

Díaz-Canel confirms the beginning of clinical trial with Soberana Plus



Clinical trial of Soberana Plus in the pediatric population convalescing from COVID-19.

Havana, Oct 2 (RHC) Miguel Díaz-Canel Bermúdez, President of the Republic of Cuba, confirmed on his Twitter social network account the beginning next Tuesday, Oct. 5th, of the clinical trial with Soberana Plus in the convalescent pediatric population of COVID-19.

"Clinical trial with Soberana Plus in the COVID-19 convalescent pediatric population will start on October 5. #PonleCorazónACuba," tweeted the president and linked to his message an article from the Cuban newspaper Granma on the subject.

Granma reports that around 40 children and adolescents recovered from COVID-19 will receive a single dose of Soberana Plus at the Juan Manuel Márquez Hospital in the capital, as part of the beginning of the clinical trial in the convalescent pediatric population with the immunogen from the Finlay Vaccine Institute (IFV).

The newspaper points out that Soberana Plus Pediatrics will be a Phase I/II, open, adaptive study to evaluate the safety, reactogenicity and immunogenicity of this Cuban vaccine in a total sample of 520 adolescents and children convalescing from COVID-19, in the provinces of Havana and Cienfuegos.

He adds that Phase I of the study will include 40 subjects, 20 from 12 to 18 years old, and another 20 from two to 11 years old. Each group with ten asymptomatic and ten symptomatic patients.

Once inoculated with the single dose, adverse events will be monitored for the next 72 hours, with face-to-face consultations at the clinical site and in general during the following seven, 14 and 28 days.

Based on the results of the application of the safety hypothesis, obtained in the period of one week, the continuity of the study will be evaluated and also the passage to Phase II, which will be extended to the province of Cienfuegos, reports Granma.

Meanwhile, the text adds that Phase II will include 480 subjects, of which 240 will be from the 12 to 18 years old group, and another 240 between two and 11 years, with a distribution of 120 asymptomatic and 120 symptomatic patients for each segment. (Source:ACN)

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