

# PHASE 3 TRIAL OF INVESTIGATIONAL GENE THERAPY FOR HEMOPHILIA A HAS RESUMED DOSING

**Brisbane, California, November 16, 2022** – Dosing has resumed in the Phase 3 AFFINE study evaluating giroctocogene fitelparvovec, an investigational gene therapy for patients with moderately severe to severe hemophilia A. Dosing resumed on November 10, 2022. All trial sites are anticipated to be active by the end of 2022 and a pivotal readout is expected in the first half of 2024.

Giroctocogene fitelparvovec is being developed as part of a collaboration agreement for the global development and commercialization of gene therapies for hemophilia A between Sangamo Therapeutics and Pfizer Inc. In late 2019, Sangamo transferred the manufacturing technology and the Investigational New Drug (IND) application to Pfizer.

## About the AFFINE Study

The Phase 3 AFFINE (NCT04370054) study is an open-label, multicenter, single arm study to evaluate the efficacy and safety of a single infusion of giroctocogene fitelparvovec in more than 60 adult (ages 18-64 years) male participants with moderately severe to severe hemophilia A. Eligible study participants will have completed at least six months of routine FVIII prophylaxis therapy during the lead-in Phase 3 study (NCT03587116) in order to collect pretreatment data for efficacy and selected safety parameters.

The primary endpoint is impact on annualized bleeding rate (ABR) through 15 months following treatment with giroctocogene fitelparvovec. This will be compared to ABR on prior FVIII prophylaxis replacement therapy. The secondary endpoints include FVIII activity level after the onset of steady state and through 15 months following infusion of giroctocogene fitelparvovec.

## About giroctocogene fitelparvovec

The U.S. Food and Drug Administration has granted Orphan Drug, Fast Track, and regenerative medicine advanced therapy (RMAT) designations to giroctocogene fitelparvovec, which also received Orphan Medicinal Product designation from the European Medicines Agency. Giroctocogene fitelparvovec is being developed as part of a collaboration agreement for the global development and commercialization of gene therapies for hemophilia A between Sangamo and Pfizer. In late 2019, Sangamo transferred the manufacturing technology and the IND application to Pfizer. Giroctocogene fitelparvovec is currently being studied in the Phase 3 AFFINE study.

## **About Sangamo Therapeutics**

Sangamo Therapeutics is a clinical-stage biopharmaceutical company with a robust genomic medicines pipeline. Using ground-breaking science, including our proprietary zinc finger genome engineering technology and manufacturing expertise, Sangamo aims to create new genomic medicines for patients suffering from diseases for which existing treatment options are inadequate or currently don't exist. To learn more, visit <u>www.sangamo.com</u> and connect with us on <u>LinkedIn</u> and <u>Twitter</u>.



## Disclosure Notice

This release contains forward-looking statements regarding Sangamo's current expectations. These forward-looking statements include, without limitation, statements regarding plans and timing regarding active trial sites in the Phase 3 AFFINE clinical trial, including expectations regarding the anticipated timing of data readouts for the Phase 3 AFFINE trial, and other statements that are not historical fact. These statements are not guarantees of future performance and are subject to risks and uncertainties that are difficult to predict. Sangamo's actual results may differ materially and adversely from those expressed in these forward-looking statements. Factors that could cause actual results to differ include, but are not limited to, risks and uncertainties related to: the evolving COVID-19 pandemic and its impact on the global business environment, healthcare systems and the business and operations of Sangamo and Pfizer, including the enrollment of patients and operation of clinical trials; the research and development process; the uncertain timing and unpredictable nature of clinical trial results, including the risk that therapeutic effects in the Phase 3 AFFINE trial will not be durable in patients; the unpredictable regulatory approval process for product candidates across multiple regulatory authorities; the manufacturing of products and product candidates; the commercialization of approved products; the potential for technological developments that obviate technologies used by Sangamo and Pfizer in giroctocogene fitelparvovec; the potential for Pfizer to terminate the giroctocogene fitelparvovec program or to breach or terminate its collaboration agreement with Sangamo: the potential for Sangamo to fail to realize its expected benefits of its collaboration with Pfizer; Sangamo's lack of resources to fully develop, obtain regulatory approval for and commercialize its product candidate, giroctocogene fitelparvovec; and other risks and uncertainties described in Sangamo's filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2021, as supplemented by Sangamo's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022. The information contained in this release is as of November 16, 2022, and Sangamo undertakes no duty to update forward-looking statements contained in this release except as required by applicable laws.

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