

**Recommendations of the SEC (Investigational New Drugs) made in its 10<sup>th</sup>/25 meeting held on 04.11.2025 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>IND Division</b>			
1.	IND/CT04/FF/2024/46992  AUR 103 Ca	M/s Aurigene Oncology Limited	<p>In light of earlier SEC recommendation dated 08.07.2025, firm has presented Clinical study report of Phase I/IIa (Part 1, Part 2A) along with Phase II study protocol no. AUR 103-202, version 2.0, Dated 04.07.2025 (proof of concept study), before the committee.</p> <p>The committee has noted the safety results of Phase I/IIa (Part 1, Part 2A) study, (Part 2B study in Intermediate / High-Risk / Very High Risk MDS patients is yet to be conducted).</p> <p>After detailed deliberation, committee has recommended for approval of Phase II study protocol no. AUR 103-202, version 2.0, Dated 04.07.2025 in patients with Advanced, Well or Moderately differentiated Neuroendocrine Tumours, as presented by the firm.</p>