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In-clinic Real World Observational Study to Assess the Safety and Tolerability of EasySix™ Vaccine in Healthy Infants During Primary Immunization

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Abstract:

Pertussis is a serious infectious disease of the human respiratory tract, caused by Gram-negative bacteria *Bordetella pertussis*. Current pertussis vaccines consist of dead cells of *B. pertussis* (whole cell pertussis vaccine (wP)) or purified antigens (2 to 5) (acellular pertussis vaccine (aP). The aP vaccines are less reactogenic and have been widely used in developed countries for more than two decades, but accelerated rate of epidemic outbreaks has led to the hypothesis that aP vaccines are less effective than the wP vaccines.

EasySix (manufactured by Panacea Biotec Ltd., India) is a combination vaccine of diphtheria, tetanus, whole cell pertussis, *Haemophilus influenza* type B, hepatitis B and inactivated poliovirus (P1, P2 and P3) (DTwP-Hib-Hep B-IPV) approved and widely in India. We conducted multi-centric, *in-clinic observational* study across the country to evaluate the safety of EasySix vaccine in real world scenario, wherein, observations were recorded online in the eCRF form after primary vaccination (6, 10 and 14 week schedule) at 30 min and on day 3 and day 28.

In this observational study, there were 18,843 doses administered and the cumulative incidence of AEFI (Adverse Event Following Immunization) was reported. The intensity of events were mild to moderate, which resolved in a day or two. Most common adverse event observed was pain, which were recorded in 4,292 infants (22.78%), fever in 3,824 infants (20.29%) and swelling in 2,848 infants (13.18%). No serious AEFI's were reported during the study period. The prevalence of AEFIs following EasySix vaccine was significantly more after the first dose compared to subsequent doses.

Current study gives more realistic results as they occur in a more natural setting and afford evidence to safeguard or enhance the safety of approved vaccine in real world scenario. Therefore, the current

findings demonstrates that EasySix™ (Fully Liquid Hexavalent DTwP-Hib-HepB- IPV) is safe & well tolerated.

Keywords: AEFI, reactogenicity, whole cell pertussis, acellular pertussis, hexavalent vaccine, immune response

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