# PFIZER AND SANGAMO THERAPEUTICS ANNOUNCE PHASE 3 TRIAL OF INVESTIGATIONAL GENE THERAPY FOR HEMOPHILIA A HAS RE-OPENED RECRUITMENT

September 22, 2022

- *Patient dosing is expected to resume in October*

**New York, NY, and Brisbane, California, September 22, 2022 –** Pfizer and Sangamo Therapeutics announced that the Phase 3 AFFINE study evaluating giroctocogene fitelparvovec, an investigational gene therapy for patients with moderately severe to severe hemophilia A, has re-opened recruitment. Trial sites will begin to resume enrollment this month, with dosing expected to resume in October. 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.

**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 Investigational New Drug (IND) application to Pfizer. Giroctocogene fitelparvovec is currently being studied in the Phase 3 AFFINE study.

**About Pfizer: Breakthroughs That Change Patients' Lives**
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world.

For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

**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 www.sangamo.com and connect with us on LinkedIn and Twitter.

***Pfizer Disclosure Notice***
*The information contained in this release is as of September 22, 2022. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.*

*This release contains forward-looking information about an investigational hemophilia A therapy, giroctocogene fitelparvovec, including its potential benefits and the phase 3 AFFINE study, including anticipated timing of active trial sites, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; risks associated with interim data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications for any potential indications for giroctocogene fitelparvovec may be filed in any jurisdictions; whether and when regulatory authorities in any jurisdictions may approve any such applications, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether giroctocogene fitelparvovec will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of giroctocogene fitelparvovec; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.*

*A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.*

***Sangamo Therapeutics 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 the resumption of patient enrollment, expectations regarding the anticipated timing of dose resumption and 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 June 30, 2022. The information contained in this release is as of September 22, 2022, and Sangamo undertakes no duty to update forward-looking statements contained in this release except as required by applicable laws.*

Contact

Pfizer Media Contact
+1 (212) 733-1226
PfizerMediaRelations@Pfizer.com

Pfizer Investor Contact
+1 (212) 733-4848
IR@Pfizer.com

Sangamo Investor Relations & Media Contact
Louise Wilkie
ir@sangamo.com
media@sangamo.com