Apple Tree Partners Launches Red Queen Therapeutics to Bring Potentially Lifesaving Treatments to People at Greatest Risk from Viral Infections

Red Queen uses a novel antiviral platform to create pan-variant treatments for coronaviruses, influenza, RSV, and other serious viral diseases, with recent clinical validation in COVID-19 patients

Company operates with $55 million Series A funding from ATP and a contract with BARDA for preclinical development of a pan-influenza therapeutic

CAMBRIDGE, MASS., August 6, 2024/ PR Newswire / -- Existing and emerging viral threats endanger all of us, but people with impaired immune systems are at substantially greater risk. **Apple Tree Partners (ATP)**, a leader in life sciences venture capital, today unveiled **Red Queen Therapeutics**, a clinical-stage biotechnology company developing novel antiviral treatments for the general population and especially for immunocompromised patients who are at increased risk of serious illness or death from common and emerging viral pathogens.

Red Queen Therapeutics is co-founded by ATP and **Loren Walensky, M.D., Ph.D.**, Professor of Pediatrics at Harvard Medical School, Principal Investigator and Attending Physician in the Department of Pediatric Oncology at the Dana-Farber Cancer Institute/Boston Children's Hospital, and Director of the Harvard/MIT M.D.-Ph.D. Program. Red Queen is operating with a $55 million Series A commitment from ATP. The company also has additional funding from the **Biomedical Advanced Research and Development Authority (BARDA)**, part of the Administration for Strategic Preparedness and Response within the U.S. Department of Health and Human Services, specifically for preclinical development of a pan-influenza therapeutic.

"As existing viruses circulate and spread and new viruses arise, treating sick individuals and curtailing transmission in vulnerable communities is an ever-present urgent medical need and public health imperative," said **Seth Harrison, M.D.**, Founder and Managing Partner of Apple Tree Partners and Chair of the Board of Directors of Red Queen Therapeutics. "With ATP support, Red Queen has successfully brought its novel technology for rapidly designing and developing new antivirals through clinical proof of concept, and we anticipate continued strong progress of the company's programs in multiple viral diseases."

Novel, versatile, rapid-response platform

Red Queen applies its novel stapled lipopeptide platform technology to rapidly design and develop new antiviral therapies. The platform's specific mechanism of fusion inhibition represents a new mode of early intervention that offers the following important advantages over available antiviral therapies or vaccines:

- Inhibiting viral fusion blocks viral entry, thus preventing or slowing host-cell infection and accelerating viral clearance.

- A single fusion-inhibiting lipopeptide agent can work against multiple variants and even across viruses within a family.
- The fusion-inhibiting mechanism acts on the virus itself and is not dependent on a well-functioning host immune system.

“Red Queen’s stapled lipopeptides act on the core fusion machinery of the virus, which is highly conserved across variants. This mechanism enables sustained activity against emerging variants and makes Red Queen therapies well-suited not only for individualized care in high-risk patients but also stockpiling and rapid deployment for population-level interventions,” said **Mark Mitchnick, M.D.**, Chief Executive Officer of Red Queen Therapeutics and a Venture Partner at ATP. “Our platform technology has demonstrated its potential for activity across many families of viruses, and we have refined our capabilities to a point where we can customize lipopeptides in weeks. We are excited by both the broad and ready utility of the platform and the therapeutic promise of the product candidates it produces. We just completed a very promising Phase 1 trial of our SARS-CoV-2 therapeutic and are in discussions around the Phase 2, and we have a robust pipeline.”

Earlier this year, *Nature Communications* published preclinical data from the Walensky Lab showing that stapled lipopeptides successfully blocked infection by a broad spectrum of SARS-CoV-2 variants, and prevented and mitigated disease in hamsters, including decreasing viral transmission.[i] The publication demonstrated how stapled lipopeptides foiled the fusion mechanism used by enveloped viruses responsible for severe illness and mortality, including SARS, respiratory syncytial virus (RSV), and Nipah, with application to many more. “Our aim is to address the unmet need for convenient, on-demand medicines to prevent and treat COVID-19 and other viral diseases, with the goal of avoiding infection before or after exposure – particularly for those immunocompromised individuals who cannot respond effectively to vaccines or tolerate other regimens,” said Dr. Walensky, who is senior author of the study.

