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Division of Advisory Committee and Consultant Management
Office of Executive Programs
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

RE: Treatment of SARS-CoV-2 infection in moderate to severe COVID-19 infections at high risk of acute respiratory distress syndrome

Dear Chairman Dr. Au, Dr. Stevenson, and Committee Members,

Since the beginning of the pandemic, 1,066,174 American lives have been lost to date.
The global pandemic caused by the coronavirus SARS-CoV-2 is entering its third year. While much progress has been made, there remains an unmet medical need for new effective treatments for hospitalized adult patients with moderate to severe COVID-19 symptoms at high risk for Acute Respiratory Distress Syndrome (ARDS) and death.

Despite the availability of vaccines and treatment options for patients with mild to moderate disease, health care providers continue to lack the therapeutics needed to improve outcomes for those at the highest risk of hospitalizations and death. Those at highest risk include seniors, persons with disabilities, communities of color (including Hispanics, African Americans, and Native Americans), as well as those who are immunocompromised, have a respiratory illness, or have a chronic disease such as diabetes or obesity. These vulnerable populations would greatly benefit from additional therapies.

As we enter the traditional respiratory viral season complicated by the emergence of flu and RSV, there remains an urgent need for proven therapeutics to help vulnerable patients recover from a moderate to severe COVID-19 infection. An average of 300-400 people continue to die every day from the impact of COVID-19, and an additional tool in the medical toolbox to treat patients is essential. Also notable is that more than 80% of patients discharged from the hospital report a negative impact on productivity and quality of life. For many, the COVID-19 pandemic is not over.

Promising treatments continue to be sought. In the phase 3 clinical trial for sabizabulin oral capsule, a tubulin polymerization inhibitor showed a statistically significant and clinically meaningful 55.2% reduction in deaths compared to placebo in moderate to severe hospitalized COVID-19 patients.
Now is the time to act. The need for novel therapies is critical to help prevent further loss of life and disability.

The representative organizations below agree that there is an unmet need to treat high-risk patients with acute respiratory diseases and urge the Pulmonary-Allergy Drugs Advisory Committee to approve all safe and effective therapies to improve outcomes and save lives.

Thank you,

Aimed Alliance
Allergy & Asthma Network
Alliance for Aging Research
Alliance for Patient Access
American Senior Alliance
Amputee Coalition
AnCan Foundation
ARDS Alliance, Inc.
AsianAlliances.com
Association of Migraine Disorders
Chronic Migraine Awareness
Clusterbusters, Inc
Coalition for Headache and Migraine Patients
Derma Care Access Network
Epilepsy Alliance America
Foundation for Sarcoidosis Research (FSR)
Global Healthy Living Foundation
Lupus and Allied Diseases Association, Inc.
Miles for Migraine
National Association For Continence
National Headache Foundation
Respiratory Health Association
RetireSafe
Survivor's Cancer Action Network of Louisiana
The Headache and Migraine Policy Forum
The Mended Hearts, Inc.
The Partnership to Advance Cardiovascular