

Despite 2018's successes in the neurology market, research and development (R&D) setbacks in the field of Alzheimer's disease continue to disappoint, says GlobalData, a leading data and analytics company.

The Alzheimer's disease market received major blows when several amyloid targeting  $\beta$ -secretase (BACE) inhibitors dropped out during the year. Merck & Co. terminated verubecestat due to lack of efficacy, Johnson & Johnson dropped atabecestat due to liver safety issues and in June, Eli Lilly/AstraZeneca's lanabecestat was also abandoned after an independent Data Monitoring Committee (DMC) stated that the trials were unlikely to meet their primary endpoints and should be stopped for futility.

Maura Musciacco, Director of Neurology & Ophthalmology at GlobalData comments, "Eli Lilly also terminated two other projects; although specific reasons for the terminations were not given, they indicate that Eli Lilly has given up on this drug class, sparking a new round of debate about whether Alzheimer's patients will ever see a new medication on the market."

On the other hand, the migraine market saw the launch of the highly anticipated calcitonin gene-related peptide (CGRP) antagonists. Amgen's and Novartis' Aimovig (erenumab) secured the first-to-market position following its FDA approval in May 2018. Teva's Ajovy (fremanezumab) and Eli Lilly's Emgality (galcanezumab) rapidly followed suit, with both drugs receiving FDA approval in September 2018.

Musciacco continues: "Although CGRP antagonists are expected to revolutionize the migraine market, securing preferred coverage from pharmacy benefit managers in the US has been challenging so far, perhaps due to their high price and only having subtle differences between these three drugs."

Cannabis has been receiving some serious media attention in 2018. Canada became the second country in the world to legalize cannabis for recreational use, after Uruguay. From a medical standpoint, the first patient in the UK finally succeeded in obtaining a long-term personal license for medical cannabis. In the US, the FDA approved the first pure cannabis-derived drug, Epidiolex (cannabidiol [CBD]), a liquid formulation developed by GW Pharmaceuticals for the treatment of two rare and severe forms of epilepsy: Lennox-Gastaut syndrome (LGS) and Dravet syndrome, two of the most difficult to treat forms of

childhood-onset epilepsy.

Musciacco states: “Epidiolex’s June 2018 approval meant that the US Drug Enforcement Administration (DEA) had to reclassify Epidiolex from Schedule I to Schedule V, which demonstrated that the medication has a proven medical use and a low potential for abuse.”

In July 2018, the FDA approved Indivior’s Perseris (risperidone), making it the first once-monthly long-acting injectable (LAI) for schizophrenia, delivering the established antipsychotic risperidone subcutaneously.

Musciacco concludes: “Given the fact that compliance is a major unmet need for this market, Perseris has the potential to address this issue by providing fewer hospital visits.”