COVID-19 ICMRA Check-In TeleConference (TC) #5
Date: 12/06/2020 Time: 07h00 EDT, 13h00 CET

Policy Tracker

1. Medicines under investigation

a. For treatment or prevention of COVID-19

Issues of concern
The following is the list of ongoing clinical trials (SIT, IIT) in Korea: (For more information, refer to https://nedrug.mfds.go.kr) < Therapeutics> 1. Remdesivir: A phase 3 randomized study to evaluate safety and antiviral activity of remdesivir (GS-5734™) in participants with severe COVID-19 2. Remdesivir: A phase 3 randomized study to evaluate safety and antiviral activity of remdesivir (GS-5734™) in participants with moderate COVID-19 compared to standard of care treatment 3. Remdesivir: A multicenter, adaptive, randomized blinded controlled trial of safety and efficacy of investigational therapeutics for the treatment of COVID-19 in hospitalized adults 4. Lopinavir / ritonavir vs hydroxychloroquine: comparison of lopinavir / ritonavir vs hydroxychloroquine vs control group in patients with mild COVID-19 infection; open-labelled randomized controlled clinical trial 5. Hydroxychloroquine: A study of hydroxychloroquine as post exposure prophylaxis for SARS-CoV-2 (HOPE trial) 6. Ciclesonide : A Trial of Ciclesonide in Adults with Mild COVID-19 7. Clevudine: A phase 2, open-labelled randomized study to evaluate safety and efficacy of clevudine and hydrochloroquine in patients with moderate COVID-19 8. Nafamostat mesilate: Comparison of nafamostat mesilate plus standard therapy vs. standard therapy in patients with COVID-19 pneumonia; open-labelled randomized controlled clinical trial

9. Ifenprodil : An open-label physician initiated 28 day phase 2a study of ifenprodil on lung function in confirmed COVID-19 infected patients with severe pneumonia

10. EC-18 (PLAG): A multi-center, randomized, double-blinded, phase 2 trial to evaluate safety and efficacy of EC-18 in COVID19 patients with pneumonia

11. Pyramax: A multi-center, randomized, double-blind, parallel, placebo-controlled, phase Ⅱ/Ⅲ clinical trial to evaluate efficacy and safety of Pyramax in mild to moderate COVID-19 patients

12. Baricitinib(LY_3009104): A Multicenter, adaptive, randomized blinded controlled trial of safety and efficacy of investigational therapeutics for treatment of COVID-19 in hospitalized adults

< Vaccine >

13. INO-4800(pGX9501) (DNA Vaccine) : A Phase I/IIa Dose-Ranging Study to Evaluate Safety, Tolerability and Immunogenicity of INO-4800, a Prophylactic Vaccine against SARS-CoV-2, Administered Intradermally Followed by Electroporation in Healthy Adults

14. GX-19(pGX27-S1S2) (DNA Vaccine) : A Phase 1/2a, Multi-center, Randomized, Double-blind, Placebo-controlled Study to Investigate the Safety, Tolerability, and Immunogenicity of GX-19, a COVID-19 preventive DNA Vaccine in Healthy Subjects

The following is the list of products for compassionate use to treat COVID 19:

1. HzVSF v13 (recombinant protein/neutralizing antibody): Approved 7 cases for individual patients and 1 for a small group (2 - 24 patients) to treat COVID 19 (developed by ImmuneMed)

2. Cellgram-AKI (allogeneic mesenchymal stem cell): Approved to treat a small group of ARDS (Acute Respiratory Distress Syndrome) induced by COVID 19 (developed by Pharmicell)

3. GV1001 (Tertomotide): Approved 4 cases for individual patients to treat COVID 19 (developed by GemVax & KAEL) 4. ALLO-ASC (allogeneic mesenchymal stem cell): Approved to treat a small group of ARDS induced by COVID 19 (developed by Antrogen) 5. SCM-AGH (allogeneic mesenchymal stem cell): Approved 1 case for individual patient to treat COVID 19 (SCM Life Science) 6. Furestem-RA®: (allogeneic mesenchymal stem cell): Approved to treat a small group of ARDS induced by COVID 19 (developed by: Kangstem Biotech)
Policy/guidance for industry
The list of clinical trials approved in Korea can be found on the MFDS website (See: https://nedrug.mfds.go.kr/searchClinic).
Planned future collaboration/coordination in policy areas
The MFDS has initiated a policy to support and expedite development and approval of COVID-19 therapeutics and vaccines. (See: https://www.mfds.go.kr/brd/m_726/list.do).

a. For other non-COVID-19 therapeutics development

Issues of concern
Policy/guidance for industry
Planned future collaboration/coordination in policy areas

3. **Availability of medicines**

b. Currently used in the treatment of COVID-19

Issues of concern
Under the guidance from the Korean Society of Infectious Diseases (KSID), Kaletra, Hydroxychloroquine, Interferon and Ribavirin are now used to treat coronavirus patients in Korea. - Two tablets of Kaletra can be administered twice a day as a monotherapy (For children, use syrup).

− 400 mg of hydroxychloroquine can be administered once a day as a monotherapy. − Interferon can be administered in combination with lopinavir/ritonavir − Ribavirin is not considered as a primary treatment because of its adverse reactions. When drugs recommended for the primary intervention is difficult to be used or ineffective, use of ribavirin can be considered in combination with lopinavir/ritonavir or interferon (Ribavirin is not recommended to be used as a monotherapy). Recommended duration of use is 7-10 days.
Policy/guidance for industry
Planned future collaboration/coordination in policy areas
In case of shortages, different approaches could be applied including consultation through email and establishing virtual or face-to-face meetings, in accordance with the ICMRA SOP for Crisis Management. Discussion is needed among ICMRA members to identify how to support countries with shortages of essential medicines during a pandemic like the current COVID-19.

c. Currently used for other non-COVID-19 conditions

Issues of concern
Policy/guidance for industry
Planned future collaboration/coordination in policy areas

3. Bring Forward Agenda items / issues for discussion