to be determined*).

Expected FDA decision: December 17, 2021.

Efgartigimod is in development for treatment of generalized myasthenia gravis.

In trials more patients treated with efgartigimod showed improvement in their daily activities of living compared to placebo.

The current standard of care for myasthenia gravis is immunotherapy, which is typically successful. Therefore, efgartigimod would likely be used in more severe cases.

Prices are not known, but similar treatments are very expensive. For reference, Soliris® costs approximately \$565,000 per year.



Ciltacabtagene autoleucel (*brand name to be determined*).

Expected FDA decision: November 29, 2021.

Ciltacabtagene autoleucel is for patients with relapsed and/or refractory multiple myeloma.

Ciltacabtagene autoleucel is a chimeric antigen receptor (CAR) T cell therapy. It takes naturally occurring infection-fighting cells ('T-cells') and re-engineers them to be more effective.

Trial results appear positive. However, ciltacabtagene autoleucel shares drawbacks with all CAR T therapies, including cytokine release syndrome, neurotoxicity, possible long delays in the treatment process, and a high one-time cost.

For reference, the cost for its direct competitor is \$419,500 for a one-time dose.