with either *R. delemar* or *M. cicrinelloides vs.* placebo mice (0% survival, $P < 0.02$). Importantly, VX01 acted synergistically in protecting mice when combined with liposomal amphotericin B or posaconazole in a severe model of mucormycosis with treatment starting 48 h post infection (~70% survival for combination *vs.* 0-20% survival for monotherapy and reduced lung fungal burden by 1.5 log, $P< 0.001$). GLP-tissue cross reactivity studies of VX01 showed favorable safety profiles.

Conclusion. VX01 shows enhanced binding to CotH3 protein and maintained the protective features of C2 MAb against murine mucormycosis. Clinical testing of combination therapy of VX01 + antifungals is warranted. VX01 is currently in manufacturing.

Disclosures. **Yiyou Gu, PhD**, **Vitalex Biosciences** (Shareholder) **Ashraf S. Ibrahim, PhD**, **Vitalex Biosciences** (Shareholder)

120. An open-label comparative trial of SUBA-itraconazole (SUBA) versus conventional itraconazole (c-itra) for treatment of proven and probable endemic mycoses (MSG-15): a pharmacokinetic (PK) and adverse Event (AE) analysis

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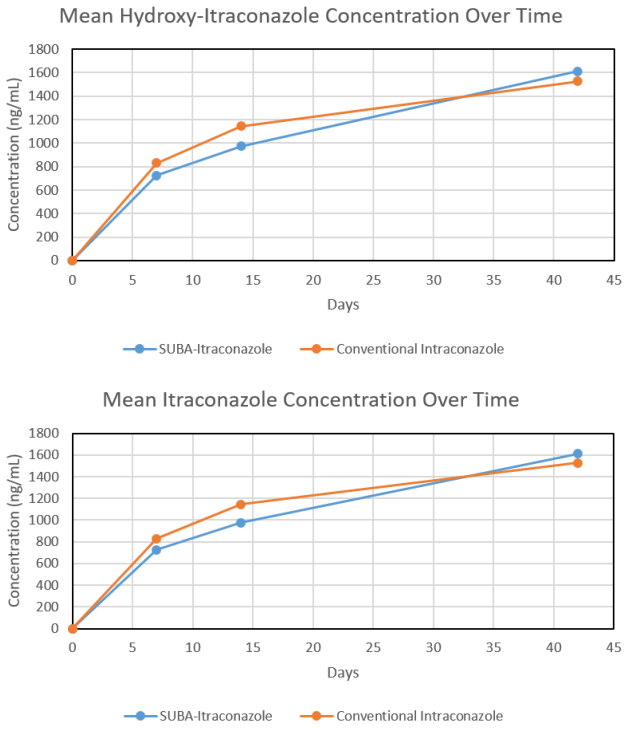
Session: O-25. New Findings in Medical Mycology

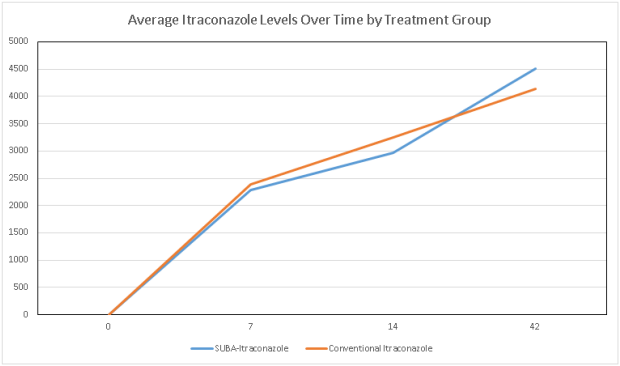
Background. C-itra is the drug of choice for treatment of most non-CNS, non-life-threatening forms of endemic mycoses (EM), including histoplasmosis, blastomycosis, coccidioidomycosis, sporotrichosis and talaromycosis. SUBA represents a new formulation of itraconazole that utilizes nanotechnology to improve bioavailability when administered orally. SUBA is formulated as nanoparticles allowing for absorption in the small bowel while not relying on gastric acidity for optimal absorption. MSG-15 is an open-label, comparative clinical trial comparing SUBA to c-itra for the treatment of EM. Herein we report the final PK and AE profiles of these two compounds.

Methods. Subjects with proven and probable EM were eligible this open-label comparative study. The protocol allowed up to 14 d of prior therapy with any antifungal for this episode of EM. Subjects were randomized to receive either SUBA 130 mg po bid or c-itra 200 mg po bid for up to 6 months. Follow up occurred at 7, 14, 28, 42, 84 and 180 d post-enrollment. PK samples were obtained at 7, 14, and 42 d. Clinical assessment, including symptom assessment, AEs, overall drug tolerance, and quality of life were assessed at each visit. We used descriptive statistics for this analysis.

