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## Press Release

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# Preliminary Research Involving Members of The US Oncology Network Finds Cancer Drug May Benefit Advanced COVID-19 Patients

Results showing off-label use of commercially available acalabrutinib (CALQUENCE®) led to rapid improvements in small number of patients appear in *Science Immunology*

**THE WOODLANDS, Texas, June 5, 2020**—Rapid improvements have been seen in acutely ill patients with COVID-19 treated with the cancer drug acalabrutinib (Calquence) by researchers, including physicians within [The US Oncology Network](#) (The Network). Results of the exploratory research, which was conducted in collaboration with AstraZeneca (AZ) and the National Institutes of Health (NIH), appear in *Science Immunology*.

Nineteen patients with acute respiratory distress syndrome (ARDS) from COVID-19 were treated with acalabrutinib for 10-14 days. Most patients demonstrated measurable improvements in oxygenation, often within 1-3 days. Nine out of 11 (82%) patients who had been receiving supplemental oxygen when treated with acalabrutinib were discharged from the hospital and no longer required supplemental oxygen. In addition, four out of eight (50%) patients who were receiving invasive mechanical ventilation prior to acalabrutinib administration were extubated and discharged without the need of supplemental oxygen. Improvement in key laboratory assessments measuring disease progression, including c-reactive protein level and lymphocyte levels, were also seen. There were no observed toxicities attributable to acalabrutinib, including those outlined in the product's important safety information, such as cardiac arrhythmia, bleeding, diarrhea or opportunistic infection.

“When COVID-19 infects the respiratory pathway, the body creates a hyperactive immune response to ward off this novel virus for which it has no prior immunity. This robust response produces excessive inflammation that causes more damage than the virus itself, leading to acute respiratory distress syndrome,” said [Jeff Sharman, MD](#), co-author of the manuscript and medical director of Hematology Research for The US Oncology Network. “As lead investigator in the clinical trial which led to the approval of acalabrutinib for people with chronic lymphocytic leukemia, I have seen the drug's ability to modify key immunologic signaling pathways shared by both cancer and the virus. I am encouraged by these initial results but further research is necessary to better understand the role of acalabrutinib in treating COVID-19.”

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Acalabrutinib is a member of a class of drugs known as Bruton’s tyrosine kinase (BTK) inhibitors, which are used to treat B-cell leukemias and lymphomas. Physicians in The US Oncology Network became engaged in this research due to their deep knowledge and active role in development of the BTK-inhibitor drug class, specifically acalabrutinib, and their commercial experience with the drug. These community oncologists were asked to lend their expertise at select hospitals where they have “practicing privileges” to advise treating physicians on how best to administer the drug and explore the potential for this commercially available oncology treatment to address the body’s overreaction to COVID-19.

The decision to explore the application of acalabrutinib in this patient population was based on known COVID-19 biology, the product’s mechanism of action and safety profile, and published preclinical data examining acalabrutinib in a mouse model for influenza.

“This project is an excellent example of community oncologists with knowledge and experience with acalabrutinib working together with colleagues at the NIH/NCI and AstraZeneca during this pandemic to determine if the drug can be repurposed to treat hospitalized patients with advanced COVID-19 disease, said [Stephen Wrzesinski, MD, PhD](#), co-author of the manuscript and director of Immunooncology and Cellular Therapy at New York Oncology Hematology in Albany, NY. “Being able to collaborate with other healthcare professionals on the front lines at the local and national levels to care for the sickest patients infected with this virus demonstrates how integrated collaborative research of this magnitude has the potential to benefit everyone during this unprecedented time.”

The patients, who range in age from 45 to 84, received the drug “off label” and were treated at Rocky Mountain Cancer Centers ([RMCC](#)) in collaboration with [Centura Health](#) in Colorado, St. Peter’s Hospital in collaboration with New York Oncology Hematology ([NYOH](#)) in New York and Walter Reed Medical Center in Washington, D.C. Patients or their medical proxy were approached about participating in the exploratory study of acalabrutinib, advised of the safety and potential risks involved, and all agreed to participate.

“We chose to do this exploratory research based on very good science and the early experience from the NIH. And while it is very gratifying to see patients who were in, or at risk of being admitted to, the ICU respond well, get off ventilators and leave the hospital, it is essential that we collect additional evidence in a randomized, controlled trial. I am looking forward to seeing more data on this drug in the future,” said [M. Andrew Monticelli, MD](#), co-author of the manuscript and medical oncologist and hematologist at Rocky Mountain Cancer Centers.

Based on the findings of this exploratory research, AstraZeneca has initiated additional clinical studies evaluating acalabrutinib in seriously ill patients with over-reactive immune responses (cytokine storm) attributed to COVID-19 infection. These studies will examine acalabrutinib in two phase II trials in which acalabrutinib is compared to best supportive care in patients hospitalized with COVID-19, regardless of whether they are in an intensive care unit (ICU).

Researchers from The US Oncology Network were involved in the exploratory research due to their experience in the clinical development of acalabrutinib in B-cell chronic lymphocytic leukemia (CLL). Sites selected to participate in the exploratory research were based on several criteria including regional COVID-19 infection rates/prevalence,

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familiarity/experience with acalabrutinib, affiliation with a treating hospital system, and product availability and agreement with the institution's leadership. These sites are being considered for the larger randomized clinical study.

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### About The US Oncology Network

Every day, [The US Oncology Network](#) (The Network) helps more than 1,350 independent physicians deliver value-based, integrated care to patients — close to home. Through The Network, these independent doctors come together to form a community of shared expertise and resources dedicated to advancing local cancer care and to delivering better patient outcomes. The Network provides practices with access to coordinated resources, best business practices, and the experience, infrastructure and support of [McKesson Corporation](#). This collaboration allows the providers in The Network to focus on the health of their patients, while McKesson focuses on the health of their practices. The Network is committed to the success of independent practices, everywhere.