Part of EU-RESPONSE

EU SOLIDACT

Newsletter No. 4 – January 2022

NEWSLETTER #4

REMEMBER WE HAVE AN INTERNET PAGE: HTTPS://EU-RESPONSE.EU/EU-SOLIDACT/

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● UPDATED WHO GUIDELINES ● IMMUNOCOMPROMISED PATIENT FOCUS ● UPCOMING DSMB MEETING
● NEW INVESTIGATOR'S BROCHURE ● COMPLETION OF eCRF AFTER DISCHARGE

OVERVIEW AS PER 20 JANUARY 2022

We have randomised 245 patients in 8 countries. Sites in three other countries (Hungary, Portugal and Slovakia) are ready to include.

BARICITINIB RECOMMENDED BY WHO GUIDELINES – DSMB MEETING SCHEDULED

On January 14th, the WHO guidelines were updated with a strong recommendation for the use of baricitinib in moderate and critical COVID-19. The evidence level of the recommendation is moderate, pending results from the RECOVERY trial, which are expected in early February. The recommendation by our DSMB is to continue inclusions in Bari-SolidAct until a planned DSMB meeting on February 16th.

AMENDED PROTOCOL TO TARGET IMMUNOCOMPROMIZED PATIENTS

Although immunomodulators, including baricitinib, are now recommended for severe and critical Covid-19, their use in immunocompromised patients is unknown. The amended Bari-SolidAct protocol is now approved in several countries and opens for inclusion of immunocompromised patients. After training has been documented and the new protocol signed, sites can start recruitment to the new protocol. Trainings will be organized by the sponsor team. Please reach out of you want to schedule a date for training.

NEW IB AND RENAL FAILURE

A new investigators brochure (IB) for baricitinib has been shared with the sites and should be used as new reference document for safety. The new IB contains more information on COVID trials. The most important change is that the threshold for discontinuation of baricitinib in patients with renal failure has changed, as previously communicated in newsletter #3. Of note, baricitinib/placebo should be discontinued in patients with eGFR < 30. This will be amended in the next version of the protocol, planned for regulatory submission in February.

NEW STUDY ARM

A new study arm is planned for SolidAct part A (moderate COVID). Further information will be provided once the contract is signed by the company providing IMP.

ECRF UPDATES

Please remember to update the eCRF as much as possible, including survival information on D29, D61 and D91. The data is needed for analysis for the DSMB meeting in February.

QUESTION & ANSWERS? SEE OUR INTERNET PAGE EU-SOLIDACT - EU-RESPONSE