Entadfi™ (finasteride/tadalafil) – New drug approval

- On December 13, 2021, Veru announced the FDA approval of Entadfi (finasteride/tadalafil), to initiate treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate for up to 26 weeks.
    - Entadfi is not recommended for more than 26 weeks because the incremental benefit of tadalafil decreases from 4 weeks until 26 weeks, and the incremental benefit beyond 26 weeks is unknown.
- Generic finasteride and tadalafil are both currently available as single-ingredient products for the treatment of BPH.
- The efficacy of Entadfi is based on a previous adequate and well-controlled study of tadalafil coadministered with finasteride. Tadalafil and finasteride administered together demonstrated statistically significant improvement in the signs and symptoms of BPH vs. placebo with finasteride, as measured by the total symptom score at 12 weeks, the primary study endpoint.
- Entadfi is contraindicated in the following situations:
    - Concomitant use of any form of organic nitrate, either regularly and/or intermittently. Entadfi can potentiate the hypotensive effect of nitrates
    - Patients with known hypersensitivity to finasteride, tadalafil, or to any of the components of Entadfi
    - Pregnancy
    - Concomitant use with a guanylate cyclase (GC) stimulator. Entadfi may potentiate the hypotensive effects of GC stimulators.
- Warnings and precautions for Entadfi include cardiovascular risk; potential for drug interactions when taking Entadfi; concomitant use with alpha-blockers or antihypertensives; consideration of other urological conditions prior to initiating treatment for BPH; effects on prostate specific antigen (PSA) and the use of PSA in prostate cancer detection; increased risk of high-grade prostate cancer; risk to male fetus from topical Entadfi exposure to pregnant females; hypersensitivity reactions; prolonged erection and priapism; ocular adverse reactions; sudden hearing loss; concomitant use with alcohol; concomitant use with strong inhibitors of CYP3A4; and effects on bleeding.
- The most common adverse reactions associated with finasteride monotherapy (≥ 1%) in a 4-year study were impotence, decreased libido, decreased volume of ejaculate, breast enlargement, breast tenderness, and rash.
- The most common adverse reactions (≥ 2%) associated with tadalafil were headache, dyspepsia, back pain, myalgia, nasal congestion, flushing, and pain in limb.
- The recommended dose of Entadfi is one capsule (containing finasteride 5 mg and tadalafil 5 mg) orally once daily at approximately the same time every day for up to 26 weeks.

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- Veru plans to launch Entadfi in early 2022. Entadfi will be available as a fixed-dose combination capsule containing 5 mg finasteride and 5 mg tadalafil.

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