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## 226. Higher Doses of Adintrevimab, an Extended Half-Life Monoclonal Antibody, for the Treatment and Prevention of COVID-19: Preliminary Results from a Phase 1 Single Ascending-Dose Study

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***Background.*** Adintrevimab is a fully human IgG1 monoclonal antibody engineered to have potent and broad neutralization against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and other SARS-like CoVs with pandemic potential. Adintrevimab is being assessed in two separate phase 2/3 clinical trials: the EVADE trial for prevention of COVID-19 in both post-exposure and pre-exposure settings and the STAMP trial for treatment of COVID-19. Here we report higher doses being evaluated in a healthy volunteer study given that emerging variants may have varying susceptibilities to adintrevimab. Previous results 300 mg IM, 600 mg IM, and 500 mg IV cohorts have been reported.

***Methods.*** This is an ongoing Phase 1, randomized, placebo (PBO)-controlled, single ascending-dose study of adintrevimab administered intramuscularly (IM) or intravenously (IV) to healthy adults aged 18–50 years with no current SARS-CoV-2 infection. Participants were randomized 8:2 in 3 high dose cohorts (N=10/cohort: n=8 adintrevimab, n=2 PBO): adintrevimab 1200 mg IM, 1200 mg IV, and 4500 mg IV. Safety, tolerability, and pharmacokinetics (PK) were assessed up to 21 days post dose.

***Results.*** Overall, 30 participants received adintrevimab (n=24) or PBO (n=6). Blinded safety data for all cohorts and PK for 1200 mg IV are reported. Through 21 days post dose all doses were well-tolerated, with no study drug-related adverse events (AEs), serious AEs, injection site reactions, or hypersensitivity reactions reported. The observed PK profile of the 1200 mg IV dose included Cmax of 423±105 μg/ml. Comparison of 500 mg and 1200 mg IV doses indicate dose proportionality of Cmax and exposure (AUC Day 21).

***Conclusion.*** A single dose of adintrevimab, up to 4500 mg, was well tolerated. These preliminary safety data and PK support potential use of higher doses of adintrevimab as needed to address emerging SARS-CoV-2 variants.

***Disclosures.*** **Xia Pu, PhD**, Adagio Therapeutics: Employee|Adagio Therapeutics: Stocks/Bonds **Jean Gong, PhD**, Adagio Therapeutics: Employee|Adagio Therapeutics: Stocks/Bonds **Ed Campanaro, BSN, MSHS**, Adagio Therapeutics: Employee|Adagio Therapeutics: Stocks/Bonds **Kristin Narayan, PhD**, Adagio Therapeutics: Employee|Adagio Therapeutics: Stocks/Bonds **Deepali Gupta, B.Sc**, Adagio Therapeutics: Employee|Adagio Therapeutics: Stocks/Bonds **Frank Engler, PhD**, Adagio Therapeutics: Advisor/Consultant **Amanda Copans, PharmD**, Adagio Therapeutics: Employee|Adagio Therapeutics: Stocks/Bonds **Pete Schmidt, MD**, Adagio Therapeutics: Employee|Adagio Therapeutics: Stocks/Bonds.