

Process Enablement of COVID-19 Oral inhibitor PF-07321332 at unprecedented speed: from mg to MT in 18 months

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Shortly after the COVID-19 pandemic was declared in March 2020 by the WHO, Pfizer initiated a multi-front approach to combat the virus, which included the vaccine but also recognized very early the need for an orally dosed treatment able to help infected patients. This initiative resulted in the discovery of PF-07321332 from the Groton labs, the first SARS-CoV-2-specific protease inhibitor treatment available under emergency use by the FDA. I will share the story of this API, from its initial milligram quantities in Summer 2020 to metric tons supplied in late 2021 and into 2022. The presentation will disclose the different routes we developed to manufacture clinical lots as well as the design of the final commercial process. How the team managed to dramatically accelerate to deliver this new therapy at unprecedented speed, along with the challenges encountered along the way will also be discussed.

