Pfizer Logo

Pfizer and Clear Creek Bio to Collaborate on a Research Program Targeting SARS-CoV-2 Papain-Like Protease

Tuesday, December 06, 2022 - 06:45am

- *Agreement aims to advance discovery and development of novel papain-like protease (PLpro) inhibitors and potentially introduce a new class of oral antivirals in the fight against COVID-19*
- *Expands Pfizer's innovative anti-infective pipeline, complementing the company's existing portfolio of COVID-19 products*

NEW YORK & CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and Clear Creek Bio, Inc. today announced a research collaboration and exclusive license agreement to advance the discovery and development of potential inhibitors of the SARS-CoV-2 papain-like protease (PLpro) for the oral treatment of COVID-19. PLpro is an essential enzyme, which, along with the main protease (Mpro), plays an important role in viral replication. This program will expand Pfizer's innovative anti-infective pipeline and, if successful, will complement Pfizer's existing portfolio of COVID-19 products with direct-acting antiviral agents against different SARS-CoV-2 targets.

This press release features multimedia. View the full release here:
https://www.businesswire.com/news/home/20221206005107/en/

"COVID-19 has proven to be a devastating and highly unpredictable disease, one with the potential to remain a global health concern for years to come," said Charlotte Allerton, Chief Scientific Officer, Anti-Infectives and Head of Medicine Design, of Pfizer. "It is critical that we try to stay ahead of the virus, continuing to advance clinical development opportunities for our current oral therapy as well as innovating through our internal programs and strategic partnerships to bring forward additional monotherapy and/or combination treatment candidates that we believe may play a role in the ongoing fight against COVID-19."

"As COVID-19 continues to evolve, there is a significant need for oral antivirals with novel mechanisms of action," said Vikram Sheel Kumar, M.D., Chief Executive Officer of Clear Creek Bio. "We explored the druggable SARS-CoV-2 genome and identified PLpro as a promising and untapped target. Leveraging our team's expertise and success in bringing novel drugs from idea to approval, we internally developed highly potent PLpro inhibitors. We look forward to working with Pfizer, a global leader in antiviral development, to advance a new class of oral antivirals for COVID-19."

Under the terms of the agreement, the two companies will work together to identify a PLpro candidate to progress into the clinic, at which time Pfizer will be solely responsible for further development and commercialization activities. Clear Creek Bio will receive an undisclosed upfront payment and will be eligible to receive additional potential milestone payments plus royalties on future product sales.

About SARS-CoV-2 PLpro
SARS-CoV-2 has two essential proteases, the main protease (Mpro) and the papain-like protease (PLpro), both

required to fully process the viral polyprotein and assemble a functional replicase complex. In addition to its critical role in viral replication, the PLpro also contributes to dysregulation of host innate immunity and immune evasion.

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.

Pfizer Disclosure Notice
The information contained in this release is as of December 6, 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 a research collaboration and exclusive license agreement between Pfizer and Clear Creek Bio to advance the discovery and development of potential inhibitors of the SARS-CoV-2 papain-like protease (PLpro) for the oral treatment of COVID-19, Pfizer's oral therapy for COVID-19, and Pfizer's innovative anti-infective pipeline, including their potential benefits, 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 clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data (including the data discussed in this release), including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the ability to produce comparable clinical or other results including efficacy, safety and tolerability profile observed to date, in additional studies or in larger, more diverse populations following commercialization; the ability of Pfizer's current oral therapy for COVID-19 to maintain efficacy against emerging virus variants; the risk that serious and unexpected adverse events may occur that have not been previously reported with use of Pfizer's current oral therapy for COVID-19; the risk that preclinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from these and any future preclinical and clinical studies; whether and when applications may be filed in any jurisdictions for any potential indications for any candidates resulting from the collaboration or any drug applications or submissions to request emergency use or conditional marketing authorization for any potential indications for Pfizer's current oral therapy for COVID-19 may be filed in particular jurisdictions and if obtained, whether or when such emergency use authorization or licenses will expire or terminate; whether and when regulatory authorities in any jurisdictions may approve any such applications for any candidates resulting from the collaboration or applications or submissions for Pfizer's current oral therapy for COVID-19 that may be pending or filed, 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 any candidates resulting from the collaboration will be commercially successful; decisions by regulatory authorities impacting labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of any candidates resulting from the collaboration or Pfizer's current oral therapy for COVID-19, including development of products or therapies by other companies; risks related to the availability of raw materials for Pfizer's current oral therapy for COVID-19; the risk that we may not be able to create or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand, which would negatively impact our ability to supply the estimated numbers of courses of Pfizer's current oral therapy for COVID-19 within the projected time periods; whether and when additional purchase agreements will be reached; the risk that demand for any products may be reduced or no longer exist which may lead to reduced revenues or excess inventory; whether our collaboration with Clear Creek Bio will be successful; 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.

About Clear Creek Bio

Clear Creek Bio is a private biotechnology company focused on developing therapeutics for global unmet needs. Activities span in-house small molecule discovery through early clinical development. In addition to the PLpro program, Clear Creek Bio is evaluating brequinar, a potent oral inhibitor of dihydroorotate dehydrogenase (DHODH), in combinations with other therapeutics against a wide range of RNA viruses. For additional information, please visit www.clearcreekbio.com.

View source version on businesswire.com: https://www.businesswire.com/news/home/20221206005107/en/

Pfizer:

Media Relations
+1 (212) 733-1226
PfizerMediaRelations@pfizer.com

Investor Relations
+1 (212) 733-4848
IR@pfizer.com

Clear Creek Bio:

Company
Cindy Motaka
cmotaka@clearcreekbio.com

Media Relations
Jessica Yingling, Ph.D.
+1 (858) 344-8091

jessica@litldog.com

Source: Pfizer Inc.