Review Article

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Novel Drugs and Biologics of 2016: A Boom for Neurodrugs in the Pipeline

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ABSTRACT

This article provides a brief overview of novel drugs approved by the U.S. FDA in 2016. It also focuses on the emerging boom in the development of neurodrugs for central nervous system (CNS) disorders. These new drugs are innovative products that often help advance clinical care worldwide, and in 2016, twenty-two such drugs were approved by the FDA. The list includes the first new drug for disorders such as spinal muscular atrophy, Duchenne muscular dystrophy or hallucinations and delusions of Parkinson's disease, among several others. Notably, nine of twenty-two (40%) were novel CNS drugs, indicating the industry shifting to neurodrugs. Neurodrugs are the top selling pharmaceuticals worldwide, especially in America and Europe. Therapeutic neurodrugs have proven their significance many times in the past few decades, and the CNS drug portfolio represents some of the most valuable agents in the current pipeline. Many neuroproducts are vital or essential medicines in the current therapeutic armamentarium, including dozens of "blockbuster drugs" (drugs with $1 billion sales potential). These drugs include antidepressants, antimigraine medications, and anti-epilepsy medications. The rise in neurodrugs' sales is predominantly due to increased diagnoses of CNS conditions. The boom for neuromedicines is evident from the recent rise in investment, production, and introduction of new CNS drugs. There are many promising neurodrugs still in the pipeline, which are developed based on the validated "mechanism-based" strategy. Overall, disease-modifying neurodrugs that can prevent or cure serious diseases, such as multiple sclerosis, epilepsy, and Alzheimer's disease, are in high demand.

KEYWORDS: Novel drugs; NCEs, First-in-class; CNS drugs; Blockbuster drugs; Neurodrugs.