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Results from the Phase 2/3 Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Adintrevimab (ADG20) in the Treatment of Ambulatory Participants with Mild or Moderate COVID-19 (STAMP)

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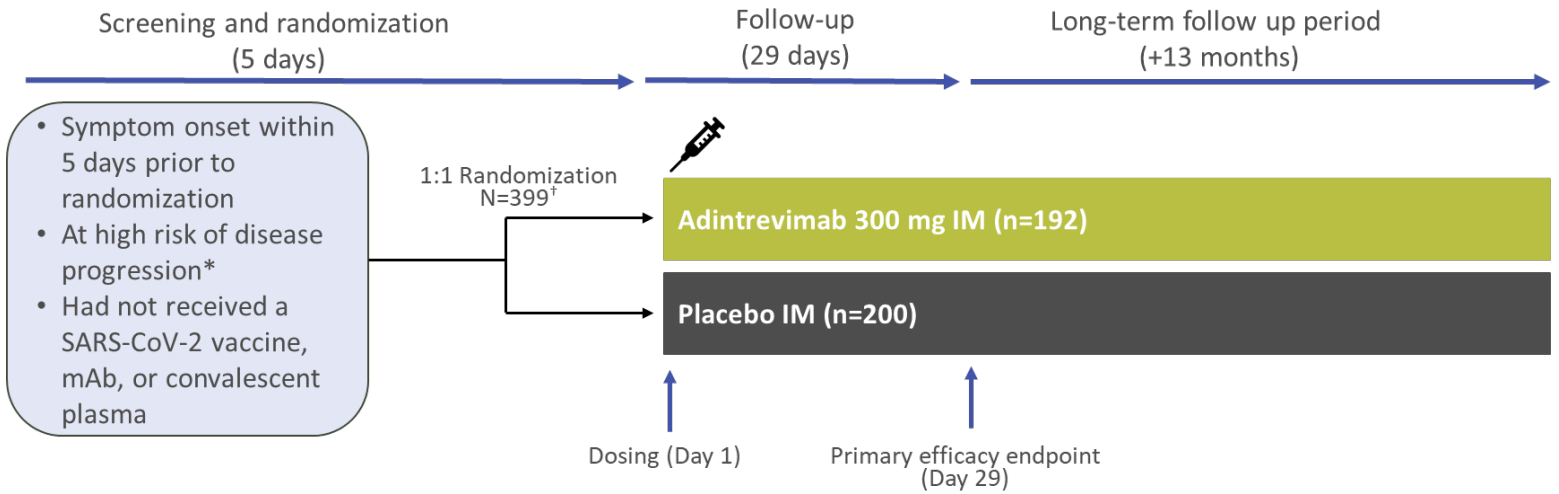
Adintrevimab (ADG20), a monoclonal antibody designed to target the SARS-CoV-2 spike protein, is being evaluated for the treatment and prevention of COVID-19

- Adintrevimab was derived from a survivor of the 2003 SARS-CoV epidemic and designed to possess high potency and broad neutralization against SARS-CoV, SARS-CoV-2, and preemergent SARS-like CoVs[1-4]
- Binds to an epitope in the RBD of the spike glycoprotein that partially overlaps the ACE2 binding site and has potential to prevent viral entry into human ACE2 cells[2,5]
- Contains an Fc modification designed to extend the half-life (median of 123 days)[2,5-6]

The STAMP trial (NCT04805671) is evaluating the safety and efficacy of adintrevimab as a potential treatment for mild or moderate COVID-19 in ambulatory patients with a high risk of disease progression based on age or comorbidities



Primary endpoints

Clinical Efficacy (non-Omicron population)[a]
- Proportion of participants with a COVID-19-related hospitalization or all cause death through Day 29

Safety and tolerability:
- Treatment emergent adverse events
- Changes from baseline in vital signs and safety laboratory
- Solicited injection site reactions (through Day 4)

