7-10 and Amsel criteria was also significantly lower for Astodrimer Gel vs placebo. Efficacy results during follow-up were in line with those for the 16-week treatment phase. Incidence of AEs was similar between groups. During treatment, potentially related AEs occurred in 12.2% (Astodrimer) vs 11% (placebo) (genitourinary AEs: 11.6% vs 10%). The rate of candidiasis was 14.6% for Astodrimer vs 8.9% for placebo during treatment, and 4.1% vs 5.8% in follow-up.

CONCLUSION: This study demonstrated Astodrimer 1% Gel is safe and effective for prevention of recurrent BV, a condition for which there is no approved therapy in the US. There was low potential for development of vulvovaginal candidiasis, which is a very common side effect of antibiotic therapies.

LEARNING OBJECTIVES: Learners will be informed that Astodrimer Gel has potential as a safe and effective novel, non antibiotic therapy for reducing recurrent BV, being associated with very low rates of vulvovaginal candidiasis, and thereby constituting an alternative to off-label therapeutic strategies based on conventional antibiotics.

18 A phase 2b, dose-selection study evaluating the efficacy and safety of oral ibrexafungerp vs fluconazole in vulvovaginal candidiasis (DOVE)

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OBJECTIVES: Ibrexafungerp (formerly SCY-078) is a novel IV/oral antifungal currently in development for the treatment of invasive and mucocutaneous fungal infections. Ibrexafungerp has broad activity against Candida spp., including azole-resistant strains. A phase 2b, dose-finding study was conducted to evaluate the safety and efficacy of oral ibrexafungerp in subjects with moderate to severe vulvovaginal candidiasis (VVC). We present the results of this phase 2b study here with focus on clinical response at Day-25 (secondary endpoint). Currently, oral ibrexafungerp is being tested in 2 pivotal phase 3 studies for patients with acute VVC.

METHODS: Randomized, double-blind, double-dummy study including 5 oral ibrexafungerp treatment groups (750mg-QD 1 day, 300mg-BID 1 day, 450mg-BID 1 day, 150mg-BID for 3 days, and 300-BID for 3 days) and an active comparator (oral fluconazole [FLU] 150mg single dose). Subjects were evaluated at Day-10 and Day-25 for clinical cure and mycological eradication.

RESULTS: 153 subjects with culture-confirmed VVC composed the primary population for analysis (mITT). The ibrexafungerp dose of 300mg BID for 1 day (600mg-dose) showed the best combination of clinical efficacy and tolerability. At Day-10, clinical cure, defined as complete resolution of all signs and symptoms (S&S), was observed in 14 of 27 (52%) subjects in the 600mg-dose arm and 14 of 24 (58%) subjects in the FLU arm. At Day-25, the clinical cure rate in the ibrexafungerp 600mg-dose arm increased to 70% vs. a decrease to 50% in the FLU arm. At Day-25 none of the subjects receiving the 600mg-dose had S&S >3 in contrast with 30% of subjects in the FLU group reporting S&S >3 and 17% reporting S&S ≥ 7. The most common AEs were mild nausea and diarrhea.

CONCLUSION: These results support the selection of ibrexafungerp 600mg-dose for Phase 3 registration studies in VVC and provide additional information on the efficacy and safety of ibrexafungerp in patients with VVC.

LEARNING OBJECTIVES: Learners will be able to evaluate the efficacy and safety of ibrexafungerp, a novel triterpenoid antifungal, in the treatment of vulvovaginal candidiasis as compared to standard of care, fluconazole. At the end of the presentation the learner will be aware of the potential of ibrexafungerp to treat VVC and the dose selected in this phase 2b study.

19 Physiologic parameters and sepsis bundle initiation among third trimester gravidas with influenza-like illness, 2017-2018 influenza season

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OBJECTIVES: To characterize maternal vital signs of third trimester gravidas with influenza-like illness during the 2017-2018 flu season in the context of a hospital-wide sepsis bundle initiative, triggered by any 2 abnormal vital signs defined as: temperature $<36°C$ or $>38°C$, heart rate >90/min, systolic blood pressure <90mmHg, and respiratory rate>20/min.

METHODS: This was a retrospective cohort study of third-trimester women presenting with influenza-like symptoms during the 2017-2018 influenza season, who subsequently delivered at our hospital. Influenza-like illness was defined as respiratory symptoms for which a provider ordered a rapid flu test. Women testing positive for RSV, diagnosed with pyelonephritis, and those admitted for non-influenza related indications were excluded. We compared minimum and maximum vital signs recorded within the first 4 hours of presentation among third trimester gravidas with positive versus negative rapid influenza tests. For women in the outpatient setting, missing values were assumed to be within normal parameters for categorical analysis. We compared odds of flu+ versus flu- gravidas qualifying for sepsis bundle initiation based on 2 vital signs outside specified parameters.

RESULTS: A total of 423 women were evaluated for influenza-like illness in the third trimester between September 1, 2017 and March 31, 2018. Of these, 85 (20%) were excluded. Of the remaining 338, 136(40%) tested positive for influenza A or B, and 202(60%) tested negative. Median gestational age at presentation was 34.7 ± 4 weeks for flu+ and 34.9 ± 4 weeks for flu- women ($p=0.63$). Compared with flu - women, flu+ women had higher maximum temperature (37.6 ± 0.7 vs 37.1 ± 0.6 °C, $p<0.001$) and heart rate (115 [100,125] vs 99 [88,112] beats/min,$p<0.001$) within 4 hours of initial presentation. In categorical analysis, flu+ women were 3.86 times more likely than flu- women to have fever $>38°C$ within 4 hours of presentation. Flu+ women had 4.00 higher odds (95%CI 2.17, 7.38) of maximum heart rate >90 beats per minute compared with flu- women. Sixty five percent of flu+ and 18% of flu- women met vital signs criteria for sepsis bundle initiation; flu+ women in the third trimester were 8.73 times more likely to meet criteria than flu- women (95% CI 5.27, 14.46). Despite this, only 2(1%) flu+ and 0 flu- women required ICU admission. Overall, one fifth of women delivered within 2 days of evaluation.

CONCLUSION: Flu+ women in the third trimester of pregnancy are more likely to present with fever and elevated heart rate than flu- women. Women with influenza-like illness in the third trimester of pregnancy frequently have vital signs meeting hospital criteria for initiation of sepsis bundle initiatives. Despite this, ICU admission is rare.

LEARNING OBJECTIVES: Learners will be able to characterize maternal vital signs of third trimester gravidas with influenza-like illness and recognize limitations of vital signs criteria for sepsis bundle initiation when applied to third trimester gravidas.