Efficacy, Safety, and Pharmacokinetics of AZD7442 (Tixagevimab/Cilgavimab) for Prevention of Symptomatic COVID-19: 15-Month Final Analysis of the PROVENT and STORM CHASER Trials

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PROVENT and STORM CHASER phase 3 trials assessed AZD7442 (tixagevimab/cilgavimab) for prevention of symptomatic COVID-19

PROVENT: Pre-exposure prophylaxis

Predicted to be poor vaccine responders or at increased SARS-CoV-2 exposure risk

Participants

STORM CHASER: Post-exposure prophylaxis

Potential exposure within 8 days to an individual with SARS-CoV-2 infection

Randomized 2:1

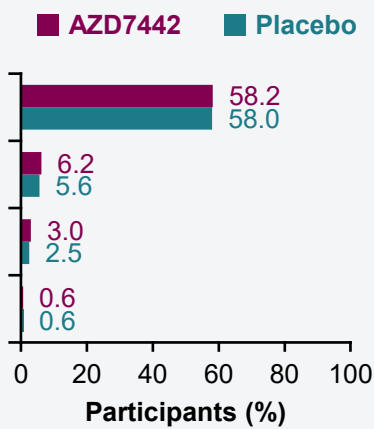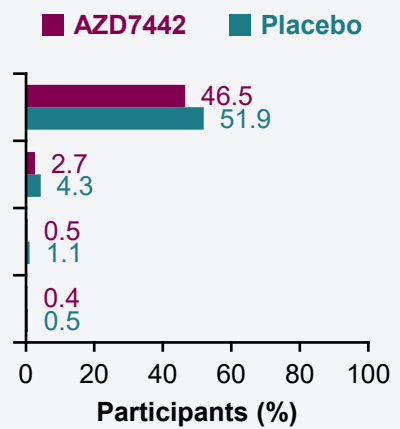**AZD7442** (single 300-mg IM dose) *N* = 3460 — **Placebo** *N* = 1737

Randomized 2:1

AZD7442 (single 300-mg IM dose) *N* = 749 — **Placebo** *N* = 372

Safety of AZD7442 was similar to placebo over 15 months

PROVENT

	AZD7442	Placebo
AEs	58.2	58.0
SAEs	6.2	5.6
AESIs	3.0	2.5
Deaths	0.6	0.6

Participants (%)

STORM CHASER

	AZD7442	Placebo
AEs	46.5	51.9
SAEs	2.7	4.3
AESIs	0.5	1.1
Deaths	0.4	0.5

Participants (%)

AZD7442 as pre-exposure prophylaxis protected against symptomatic and severe COVID-19

PROVENT

Primary analysis	Day 183	Day 366
76.7%**	83.0%**	46.3%**

91.4% RRR in severe/critical COVID-19 by day 366[a]

RRR in symptomatic COVID-19 versus placebo

STORM CHASER

Primary analysis	Day 183	Day 366
33.3%	43.3%*	3.4%

70.2% RRR at day 183 (participants with a negative or missing SARS-CoV-2 RT-PCR status at baseline)

*p <0.05, **p < 0.001
AE adverse event, *AESI* AE of special interest, *COVID-19* coronavirus disease 2019, *RRR* relative risk reduction, *RT-PCR* reverse transcription-polymerase chain reaction, *SAE* serious AE, *SARS-CoV-2* severe acute respiratory syndrome coronavirus 2
[a]Endpoint not assessed in STORM CHASER due to too few events

Adis