Secondary endpoints

Virologic Efficacy (non-Omicron)
- Change from baseline in viral load to Days 5 and 7 (assessed by RT-qPCR from saliva samples)

Fc, fragment crystallizable; IM, intramuscular; LTFU, long-term follow-up; mAb, monoclonal antibody.*At high risk defined as age >55 years or age ≤55 years with one or more preexisting medical condition: obesity, diabetes, chronic kidney disease, chronic lung disease, cardiac disease, sickle cell disease or thalassemia, solid organ or blood stem cell transplant recipients, other immunodeficiency due to underlying illness or immunosuppressant medication, Down Syndrome, stroke or cerebrovascular disease, substance use disorder, pregnant. †7 patients were not dosed. [a]Non-omicron population definition refer to footnote slide 3

1. Wec AZ, et al. Science. 2020;369:731-736. 2. Rappazzo CG, et al. Science. 2021;371:823-829. 3. Kaku C, et al. ECCMID 2021. Abstract 647. 4. Data on File ADG-DOF-006. 5. Adagio Therapeutics. Investigator's Brochure. 2021. 6. Rubino CM, et al. ECCMID 2022. Presentation P2162.

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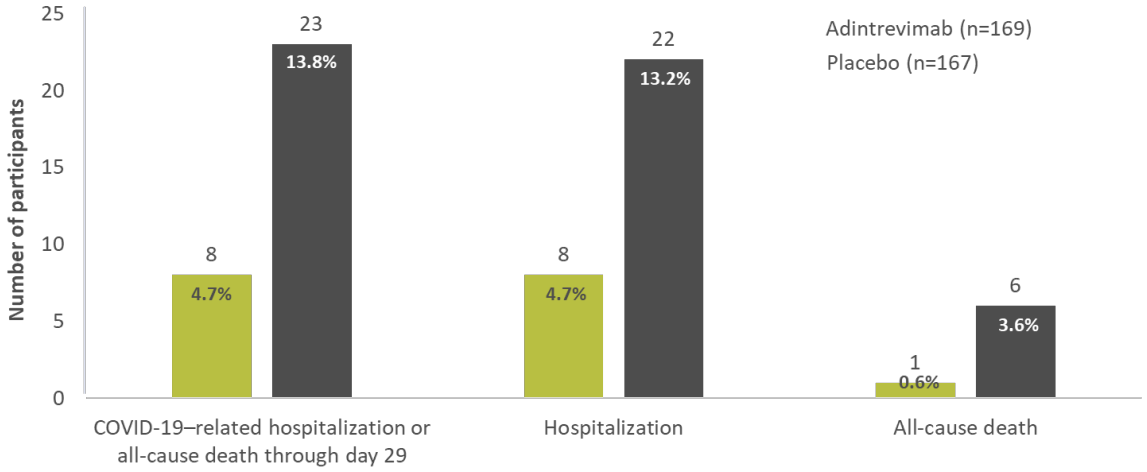
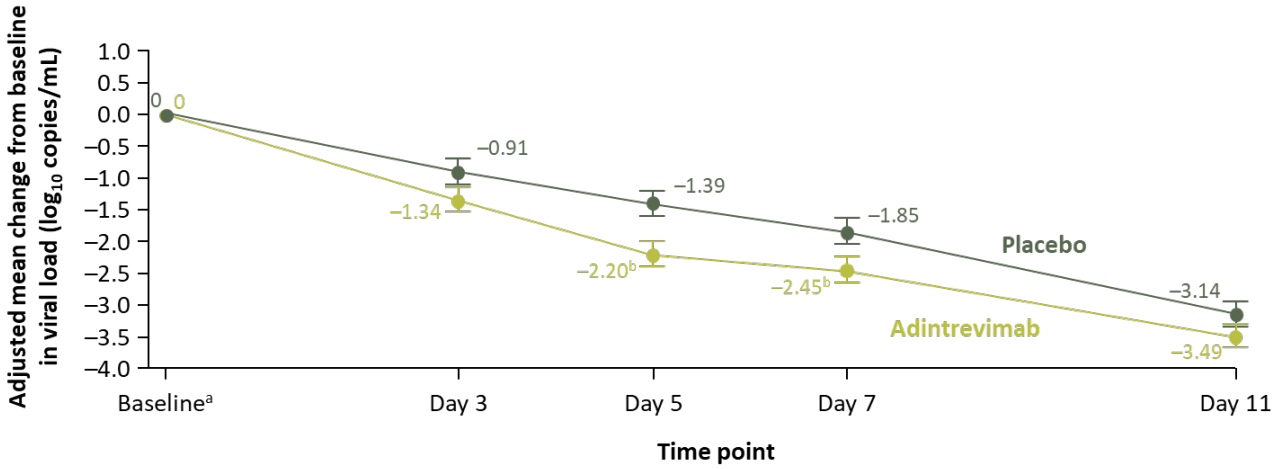
Adintrevimab met the trial's primary objective with relative risk of hospitalization or death reduced by 66% compared to placebo among non-Omicron population

