R&D Trends: Autism Spectrum Disorders - Unknown etiology and low industry interest hinders pipeline progression

Description:
Since 2006, two drugs have gained FDA approval for the symptomatic treatment of irritability in autism spectrum disorders (ASDs). However, the pipeline is also characterized by a high attrition rate, with eight pipeline candidates having been discontinued since 2009. CureMark’s Phase III candidate, CM-AT, currently represents the most advanced compound in the small ASD pipeline.

Features and benefits
- Overview of drugs in late- and early-stage clinical development for autism spectrum disorders.
- Identification of the target product profile for future autism spectrum disorders treatments.
- Summary of clinical trial design in autism spectrum disorders including exploration of key endpoints and assessment methodology.
- Identification of key challenges associated with the conduct of clinical trials in autism spectrum disorders.
- Exploration of the future treatment in autism spectrum disorders including the development of personalized treatments and the use of biomarkers.

Highlights
- The autism spectrum disorders (ASDs) pipeline is sparse relative to other conditions that are treated with psychotropic medications. The unknown etiology of ASDs poses a fundamental challenge to the therapeutic discovery process and the pipeline is characterized by a high attrition rate.
- The two approved therapies for the management of autism spectrum disorders both target the symptoms of irritability. The comparator therapy identified by Datamonitor is Risperdal (risperidone; Johnson & Johnson) as it was the first to be approved in this indication, demonstrates a strong efficacy profile and is regarded as a first-line therapy.
- Key challenges associated with the conduct of clinical trials in autism spectrum disorders are: the unknown etiology of the disorders and heterogeneous symptomology. Communication and language impairments commonly associated with autism spectrum disorders further compound these challenges.

Your key questions answered
- How many drugs are in clinical development for the treatment of autism spectrum disorders? What deters companies from investing in this area?
- What symptoms and mechanisms of action are most frequently targeted? What key companies are involved in the pipeline?
- What is the target product profile and most appropriate comparator therapy?
- What are the key challenges in the conduct of clinical trials in autism spectrum disorders?
- How is the treatment of autism spectrum disorders likely to evolve over the next 10 to 20 years?

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