



Cinisello Balsamo, 25th March 2020

Subject: COVID-19: CLINICAL TRIALS

DMD: DSC/14/2357/48 and DSC/14/2357/51

BMD: DSC/15/2357/53

Dear Duchenne Community,

ITALFARMACO team would like to take this opportunity to inform you that we have been working with our Clinical Sites to ensure givinostat clinical trials continuity under the coronavirus (COVID-19) outbreak. The COVID-19 emergency is affecting all countries and communities in a variable way, particularly the healthcare systems.

ITALFARMACO wishes to reassure you that we are continuously monitoring the COVID-19 Public Health Emergency and reviewing governments and other authority guidelines to ensure that the actions we take as a Sponsor are in line with these guidelines and that we act in the best interests of all patients, clinical sites staff, CRO employees, vendors staff and our employees.

ITALFARMACO's aim in this Emergency period is still to ensure the rights, safety and well-being of the trial subjects and that they can continue to have access to the experimental treatment, as well as to guarantee the scientific validity and integrity of the study.

ITALFARMACO has been evaluating country by country situation and each case specifically to find a suitable solution for every single clinical trial subject. We are working on an emergency plan in order to ensure the continuity of care for subjects enrolled in our clinical studies, particularly whenever it is not safe to reach the Clinical Site.

In many countries, we have intensified the home-nursing service and we've activated the shipment of the investigational drug at patients' home. People participating to Italfarmaco studies are recommended to work closely with their Clinical Physician and discuss with them the best approach for them.

To date, we have not identified any safety concerns related to COVID-19 in our clinical trials.

ITALFARMACO recognizes that this is a difficult time for everyone but please be assured that we are giving this our full attention and we will take all reasonable actions to support each patient.

We would like to thank you all for your support and cooperation in our clinical trials.

Sincerely,

Givinostat ITALFARMACO TEAM

Italfarmaco SpA

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