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Drug Development of Lisdexamfetamine

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Introduction

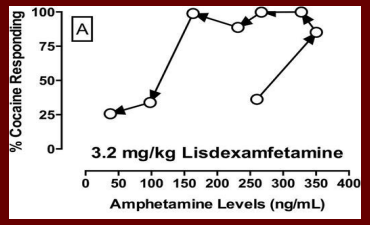
- Attention deficit hyperactivity disorder (ADHD) is a neuropsychiatric condition (Goodman 2010)
- Vyvanse is an FDA approved drug for ADHD symptoms and relieves the symptoms in children, teenagers and adults
- Should people suffering from ADHD take the drug Vyvanse to help their symptoms if they have underlying heart disease or heart conditions?
- Should more money and time be put into developing Vyvanse, since the market already has hundreds of safe and effective drugs that target ADHD symptoms?
- What should the price criteria be for the access and distribution of Vyvanse (lisdexamfetamine)?

Discussion and Conclusion

- Through the pre-clinical, clinical phase I, and clinical phase II trials, lisdexamfetamine was proved to be an efficient and safe drug in ADHD treatment (Banks et al.2015)
- Minimum adverse side effects have been observed and reported
- People with underlying heart conditions should not take Vyvanse
- Developing more drugs that target ADHD is not essential and should be discontinued.
- The price of vyvanse should be lowered so that more people with ADHD can have access to a greater variety of treatment options.

Pre-clinicals

- Tests the safety of lisdexamfetamine, vyvanse on a pre-clinical animal based study on rhesus monkeys (Banks et al., 2015, p.2)
- It compares lisdexamfetamine and d-amphetamine effects by comparing different dosages, placebo pills and the duration
- The data concluded that lisdexamfetamine has a lower potency, slower onset and faster duration of action than d-amphetamine.



Time Course of Lisdexamfetamine and d-Amphetamine Discriminative Stimulus Effects (Banks et al 2015)

Clinicals- Phase 1

- To evaluate the effectiveness and safety of the drug on humans
- Dupaul et al. (2012) conducted a study on college students aged 18-22 (p. 203-204)
- Double - blind, placebo - controlled method design
- Effects of different dosages, placebo, and no drug were recorded for student with and without ADHD
- Drug proved to be effective and safe
- Reported side effects included headache and nausea

Clinicals- Phase 2

- This study was conducted on 52 children aged 6 to 12 years old who had ADHD (Biederman et al., 2007, p. 970)
- Biederman et al. (2007) compared vyvanse and placebo while using amphetamine salts extended-release as a reference to determine which substance is the most effective against ADHD (p. 970).
- The results concluded that vyvanse was more effective than placebo and that it was relatively safe (Biederman et al., 2007, p. 976).

References:

Banks, M. L., Hutsell, B. A., Blough, B. E., Poklis, J. L., Negus, S. S. (2015). Preclinical Assessment of Lisdexamfetamine as an Agonist Medication Candidate for Cocaine Addiction: Effects in Rhesus Monkeys Trained to Discriminate Cocaine or to Self-Administer Cocaine in a Cocaine Versus Food Choice Procedure. *International Journal of Neuropsychopharmacology, 18 (8).* https://academic.oup.com/ijnp/article/18/8/pyv009/2910017

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