

Zoraxel™ Sexual Dysfunction Drug Candidate

- Target profile has potential clinical advantages over standard of care PDE-5 inhibitor drugs to treat ED
- Currently in Phase II trials to treat erectile dysfunction (ED), with potential use for treating female sexual dysfunction
- Centrally acting agent that covers all 3 sexual functions of libido, erection, and ejaculation
- Well established and excellent safety in humans

Background

Zoraxel™ is designed to treat sexual dysfunction, and works as a dual enhancer of neurotransmitters in the brain that play a key role in sexual activity phases of motivation and arousal, erection and release. (Figs 1 and 2)

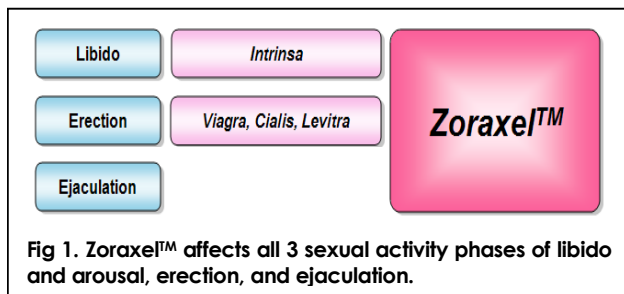


Fig 1. Zoraxel™ affects all 3 sexual activity phases of libido and arousal, erection, and ejaculation.

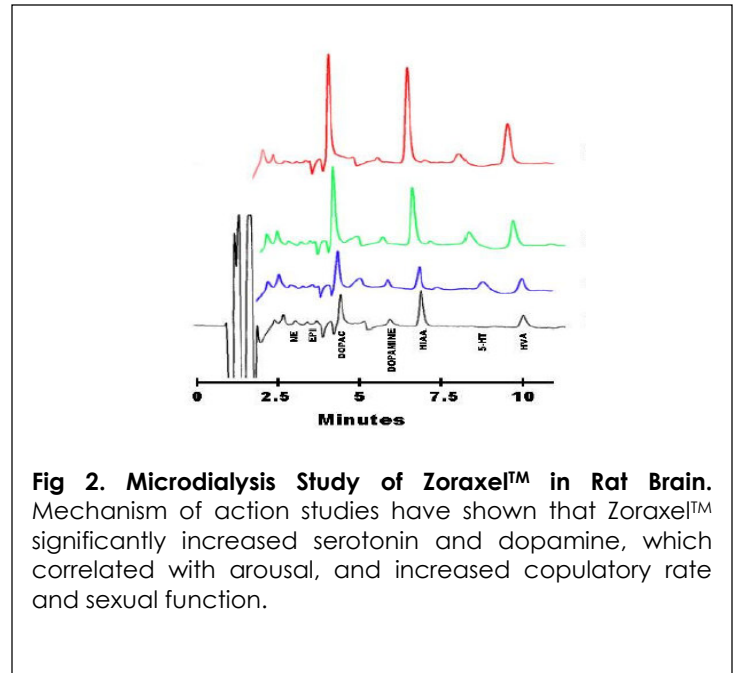


Fig 2. Microdialysis Study of Zoraxel™ in Rat Brain. Mechanism of action studies have shown that Zoraxel™ significantly increased serotonin and dopamine, which correlated with arousal, and increased copulatory rate and sexual function.

Commercial Opportunity

Approximately 150 million men worldwide and 30 million U.S. men suffer from erectile dysfunction (ED). ED drug sales were \$3 billion in 2007 (Viagra \$1.8B and Cialis \$1.1B). About 52% of men ages 40 to 70 in the U.S. report difficulty with erectile function. About 30% of patients are refractory to phosphodiesterase type-5 (PDE-5) inhibitors, providing significant market opportunity for new ED drugs.

Zoraxel™ is being developed as an orally administered tablet for on-demand use. It has well established and excellent safety in humans and appears to lack the severe side effects associated with the ED standard of care PDE-5 inhibitor drugs, such as priapism, severe hypotension, myocardial infarction, sudden death, increased intraocular pressure and sudden hearing loss. Zoraxel™ is a centrally acting, dual enhancer of neurotransmitters in the brain, whereas PDE-5 inhibitors only target end organ erectile function, and work in peripheral blood vessels. Based on findings to date, Zoraxel™ may be a more effective ED treatment for patients who are responsive or unresponsive to PDE-5 inhibitors.

Clinical Development

Rexahn has completed a Phase IIa clinical trial evaluating the safety and preliminary efficacy of Zoraxel for treatment of ED. The main study endpoints were the sexual encounter profile (SEP) and International Index of Erectile Function (IIEF) scores, both of which are validated surveys for assessing erectile function. In preclinical studies, Zoraxel induced sexual motivation and arousal, and enhanced erectile function. (Fig 3)

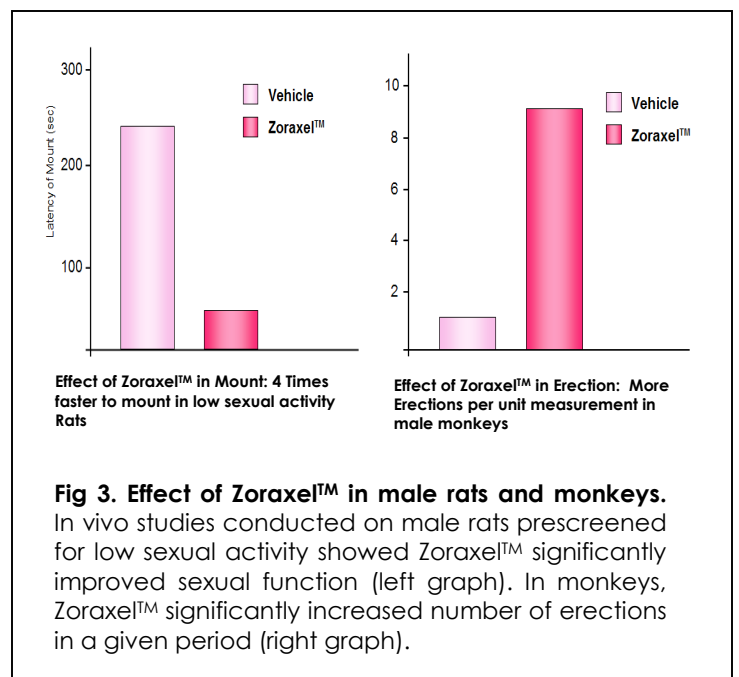


Fig 3. Effect of Zoraxel™ in male rats and monkeys. In vivo studies conducted on male rats prescreened for low sexual activity showed Zoraxel™ significantly improved sexual function (left graph). In monkeys, Zoraxel™ significantly increased number of erections in a given period (right graph).