Submission # 02

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Request for permission : Submitted by Industry

Testimony subject and nature of testimony Lupin

This request is denied for testimony during the 5/17/19 meeting of the Pharmacy and Therapeutics committee.

Hello, I am Ellen Bageac, an MSL for Lupin pharmaceuticals. I offer testimony on up-to-date bacterial vaginosis (BV) data not reflected in the TCRs.

The vaginal microbiome represents a delicate balance of good *protective* Lactobacilli and other anaerobes.[1] Multiple internal and external factors can influence this optimal balance.[2,3] They include: ethnicity, social environment, sexual activity, and health/hygiene.[2,3,4,5]

BV prevalence is higher in minority women and women having sex with women. Prevalence overall is 29%, 51% African Americans, 32% Hispanics, 23% Caucasians, and 25-50% WSW.[6,7,8]

The state of the science identifies five cervicovaginal types, and that classification depends on lactobacillus dominance.[1] In women with low-no Lactobacillus bacterial communities, anti-infectives that kill the protective lactobacillus should be reconsidered.[13] Some standard of care therapies are found to have increasing bacterial resistance levels 90 days post-treatment.[14]

Adherence is important in BV treatment outcomes. Four million women are treated for BV each year, however, only 50% complete 5-7day regimens.[9,10,11] Studies reveal the longer and more complex a drug regimen is, it may lead to poor adherence and treatment failure.[12] A national survey of HCPs revealed reasons for patient non-adherence were because of patient forgetfulness or they wanted to consume alcohol.[15]

When evaluating BV drugs, important aspects are: 1) exclude drugs no longer on the market (FlagylER), 2) consider prevalence, adherence & bacterial communities data, and 3) evaluate BV drugs against current FDA guidance documents for primary efficacy endpoints.

Only four BV drugs have been studied similarly to the most recent 2016 FDA guidance.[16]

References

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