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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

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Session: 55. Late Breaker Abstracts: COVID-19 Treatment & Prophylaxis
Thursday, September 30, 2021: 6:15 PM

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 antibodies that bind 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 an increased risk of either inadequate response to vaccination or SARS-CoV-2 exposure. The primary study endpoints were first case of SARS-CoV-2 RT-PCR-positive symptomatic illness post dose and prior to Day 183 (efficacy), and safety of AZD7442.

Results. In total, 5197 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 46.0, 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/critical 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)

	AZD7442 (N=3441)	Placebo (N=1731)
n (%)	8 (0.2)	17 (1.0)
RRR (95% CI)	77% (46.0, 90.0)	
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

AZD7442 is being developed with support from the US Government, including federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority in partnership with the Department of Defense; Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, under Contract No. W911QY-21-9-0001.

Disclosures. **Myron J. Levin, MD**, **GSK group of companies** (Employee, Research Grant or Support) **Andrew Ustianowski, MBBS**, **Vir/GlaxoSmithKline** (Advisor or Review Panel member) **Stéphane De Wit, MD**, **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, Data safety 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 Seegobin, PhD**, **AstraZeneca** (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 Sharbaugh, 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)

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

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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-pandemic 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.