



Latitude Pharmaceuticals Receives Notice of Allowance for U.S. Patent Covering the ClearSol™ Platform for Aqueous Formulation of Insoluble Drugs

SAN DIEGO, CALIFORNIA, October 17, 2022 - LATITUDE Pharmaceuticals Inc., a specialized formulation developer and GMP manufacturer for the biotech and pharma industries, has received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) related to its patent application covering ClearSol™, Latitude's highly efficient yet safe platform for the solubilization of challenging drugs.

"We are pleased the USPTO has recognized the novelty and pharmaceutical utility of our unique approach for achieving aqueous solutions of otherwise insoluble drugs," noted Andrew X. Chen, LATITUDE's President. "ClearSol™ has proven in the hands of multiple evaluators to solubilize a broader range of drugs, and in most cases to a greater concentration, than cyclodextrins. Furthermore, with ClearSol™'s ease of use and established safety, drug development can bypass the formulation stage and proceed directly to animal and human testing, greatly reducing both the time and cost of the pre-IND phase."

About ClearSol™

ClearSol™ forms stable, one-phase aqueous solutions with about 80% of insoluble drugs tested, which is much greater than achieved by other solubilizers such as cyclodextrins (e.g., sulfobutyl-ether-beta-cyclodextrin, hydroxypropyl-beta-cyclodextrin), polysorbates, and organic solvents. Furthermore, ClearSol™ formulations can be freely diluted in water or IV infusion fluids without precipitation of drug, and can be sterile-filtered through standard 0.2-micron filters. ClearSol™ is made up of three Generally Regarded As Safe (GRAS) pharmaceutical excipients that are each FDA-approved for injection, and safety of the ClearSol™ technology has been demonstrated in a U.S. Phase 1 human clinical trial under an FDA-approved IND. More information regarding ClearSol™ can be found at <https://latitudepharma.com/>.

About LATITUDE Pharmaceuticals Inc.

A small and highly customer-responsive CDMO, LATITUDE is a recognized leader in the development of innovative drug formulations and drug delivery systems for the biopharmaceutical industry. The company is highly regarded for its intellectual property portfolio and innovative approaches to developing pharmaceutical formulations for problematic and/or



highly insoluble drug molecules. LATITUDE also provides GMP manufacturing of pharmaceutical formulations for Phase 1 and Phase 2 clinical trials.

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