Results. 89 subjects with EM entered the trial, including 43 on SUBA and 46 on c-itra. We measured PK serum levels of itra and hydroxyl-itra at days 7, 14, and 42 and these data are depicted in Figures 1-3. There were no significant differences in these levels, including combined itra/hydroxyl-itra levels, among the two study arms. AUC for itra and hydroxyl-itra were similar for both arms. AEs as assessed at each study evaluation were also quite similar among the two study arms. Overall, any AE occurred in 74% vs 85% of SUBA and c-itra recipients, respectively (NS). Drug-related AEs occurred in 35% vs 41% of SUBA and itra recipients, respectively (NS). Most common drug-related AEs included cardiovascular (edema and hypertension), nausea and loss of appetite.



Combined Itraconazole and Hydroxy-itraconazole Concentration Over Time



Conclusion. Compared to c-itra, SUBA demonstrates almost identical serum levels despite being dosed at roughly 60% standard dosing for c-itra (130 mg po bid vs 200 mg po bid). SUBA is slightly better tolerated than c-itra, although the specific AEs are similar.

Disclosures. **Peter G. Pappas, MD**, **Astellas** (Research Grant or Support)**Cidara** (Research Grant or Support)**F2G** (Consultant)**Matinas** (Consultant, Scientific Research Study Investigator)**Mayne Pharma** (Research Grant or Support)**Scynexis** (Research Grant or Support) **Andrej Spec, MD, MSCI**, **Mayne Pharma** (Grant/Research Support) **Marisa Miceli, MD**, **SCYNEXIS, Inc.** (Advisor or Review Panel member) **George R. R. Thompson III, III, MD**, **Amplyx** (Consultant, Grant/Research Support)**Appili** (Consultant)**Astellas** (Consultant, Grant/Research Support)**Avir** (Grant/Research Support)**Cidara** (Consultant, Grant/Research Support)**F2G** (Consultant, Grant/Research Support)**Mayne** (Consultant, Grant/Research Support)**Merck** (Scientific Research Study Investigator)**Pfizer** (Advisor or Review Panel member)

121. Mucormycosis and COVID-19 in the United States: a Real-World Evidence Analysis of Risk Factors and Survival Among Patients with Mucormycosis, with and without COVID-19 Preceding the Infection

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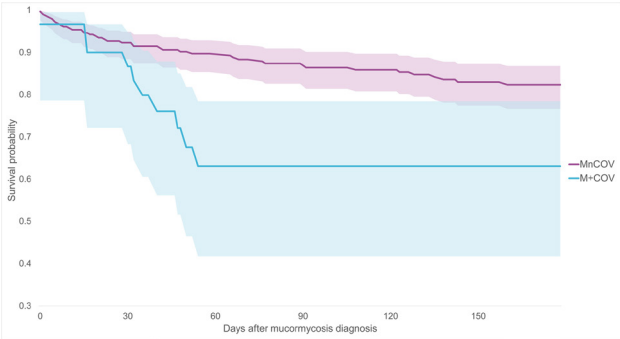
Session: O-25. New Findings in Medical Mycology

Background. Mucormycosis has been associated with COVID-19 infections, notably in India, and known risk factors for mucormycosis such as diabetes mellitus have been studied in this context. This analysis aims to characterize patients in the US with mucormycosis, with and without COVID-19, by risk factor and mortality.

Methods. Data from the TriNetX Research Network representing over 66M de-identified patient-lives in the US was used to examine characteristics and outcomes among mucormycosis patients with and without preceding COVID-19 infection. Patients must have had a mucormycosis diagnosis recorded from 1/1/2020 to 6/8/2020. Patients were then identified as having either a COVID-19 diagnosis or positive SARS-CoV-2 RNA laboratory result (M+COV) or no COVID-19 diagnosis or positive RNA result (MnCOV) any time prior to through one day after the mucormycosis diagnosis. These cohorts were evaluated across characteristics recorded in the EMR within 1 year prior to and including the date of mucormycosis record. Mortality was evaluated with Kaplan-Meier statistics as survival until recorded death on or after mucormycosis diagnosis.

Results. Of 302 patients with mucormycosis from 1/1/2020-6/8/2021, 30 patients (10%) had M+COV, and 272 (90%) had MnCOV. Among the M+COV cohort, 22 patients (73%) had mucormycosis recorded within 2 weeks of COVID-19 infection. The M+COV and MnCOV cohorts had majority male sex (60,59%;p=0.93) and a similar prevalence of transplanted organs (40,28%;p=0.16), long-term drug therapy (60,54%;p=0.56), chronic kidney disease (43,31%;p=0.16), and glucocorticoid treatment (67,64%;p=0.76). The M+COV cohort had a greater prevalence of type II diabetes mellitus (67,35%;p< 0.01), acidosis (53,22%;p< 0.01), and posthemorrhagic anemia (43,14%;p< 0.01) than the MnCOV cohort. M+COV patients seem to progress to mortality more quickly than MnCOV patients (p=0.01, see Figure 1).

Figure 1. Survival until all-cause mortality after mucormycosis diagnosis, 0-180 days, among patients with (M+COV) and without (MnCOV) COVID-19 preceding the infection.



Conclusion. This study found that patients in the US with mucormycosis and current or previous COVID-19 infection have a greater prevalence of underlying conditions, including diabetes, and more rapid progression to mortality than those