R&D Trends: Attention-Deficit Hyperactivity Disorder - Growing pipeline indicates a trend towards adjunctive and adult therapy

Description: Two drugs have progressed through the pipeline representing the first two products to receive US FDA approval for use as adjunctive therapies to stimulants: Intuniv (extended release guanfacine; Shire) and Kapvay (clonidine; Shionogi). Interest in the ADHD pipeline remains high as companies continue to attempt to demonstrate differentiation in the increasingly competitive market.

Features and benefits
- Understand key R&D dynamics in the pipeline for new ADHD therapies.
- Benchmark novel and existing therapies using the target product profile identified by Datamonitor.
- Support R&D decision making by evaluating clinical trial designs that have set a precedent.
- Evaluate the most promising new pharmacological targets in early-stage development.
- Access The prediction of how the treatment landscape may change in the next 20 years.

Highlights
The ADHD drug pipeline has almost doubled since 2008 with 25 candidates in clinical development. Although large and medium sized Pharma are present, the pipeline is dominated by smaller companies that will need licensing partners to bring their products to market.

Trends in the ADHD drug pipeline indicate a growing interest in non-stimulant agents used as add-on therapies to stimulants, with around a quarter of non-stimulants under investigation for adjunctive use. Datamonitor sees this as a viable market entry point amid high competition.

Increasingly, companies view the adult ADHD population as a more viable target than pediatric ADHD due there being less competition, increasing disease awareness, and fewer challenges in conducting clinical trials.

Your key questions answered
- What are the key trends in the ADHD pipeline?
- What key companies are involved in the pipeline? What encourages and deters companies from investing in this area?
- What is the clinical gold standard and how do new candidates have to compare to this to successfully penetrate the market?
- How is the treatment of ADHD likely to evolve over the next 10 to 20 years?

Contents:
- Executive Summary
  - Strategic scoping and focus
  - Datamonitor key findings
- Related reports
- OVERVIEW
  - Catalyst
  - Summary
- CLINICAL PIPELINE OVERVIEW
  - Overview of the ADHD clinical pipeline
  - Datamonitor has identified 25 candidates in clinical development
  - Emerging features of the ADHD pipeline
    - Activity in the ADHD pipeline indicates moderate yet growing industry interest in the market
    - The number of candidates in development for ADHD has almost doubled since
    - Phase II is the most populous phase of development
    - Varied modes of action are being explored, with clear emphasis on non-stimulant mechanisms
    - Almost one quarter of non-stimulants are under investigation in combination therapies with stimulant medications
Oral formulations continue to dominate the pipeline. Developers are increasingly targeting adult ADHD. Companies involved in the ADHD clinical pipeline are dominated by small specialist pharmaceutical companies. Large market players are involved across all phases of clinical development. Late-stage development compounds recently discontinued. Seven candidates in the late-stage ADHD pipeline have been discontinued since.

**TARGET PRODUCT PROFILE**

Adderall XR (mixed amphetamine salts extended release; Shire)

Strong clinical profile and approval for ADHD patients across lifespan makes Adderall XR the most appropriate comparator therapy for both stimulant and non-stimulant medications. Clinical trial data for Adderall XR

**CLINICAL TRIAL DESIGN IN ADHD**

Clinical trials

- Lack of published regulatory guidance on the conduct of clinical trials in ADHD
- Typical trial design in ADHD
- Commonly used primary clinical trial endpoints in ADHD
- Secondary clinical trial endpoints in ADHD
- Key challenges in the conduct of clinical trials in ADHD

Future developments in clinical trial design

- Size of clinical trials will increase in an attempt to demonstrate efficacy of adjunct therapy with stimulants
- Companies will attempt to demonstrate efficacy of adjuncts with lower stimulant doses
- Further development of outcome measures that are relevant to adult patients

**INNOVATIVE EARLY-STAGE APPROACHES**

- Abuse resistant formulations
- Reducing substance abuse concerns with stimulant drugs would confer a commercial advantage in ADHD market
- Phosphodiesterase inhibitors
- Novel mechanism targeting cognition, memory, and motor behavior in ADHD

**THE FUTURE OF TREATMENT IN ADHD**

The use of adjunctive therapies in ADHD is expected to increase. Identification of likely responders will aid physician selection of treatment of combination therapies. Obtaining reimbursement will be a growing concern, impacting the potential uptake of add-on therapies. Future commercial opportunities lie in reducing the pill burden associated with adjunctive therapies. Amendments to ADHD diagnostic criteria of the upcoming DSM-V. Proposed changes have the potential to increase adult ADHD patient population and create new indications.

- Biomarkers for ADHD
- Biomarkers may have utility in identifying appropriate patients and improving treatment outcomes
- Pharmacogenetics and neuroimaging are biomarkers under clinical investigation
- Reduced R&D spending has commercial appeal, and a competitive advantage is a bonus

**BIBLIOGRAPHY**

- Journal papers and publications
- Websites
- Datamonitor reports

**APPENDIX**

- Contributing experts
- Conferences attended
- Report methodology

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