COVID-19–related hospitalization or all-cause death through day 29 (non-Omicron mFAS)



Adjusted mean change from baseline in SARS-CoV-2 viral load (log_{10} copies/mL) assessed by RT-qPCR from saliva samples for non-Omicron population



The bars represent standard error. [a]Baseline is defined as last non-missing measurement prior to dosing. [b]*P*<0.05.

- Non-Omicron primary population:
  - 66% Relative Risk Reduction
  - Standardized risk difference (primary efficacy analysis) between adintrevimab and placebo groups was -8.7 (-14.71, -2.67), *P*=0.0047
- Omicron population: adintrevimab n=29, placebo n=34
  - 2 events of COVID-19 related hospitalization (both in placebo group) and no deaths through 29 days

- Adintrevimab provided greater reduction in viral load from baseline to Day 5, adjusted least square means difference of -0.81 (95% CI: -1.325, -0.301) in favor of adintrevimab (*P*=0.002)
- Statistical difference in change from baseline was maintained at Day 7

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Non-Omicron Population: Whole-Genome Sequencing (WGS) was used to determine a participant's SARS-CoV-2 infecting variant (Delta, Omicron, and others) based on the NP or saliva sample collected at baseline; if baseline result was missing, available WGS data from post-baseline NP or saliva sample was used. Any participants with a missing WGS result were classified as suspected non-Omicron or Omicron variant by comparing their randomization date with the date of the first WGS-confirmed Omicron participant enrolled from the same country. If there is no WGS-confirmed Omicron participant enrolled from the same country in the study, the date of emergence of Omicron in the country, based on publicly available epidemiology data were used

Safety data and conclusions

Participants with any	Adintrevimab N=192 n (%)	Placebo N=200 n (%)	Overall N=392 n (%)
Any TEAE	**51 (26.6)**	**72 (36.0)**	**123 (31.4)**
Unsolicited TEAE	36 (18.8)	56 (28.0)	92 (23.5)
Solicited TEAE (Injection Site Reactions)	25 (13.0)	20 (10.0)	45 (11.5)
Study Drug-Related TEAE	26 (13.5)	20 (10.0)	46 (11.7)
Any SAE	**12 (6.3)**	**28 (14.0)**	**40 (10.2)**
Non-COVID-19 SAE	5 (2.6)	7 (3.5)	12 (3.1)
Study Drug-Related SAE	0	0	0
SAEs Leading to Death	1 (0.5)	7 (3.5)	8 (2.0)

Conclusions

- A single dose of adintrevimab 300 mg IM provided a statistically significant reduction in the risk of COVID-19 related hospitalization or all-cause death through Day 29 when compared to placebo in high-risk ambulatory patients with mild to moderate COVID-19 in the non-omicron population
- Adintrevimab had a similar safety profile to placebo; the most common adverse events were solicited injection site reactions

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Safety Data Cut-Off Date: 28 March 2022, Median follow-up was 125 days at time of safety data cut off