

**Recommendations of the SEC (Investigational New Drugs) made in its 03<sup>rd</sup>/26 meeting held on 26.02.2026 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>IND Division</b>			
	<p>IND/CT04/FF/2025/4 7801</p> <p>ZY-19489 tablet 900 mg</p>	<p>M/s Zydus Lifesciences Limited</p>	<p>Firm presented bioavailability clinical study report as per the BA protocol approved in 08<sup>th</sup>/25 SEC-IND meeting dated 04.09.2025, and Phase III Clinical trial Protocol.</p> <p>After detailed deliberation, committee noted the results of BA clinical study report and recommended to conduct Phase III Clinical trial study as per protocol presented by the firm with following incorporation in study protocol:</p> <ol style="list-style-type: none"> <li>1. Firm should also include Rapid diagnostic test to differentiate between P. falciparum &amp; P. vivax strain before patient enrollment to the study.</li> <li>2. Firm is required to include more CT sites representative of malaria burden (like from Chhattisgarh, Odisha etc).</li> <li>3. Firm should incorporate a line to follow the Standard WHO protocol for the Quality control microscopy.</li> </ol> <p>Accordingly, firm should submit the revised protocol to CDSCO for further evaluation.</p>