

March 17, 2020

Lack of evidence to support use of darunavir-based treatments for SARS-CoV-2

There has been increasing discussion recently among the medical and scientific community regarding the consideration of HIV protease inhibitors like darunavir, as therapeutic options for COVID-19 and we wanted to take the opportunity to address this directly.

At Janssen, patients are our priority and given the large public health and humanitarian implications of COVID-19, we are committed to global efforts to care for those affected, contain the current outbreak and develop measures to tackle future outbreaks.

We support broad access to information, and we strongly believe that the development of evidence-based intervention guidelines for COVID-19 is critical. That said, our view is that the consideration of HIV protease inhibitors as therapeutic options for COVID-19 is based on limited, unpublished virologic and clinical data in the treatment of patients infected with severe acute respiratory syndrome (SARS) coronavirus.

Darunavir is a protease inhibitor marketed by Janssen for the treatment of HIV-1 and our first commitment is to the HIV patients who rely on this medicine. It is currently only approved for use with a "boosting" agent, and in combination use with other antiretrovirals. Darunavir should not be administered without a boosting agent as previous studies of unboosted darunavir resulted in subtherapeutic drug levels and was associated with a higher rate of adverse events.

Several Janssen compounds, including darunavir, are in the process of being evaluated for potential antiviral activity against SARS-CoV-2 and as soon as this data become available, we will provide an update.

We remain open to collaborating with governments, healthcare professionals and others to ensure rigorous collection and transparency of data that will allow evidence generation to guide the use of effective medicines and support the best outcomes for patients affected by COVID-19.

As part of the Johnson & Johnson Family of Companies, we have been deeply engaged in a multipronged response to the SARS-CoV-2 outbreak. Leading collaborative efforts to screen compounds in discovery and development within our organisation and across the broader pharmaceutical industry to accelerate the development of therapies, as well as initiating a high priority project to develop a SARS-CoV-2 vaccine candidate leveraging our AdVac and PER.C6 technologies.

There is no higher priority than patient health for Johnson & Johnson and we will remain on the front lines of this global public health crisis, bringing our full resources and minds to combat it.

For patients with questions regarding darunavir or other protease inhibitors, we advise speaking to your GP or healthcare professional.

If your enquiry is related to an adverse event associated with a Janssen product, please contact our Drug Safety Department on 01494 567447 or by e-mail at: dsafety@jacgb.jnj.com.

The Janssen UK team