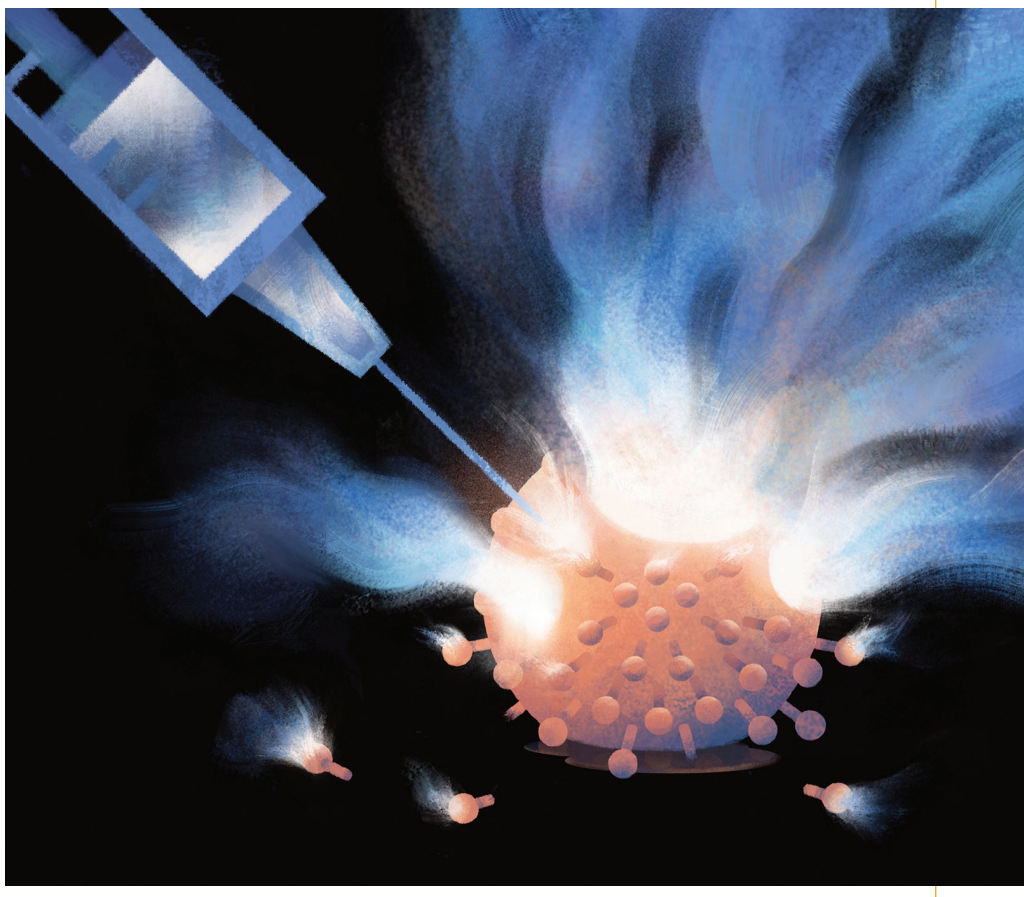
HEALTHCARE

ON TRIAL

St. Elizabeth is selected to participate in a national clinical study for a potential COVID-19 drug treatment.

–AIESHA D. LITTLE



As COVID-19 cases spiked across the country, research facilities and pharmaceutical companies ramped up efforts to create a vaccine that will stop the virus's spread. In the spring, St. Elizabeth Healthcare became the first U.S. site to participate in a Food and Drug Administration-approved Phase-2 clinical trial of the drug PUL-042, which boosts natural immunity in the lungs.

In conjunction with Covington-based research institute CTI and bio-pharmaceutical company Pulmotect, Inc., the hospital system's Edgewood campus is one of 10 clinical sites now studying the drug, which is meant to prevent COVID-19 cases from worsening when administered in early stages of the disease before lung capacity is impaired to the point where patients require additional oxygen via a ventilator.

St. Elizabeth pulmonologist Chaitaya Mandapakala, M.D., the lead physician on the clinical trial, says that the selection speaks volumes about the hospital's commitment to improving health outcomes. "St. Elizabeth got involved in this clinical trial on account of its strong interest in research and desire to help the community," he says.

To confirm whether a "nebulized" medication (a drug delivered in the form of a mist inhaled into the lungs) is safe and effective way to treat COVID-19 in its early stages, the study is a randomized controlled double-blinded trial. That means that half of the patients get PUL-042 and the other half receive a placebo. Not even those administering the medication know whether they're delivering the placebo or the experimental drug.

"At this point there is no other medication in the market available for patients in this early stage of disease, so we aren't taking any options away [for those receiving the placebo]," Mandapakala says. "If the patient worsens, every possible treatment option will be still available to them."

Patients who tested positive for COVID-19 but had no known prior lung disease or heart disease are being enrolled in the trial. After it's complete, the drug will enter Phase-3 trials, making it available to a wider testing population.

If the trial is ultimately successful, doctors and hospitals will have a treatment option for COVID-19 that can be used easily, safely, and without the need for hospitalization. This will decrease the amount of hospital resources being used to fight the disease as well as improve care while reducing the cost of care.

By building a strong strategic relationship with CTI, St. Elizabeth is taking steps to assist the community it serves in the areas where it needs it the most. "This [drug trial] confirms our reputation in the medical community that we're a trustworthy organization leading not only in Northern Kentucky but also the nation in answering some important questions in this pandemic crisis," Mandapakala says.

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