Proof-of-concept clinical trial results

Red Queen presented Phase 1 clinical data for its lead program RQ-01 on June 16, 2024, at the American Society for Microbiology (ASM) Microbe annual meeting.[ii] The study enrolled 67 mildly symptomatic COVID-19-positive patients at low risk for progression to moderate-to-severe disease who were randomized to receive treatment once daily for three days with placebo (n=21), RQ-01 5 mg (n=24), or RQ-01 10 mg (n=22), all administered with a nasal spray device. More than 25 Omicron variants were observed across the study subjects, and more than 80 percent of subjects had previously been vaccinated against and/or infected with SARS-CoV-2.

Results demonstrated placebo-like safety and a consistent dose-dependent trend for RQ-01 to completely clear SARS-CoV-2 infection more rapidly than in untreated patients by day five after three days of dosing. RQ-01 was well tolerated and was not systemically absorbed after nasal administration. The trend for more rapid clearance of viral shedding in the RQ-01 treated groups, while not statistically significant in this small Phase 1 trial powered for safety rather than efficacy, was consistent across multiple analyses and confirmed the activity of RQ-01 in inhibiting the progression of the SARS-CoV-2 infection.

“These Phase 1 results validate the Red Queen platform by showing that we can rapidly identify, develop and formulate our stapled lipopeptide fusion inhibitors and deliver them in clinically relevant doses, and that the mechanism of action can clear virus quickly and

appears safe," said **Paul Da Silva Jardine, Ph.D.**, Chief Scientific Officer of Red Queen Therapeutics and a Venture Partner at ATP.

BARDA-supported pan-influenza program

BARDA recently awarded Red Queen a contract under its Easy Broad Agency Announcement (EZ-BAA) program to develop a pan-influenza virus fusion inhibitor for rapid response to flu outbreaks. Preclinical data from Red Queen's pan-influenza program is anticipated to read out in 2025.

About Red Queen Therapeutics

Red Queen Therapeutics, a clinical-stage biotechnology company co-founded by Apple Tree Partners (ATP) and biomedical researcher Loren Walensky, M.D., Ph.D., is applying its proprietary stapled lipopeptide technology to develop and deliver new treatments for a broad range of viruses, including coronaviruses, influenzas, and other enveloped viruses. The Red Queen platform mechanism of action, fusion inhibition, is a mode of early intervention that can prevent or mitigate viral infection, enabling accelerated viral clearance and avoidance of severe disease. Because Red Queen therapies target the highly conserved mechanism of viral fusion, they can be used across entire viral families and their variants. And because Red Queen's agents do not depend upon immune system activation, they offer instantaneous protection and are particularly suitable for use by immunocompromised people. Red Queen's stapled lipopeptide therapeutics are also designed to be shelf-stable at room temperature and can be formulated and delivered in multiple ways, including topically by nasal spray or inhaler, or systematically by injection. For more information, visit redqueentx.com.

About Apple Tree Partners

Apple Tree Partners (ATP) is a leader in life sciences venture capital, with a 25-year track record of translating emerging scientific advances into novel innovative treatments. ATP creates companies starting at various stages, from pre-IP ideas to asset spinouts, investing in them from seed stage through IPO and beyond. The core of ATP's strategy is providing flexible capital and access to a world-class team, to build sustainable, research-driven enterprises that deliver therapeutics to improve human lives. For more information, visit appletreepartners.com.

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[i] Bird, G.H., Patten, J.J., Zavadoski, W., et al. A stapled lipopeptide platform for preventing and treating highly pathogenic viruses of pandemic potential. Nat Commun 15, 274 (2024). https://doi.org/10.1038/s41467-023-44361-1
[ii] Kottilli, S., Kenaston, K., Da Silva Jardine, P., et al. Phase 1 Study of Intranasal Fusion Inhibitor RQ-01 for the Treatment of COVID-19. Poster presented at American Society for Microbiology; 16 June 2024; Atlanta, GA. https://redqueentx.com/posters/2024-June-RQ-ASM-POSTER.pdf