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Greenwich LifeSciences Announces Removal of Clinical Hold Permitting Phase III Clinical Trial to Proceed

STAFFORD, Texas--(BUSINESS WIRE)-- Greenwich LifeSciences, Inc. (Nasdaq: GLSI) (the "Company"), a clinical-stage biopharmaceutical company focused on the development of GLSI-100, announced that the Food and Drug Administration (FDA) has removed the clinical hold permitting the Flamingo-01 Phase III clinical trial to proceed.

As previously announced, the Phase III clinical trial was placed on clinical hold by the FDA related to manufacturing and the pharmacy process. The Company through discussions with the FDA and testing of GP2 in the pharmacy process has satisfactorily addressed the clinical hold issues. The Company has committed to additional testing of GP2 in the pharmacy process. On July 11, 2022, the FDA formally removed the clinical hold and thus the Flamingo-01 Phase III clinical trial may proceed as planned. The Company has begun site initiation visits and will provide further updates on the progress of Flamingo-01 in the future.

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