Pardes Biosciences Presents Interim Clinical Data from Ongoing PBI-0451 Phase 1 Trial Supporting the Potential of PBI-0451 as a Stand-Alone Oral Regimen for COVID-19 at Conference on Retroviruses and Opportunistic Infections 2022

February 14, 2022

PBI-0451 administered twice-daily as a stand-alone agent achieves and maintains PK exposures anticipated to provide potent antiviral activity against SARS-CoV-2

PBI-0451 has been generally well-tolerated and has shown good oral bioavailability

Company to host conference call and webcast Tuesday, February 15, 2022 at 3:00 p.m. PT / 6:00 p.m. ET

CARLSBAD, Calif., Feb. 14, 2022 (GLOBE NEWSWIRE) -- Pardes Biosciences, Inc. (NASDAQ: PRDS), a clinical-stage biopharmaceutical company developing PBI-0451 as a potential novel direct-acting, oral antiviral drug candidate for the treatment and prevention of SARS-CoV-2 infections and associated diseases (i.e., COVID-19), announced that interim clinical data from its ongoing PBI-0451 Phase 1 trial in healthy adult volunteers has been made available to registered conference attendees at the 29th Conference on Retroviruses and Opportunistic Infections (CROI) 2022. The presentation entitled, “PBI-0451: An Orally Administered 3CL Protease Inhibitor of SARS-CoV-2 for COVID-19,” shared details around the nonclinical profile of PBI-0451 as well as interim clinical safety, tolerability, and pharmacokinetics (PK) after single- and multiple-ascending doses. Pardes will host a conference call and webcast on Tuesday February 15, at 3:00 p.m. PT / 6:00 p.m. ET to further discuss these results after the CROI late-breaker poster presentation, which is scheduled from 1:00 – 2:30 p.m. PT/ 4:00 -5:30 p.m. ET.

A presentation reviewing the non-clinical and preliminary interim clinical data presented at CROI 2022 can be found on Pardes’ website under “Events and Presentations.”

“We are highly encouraged by these initial Phase 1 observations, which support continued development of PBI-0451 as a potential stand-alone antiviral therapy for the treatment and prevention of SARS-CoV-2 infections,” said Uri A. Lopatin, M.D., Chief Executive Officer. “COVID-19 continues to take the lives of over 2,000 people a day in the United States alone and disrupts healthcare globally. Additional treatment options with the potential to treat current and emerging variants, such as protease inhibitors, continue to be needed. We are excited to continue advancing our lead protease inhibitor PBI-0451 and bring our novel oral antiviral treatment one step closer to patients in need.”

In the ongoing first in human Phase I trial, PBI-0451 has been observed to be generally well tolerated over a >20-fold single- and >14-fold multiple-total daily dose range. All treatment emergent adverse events in the study reported through January 31, 2022 have been assessed as mild in severity and resolved without intervention.

In a drug-drug interaction cohort, the pharmacokinetics of PBI-0451 was not substantially affected when co-administered with ritonavir, a potent P-glycoprotein/CYP450 3A inhibitor.

In multiple ascending dose cohorts, interim data showed that PBI-0451 twice-daily (BID; 2 x 350 mg tablets) achieved and maintained PK exposures that the company believes has the potential to provide potent antiviral activity against SARS-CoV-2 and emerging variants. Additional dose cohorts and PK evaluation in this ongoing Phase 1 study continues and will inform dose selection for the upcoming PBI-0451 Phase 2/3 study anticipated to start mid 2022 (pending regulatory interactions) to evaluate PBI-0451 as a potential treatment of SARS-CoV-2.

Conference Call and Webcast Details

Pardes Biosciences will host a conference call and webcast on Tuesday, February 15, 2022, at 3:00 p.m. PT / 6:00 p.m. ET to discuss the interim clinical data. Individuals interested in listening to the event may do so by dialing (855) 427-5533 for domestic callers, or (409) 220-9396 for international callers and reference conference ID: 5686644; or from the webcast link in the investors section of the company's website at: www.pardesbio.com. The webcast will be available in the investors section on the company's website for 30 days following the completion of the call.

About Pardes Biosciences, Inc.

Pardes Biosciences is a clinical-stage biopharmaceutical company created to help solve pandemic-sized problems, starting with COVID-19. We are applying modern reversible-covalent chemistry as a starting point to discover and develop novel oral drug candidates. For more information, please visit www.pardesbio.com.

About PBI-0451

PBI-0451, the company’s lead product candidate, is an investigational orally bioavailable direct-acting antiviral (DAA) inhibitor of the 3CL protease also called the main protease (Mpro), an essential protein required for the replication of coronaviruses, including the novel SARS-CoV-2 that causes COVID-19. This protease is highly conserved across all known coronaviruses, including emerging coronavirus variants. PBI-0451 is being developed for the treatment and prevention of SARS-CoV-2 infection and associated diseases (i.e., COVID-19). PBI-0451 is currently under evaluation in an ongoing Phase 1 placebo-controlled, blinded, randomized, dose escalation study in healthy adult volunteers in New Zealand evaluating the safety, tolerability, and pharmacokinetics of PBI-0451 after single and multiple ascending doses.

Availability of Other Information about Pardes Biosciences

Pardes Biosciences intends to use the Investors page of its website (https://ir.pardesbio.com) as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD (Fair Disclosure). Accordingly, investors should monitor Pardes Biosciences' Investors website, in addition to following Pardes' press releases, Securities and Exchange Commission filings, public conference calls, presentations and webcasts.

Forward-Looking Statements

The information in this press release contains forward-looking statements that are subject to certain risks and uncertainties that could cause actual results or events to materially differ. In some cases, you can identify forward-looking statements by the use of words, such as "anticipated," "potential" or "will" or the negative of these terms or other comparable terminology. Forward-looking statements in this press release include, but are not limited to, statements regarding the advancement of the company's product candidate, PBI-0451, the timing of reporting clinical data, the timing of future clinical trials, statements about the potential attributes and benefits of Pardes Biosciences' product candidate and the role of oral antivirals and protease inhibitors in addressing the pandemic and future pandemics. These forward-looking statements are subject to a number of significant risks and uncertainties that could cause actual results to differ materially from expected results, including, among others, development of competing therapeutic treatments for COVID-19 on Pardes Biosciences' business, results of nonclinical and early clinical studies may not be representative or predictive of the outcomes of on-going or future clinical studies, interim, "topline" and preliminary data from the company's clinical trials that it announces or publishes may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data, and/or other risks and uncertainties, including those included under the header "Risk Factors" in the final registration statement on Form S-1 recently filed with the SEC and any subsequent filings with the SEC. Most of these factors are outside of Pardes Biosciences' control and are difficult to predict. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. The forward-looking statements in this press release represent the company's views as of the date of this press release. Except as required by law, Pardes Biosciences assumes no obligation to update publicly any forward-looking statement, whether as a result of new information, future events or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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