60.0, 90.0) vs placebo (P < 0.001) (Table). Adverse events occurred in 35% and 34% of participants administered AZD7442 and placebo, respectively, and injection site reactions occurred in 2.4% and 2.1% of participants, respectively (safety analysis set). There was 1 case of severe COVID-19 and 2 COVID-19–related deaths in the placebo arm.

**Table. Primary efficacy endpoint results: first SARS-CoV-2 RT-PCR-positive symptomatic illness—censored at unblinding and/or receipt of any COVID-19 preventive product (full pre-exposure analysis set)**

| Treatment     | Median Days to First Illness | (95% CI) |
|---------------|-----------------------------|----------|
| AZD7442 (N=2441) | 8.0 (2.0)                  | 17.0 (1.0) |
| Placebo (N=1731)  |                            |          |

P-value = < 0.001

CI, confidence interval; RRR, relative risk reduction; RT-PCR, real-time polymerase chain reaction

The full pre-exposure analysis set included all study participants in the full analysis set (all randomized participants who received ≥1 dose of AZD7442 or placebo) without prior confirmed SARS-CoV-2 RT-PCR-positive infection.

**Conclusion.** The primary study endpoints were met: a one-time dose of AZD7442 demonstrated statistically significant protection against symptomatic COVID-19 and was well tolerated. AZD7442 is the first long-acting monoclonal antibody combination that represents a potential new option to augment COVID-19 prevention.

**PROVENT funding statement image**

**Funding statement**

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**LB5. PROVENT: Phase 3 Study of Efficacy and Safety of AZD7442 (Tixagevimab/Cilgavimab) for Pre-exposure Prophylaxis of COVID-19 in Adults**

**Authors:** Myron J. Levin, MD, MBA; Auworth Stiawanowski, MBBS; Vir/GlaxoSmithKline (Advisor or Review Panel member) Stéphane De Wit, MD, PhD, Gilead (Grant/Research Support) Janssen (Grant/Research Support)/Merck Sharpe & Dohme (Grant/Research Support)/ViiV Healthcare (Grant/Research Support) Odile Launay, MD, PhD, AstraZeneca (Grant/Research Support/GlaxoSmithKline [Consultant, Grant/Research Support, Other Financial or Material Support, Safety data monitoring board]) Johnson & Johnson (Consultant, Grant/Research Support)/Moderna (Consultant/Pfizer [Consultant, Grant/Research Support])/Sanofi Pasteur (Consultant, Grant/Research Support) Miles Avila, MPH, GStat, AstraZeneca (Employee, Shareholder) Seth Stegohin, PhD (Employee, Shareholder) Alison Templeton, PhD, AstraZeneca (Employee, Shareholder) Yuan Yuan, PhD, AstraZeneca (Employee, Shareholder) Philip Ambery, FRCP, AstraZeneca (Employee, Shareholder) Rosalinda H. Arends, PhD, AstraZeneca (Employee, Shareholder) Rohini Beavon, PhD, AstraZeneca (Employee, Shareholder) Karen A. Near, MD, AstraZeneca (Employee, Shareholder) Kelly W. Padilla, PharmD, AstraZeneca (Employee, Shareholder) Konstantina Psachoulia, PhD, AstraZeneca (Employee, Shareholder) Audrey Shaarbaugh, PhD, AstraZeneca (Employee, Shareholder) Katie Streicher, PhD, AstraZeneca (Employee, Shareholder) Menelas N. Pangalos, PhD, AstraZeneca (Employee, Shareholder) Mark T. Esser, PhD, AstraZeneca (Employee, Shareholder) Robert A. Gasser, Jr., MD, AstraZeneca (Employee, Shareholder) Subhash Sudharshan, PhD, AstraZeneca (Employee, Shareholder)

**Background.** Vaccines effectively prevent COVID-19, but some individuals have medical comorbidities or receive therapies that impair their immune response to vaccination, or are ineligible for vaccination. For such individuals who remain at risk of COVID-19, monoclonal antibodies may provide additional rapid protection. AZD7442 comprises 2 fully human extended half-life SARS-CoV-2–neutralizing antibody fragments that target distinct epitopes of the viral spike protein receptor binding domain. AZD7442 is in development for the prevention and treatment of COVID-19. Here, we report primary Phase 3 study results of AZD7442 for pre-exposure prophylaxis of symptomatic COVID-19.

**Methods.** PROVENT (NCT04625725) is a Phase 3, 2:1 randomized, double-blind, placebo-controlled study of a single 300-mg AZD7442 dose (2 intramuscular injections; 150 mg each of tixagevimab and cilgavimab) for symptomatic COVID-19 prevention. Participants were unvaccinated adults (≥18 years old) without prior SARS-CoV-2 infection, who may benefit from immunoprophylaxis with antibodies due to the increased risk of either inadequate response to vaccination on SARS-CoV-2 exposure. The primary study endpoints were first case of SARS-CoV-2 RT-PCR-positive symptomatic illness and dose prior to Day 183 (efficacy), and safety of AZD7442.

