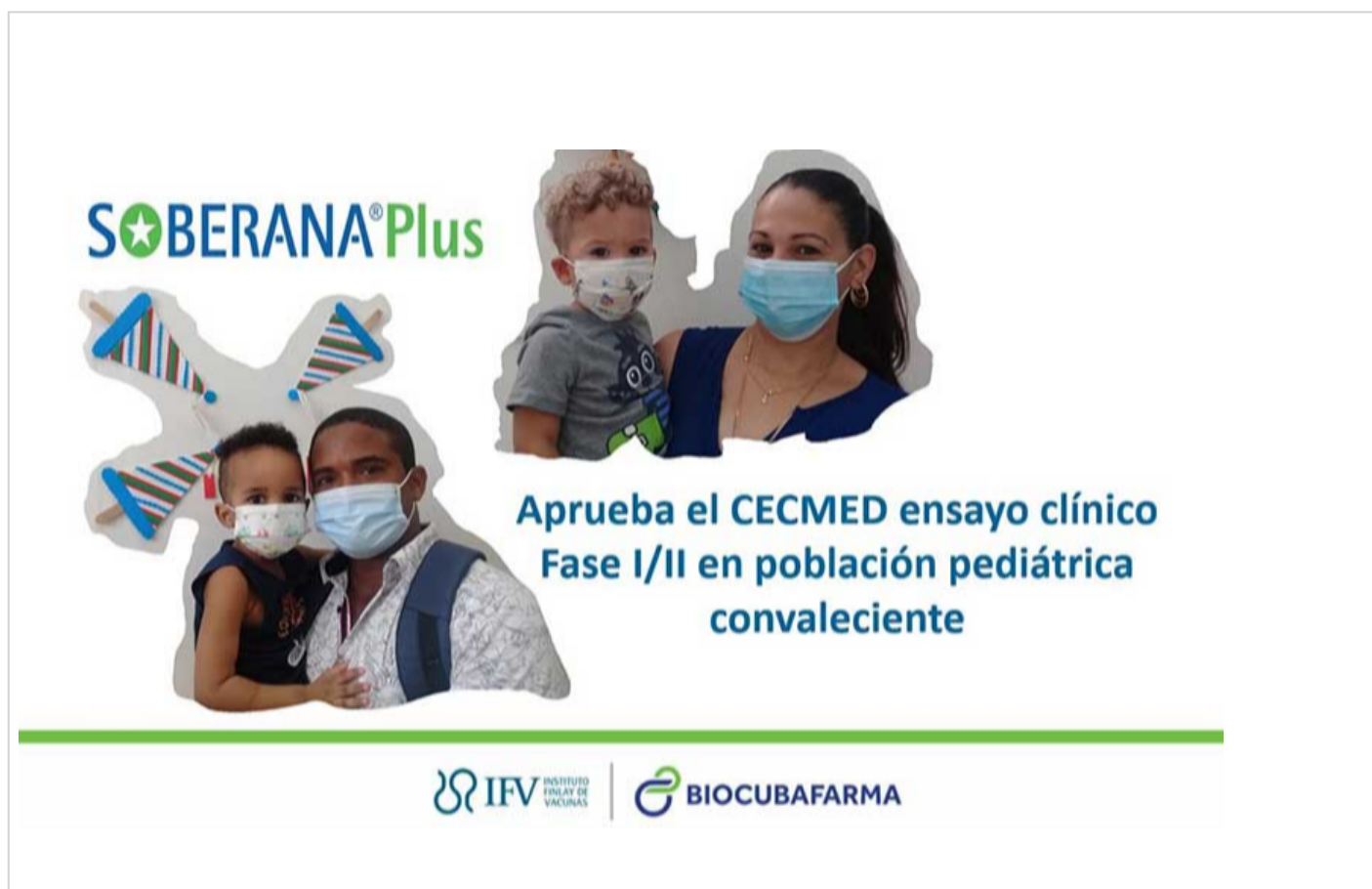


Cuba approves start of clinical trial in pediatric population convalescing from COVID-19



The advertisement features the Soberana Plus logo at the top left, which includes a green star and the text 'SOBERANA® Plus'. Below the logo are two photographs: one of a woman holding a young child, and another of a man holding a young child. Both children and the adults are wearing face masks. To the right of the photographs, the text reads: 'Aprueba el CECMED ensayo clínico Fase I/II en población pediátrica convaleciente'. At the bottom of the advertisement, there are two logos: 'IFV INSTITUTO CUBANO DE VACUNAS' and 'BIOCUBAFARMA'.

Havana, Sep 29 (RHC) On Tuesday, the Center for State Control of Medicines, Equipment and Medical Devices -CECMED-, announced the authorization to start a clinical trial with Soberana Plus for children convalescing from COVID-19.

Olga Lidia Jacobo, director of Center for State Control of Medicines, Equipment and Medical Devices said that it is necessary to carry out the clinical trial in the pediatric population and not only grant the authorization for emergency use, so the research will cover 530 infants in Havana and the central province of Cienfuegos.

During the radio-television program Mesa Redonda she pointed out that through the results of safety and immunogenicity of Soberana Plus in adults, this step is taken to protect the entire convalescent population from a possible reinfection with more contagious variants of the virus.

She ratified the rigor present in the clinical trials in children's population based on the scientific evidence of their promoters, the inspections to the clinical sites and the experience in the production of vaccines in the country.

CECMED is waiting for the results of the Abdala vaccine clinical trial, which is being developed in the province of Camagüey, to also determine its authorization for emergency use in the pediatric population.

Likewise, the institution is evaluating the Soberana Centro clinical trial in the province of Cienfuegos, which includes the Soberana 01 vaccine candidate, and its specialists are also analyzing all batches of vaccines applied in the country.

On September 23, the Cuban regulatory authority granted the authorization for emergency use of Soberana Plus for convalescent population over 19 years old. (Source: ACN).

<https://www.radiohc.cu/en/noticias/nacionales/271959-cuba-approves-start-of-clinical-trial-in-pediatric-population-convalescing-from-covid-19>



Radio Habana Cuba