AlloVir Announces the FDA Clearance of Investigational New Drug Application (IND) for ALVR109 for the Treatment of High-Risk COVID-19 Patients

September 17, 2020

- ALVR109 is an allogeneic, off-the-shelf virus-specific T cell therapy candidate designed to target SARS-CoV-2 for high-risk COVID-19 patients

- Proof-of-concept clinical trial with ALVR109 to begin in Q42020

CAMBRIDGE, Mass., Sept. 17, 2020 (GLOBE NEWSWIRE) -- AlloVir (Nasdaq: ALVR), a late clinical-stage cell therapy company, announced that the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug application (IND) for ALVR109, an allogeneic, off-the-shelf virus-specific T cell therapy candidate designed to target SARS-CoV-2, the virus that causes the severe and life-threatening viral disease, COVID-19. ALVR109 is being developed to arrest the progression of COVID-19 by eradicating SARS-CoV-2 virus-infected cells.

“SARS-CoV-2 continues to have a devastating impact on patients and families around the world,” said David Hallal, Chairman and Chief Executive Officer of AlloVir. “There is an increasing body of evidence about the important role of T cells in the body’s fight against COVID-19. At AlloVir, together with our colleagues at Baylor College of Medicine, we are working with a great sense of urgency to leverage our highly innovative virus-specific T-cell platform to advance ALVR109 into a proof-of-concept study in high-risk COVID-19 patients.”

Early research suggests that T cells play an important role in the body’s fight against COVID-19. Over 80% of hospitalized patients with COVID-19 are lymphopenic, with reduced CD8+ and CD4+ T cell counts. These reductions in T cell counts correlate negatively with survival. Reduced T cell counts have been observed to be prevalent in older COVID-19 patients and those with severe illness, regardless of age.

On March 23, 2020, AlloVir announced it expanded its research collaboration with Baylor College of Medicine (BCM) to discover and develop allogeneic, off-the-shelf, virus-specific T-cell therapies for COVID-19. Following the submission of the IND for ALVR109 by BCM, the FDA notified BCM of a clinical hold due to questions related to raw materials used in the manufacturing process for ALVR109. BCM submitted a complete response to the questions identified in the clinical hold and the FDA has removed the hold allowing the clinical study to start.

About AlloVir

AlloVir is a leading late clinical-stage cell therapy company with a focus on restoring natural immunity against life-threatening viral diseases in patients with severely weakened immune systems. The company’s innovative and proprietary technology platforms leverage off-the-shelf, allogeneic, multi-virus specific T cells targeting devastating viruses for patients with T cell deficiencies who are at risk from the life-threatening consequences of viral diseases. AlloVir’s technology and manufacturing process enables the potential for the treatment and prevention of a spectrum of devastating viruses with each single allogeneic cell therapy. The company is advancing multiple mid- and late-stage clinical trials across its product portfolio. For more information visit www.allovir.com.

AlloVir uses its website as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD. Such disclosures will be included on the Company’s website in the ‘Investors & Media’ section. Accordingly, investors should monitor such portions of the AlloVir website, in addition to following press releases, SEC filings and public conference calls and webcasts.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding AlloVir’s development and regulatory status of our product candidates and its strategy, business plans and focus. The words “may,” “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “target” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management’s current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those related to AlloVir’s financial results, the timing for completion of AlloVir’s clinical trials of its product candidates, whether and when, if at all, AlloVir’s product candidates will receive approval from the U.S. Food and Drug Administration, or FDA, or other foreign regulatory authorities, competition from other biopharmaceutical companies, and other risks identified in AlloVir’s SEC filings. AlloVir cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. AlloVir disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent AlloVir’s views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

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