**Results.** In total, 3,517 participants (mean age 53.5 years, 46% female) were randomized and dosed (safety analysis set: AZD7442 n=3460; placebo n=1737). In the primary efficacy analysis (full pre-exposure analysis set, n=5172), AZD7442 reduced the risk of developing symptomatic COVID-19 by 77% (95% confidence interval

**Session:** 55. Late Breaker Abstracts: COVID-19 Treatment & Prophylaxis

**Thursday, September 30, 2021: 6:15 PM**

**LB11. Preliminary Findings from a HIV Self-Testing Program among People Who Use Drugs**

**Authors:** Michelle Rose, MBA;1 Laura Guy, BS, CCRP;2 Steve Shamblen, PhD;3 Greg Guest, PhD;3 Adam Gilbertson, DPhil;2 Nicholas Peiper, PhD, MPH;2 Norton Healthcare, Louisville, KY; Pacific Institute for Research and Evaluation, Louisville, Kentucky; University of Louisville, Louisville, Kentucky

**Session:** 132. Late Breaker Abstracts

**Saturday, October 2, 2021: 1:15 PM**

**Background.** People who use drugs (PWUD) remain at significantly high risk for HIV infection. It is estimated that the majority of all new HIV infections are through injection drug use, with an estimated 2,500 new infections occurring annually among people who inject drugs. Although new HIV infections have been quickly rising over the past year, the Center for Disease Control and Prevention (CDC) preliminarily reported a 50% to 70% intra-seasonal decline in HIV testing. Within Kentucky, an ultra-high-risk state, multiple health departments reported all HIV testing stopped during the early stages of the COVID-19 pandemic (March-July 2020). Once testing resumed, appointments were sparse.
Methods. To address low rates of HIV testing among PWUD, we evaluated the acceptability of a HIV self-testing program (OraQuick In-Home HIV Test by OraSure Technologies, Inc.) implemented at a health department in Louisville, Kentucky that services PWUD. Descriptive statistics were calculated for testing location, testing self-efficacy, reasons and motivations, ease of use, and preferences for future services.

Results. From May to June 2021, a total of 258 PWUD engaged with the program (average of 18 per day). Most participants (87.8%) self-tested at the health department with the help of study staff, while the other 12.2% tested at home and returned at a later time. Approximately 77% of participants reported the self-test kit made them feel better about their HIV status compared to standard testing methods. The most common reasons for testing were wanting to know their status (85%), the test was free (37%), fast results (31%), more privacy (23%), and recent high-risk drug use and sexual behaviors (17%). Virtually all (97%) reported the test kits were very easy to use. For future availability of self-test kits through the health department, 33% reported they would use them monthly, 28% every three months, 22% every six months, and 17% annually. In terms of preference for future testing modality, 72% indicated a preference for taking the kits home, while the other 28% indicated a desire to test at the health department with help from staff.

Conclusion. Program participants found the self-test kits to be acceptable and easy to use. Implications for program implementation and future research will be discussed.

Disclosures. Michelle Rose, MBA, Gilead Sciences Inc. (Grant/Research Support) Laura Guy, BS, CCRC, GILEAD Sciences (Grant/Research Support, Research Grant or Support)

LB12. Exebacase Shows Rapid Symptom Resolution in a Phase 2 Study in Adult Patients with Staphylococcus aureus bacteremia

Cara Cassino, MD, Anita F. Das, PhD, Joy Lipka, MS,1 ContraFect Corporation, Yonkers, NY; 1AD Stat Consulting, Guerneville, CA; Lipka Consulting, Mullica Hill, New Jersey

Session: 132. Late Breaker Abstracts Saturday, October 2, 2021: 1:15 PM

Background. Exebacase (EXB), a recombinantly-produced lysin (cell wall hydrolase), is the first direct lytic agent to advance into Phase 3 of clinical development for the treatment of bacteremia including infective endocarditis due to Staphylococcus aureus. The microbiologic attributes of EXB, including pathogen-targeted rapid bacteriolysis, and biofilm eradication are distinct from and synergistic with those of traditional antibiotics and underpin the therapeutic potential for EXB.

Methods. The Phase 2 trial was a randomized, double-blind, placebo-controlled multinational study. Patients were randomized (2:1) to receive a single 2-hour infusion of EXB or placebo (PBO) in addition to standard of care antibiotics. Time to resolution of symptoms (shortness of breath, sweating, fatigue and confusion) attributable to the bacteremia was analyzed using Kaplan-Meier methods. Time to resolution was defined as the number of days until all attributable symptoms were absent. If a new (not present at baseline) attributable symptom was present before the baseline symptoms resolved, this new symptom also had to be absent for symptoms to be considered resolved.

Results. A total of 86 patients (53 EXB and 33 PBO) had at least one attributable symptom present at baseline. Of these, symptoms resolved in 94.3% and 87.9% of EXB and PBO patients, respectively. The median time to resolution was 3 days for EXB and 6 days for PBO patients. Median days to symptom resolution in the MRSA group was 3 and 7 days for EXB and PBO patients, respectively, and 3 and 5 days for EXB and PBO patients in the MSSA group, respectively. Time to symptom resolution in MRSA patients is presented in Figure 1.

![Figure 1. Time to Resolution of Symptoms in Patients with MRSA Bacteremia including Infective Endocarditis](image)

Conclusion. The majority of EXB and PBO patients had symptom resolution. However, EXE patients achieved symptom resolution in 3 days compared with 6 days for PBO patients overall, and 7 days for PBO patients with MRSA. These data suggest that rapid bacteriolysis may translate to a clinical benefit for patients receiving EXB and align with a median length of hospital stay of 6 and 10 days among US MRSA patients that received EXE and PBO patients, respectively. (Fowler, et al, 2020).

Disclosures. Cara Cassino, MD, ContraFect Corporation (Employee) Anita F. Das, PhD, Adagio (Consultant)2 AN2 (Consultant)Cidara (Consultant)ContraFect (Consultant)Iberum (Consultant)MicrRx (Consultant)Paratek (Consultant)Union (Consultant)Joy Lipka, MS, ContraFect Corporation (Consultant)