

# Generic Developers of Upcoming NCE-1

26 September 2024

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## About The Report

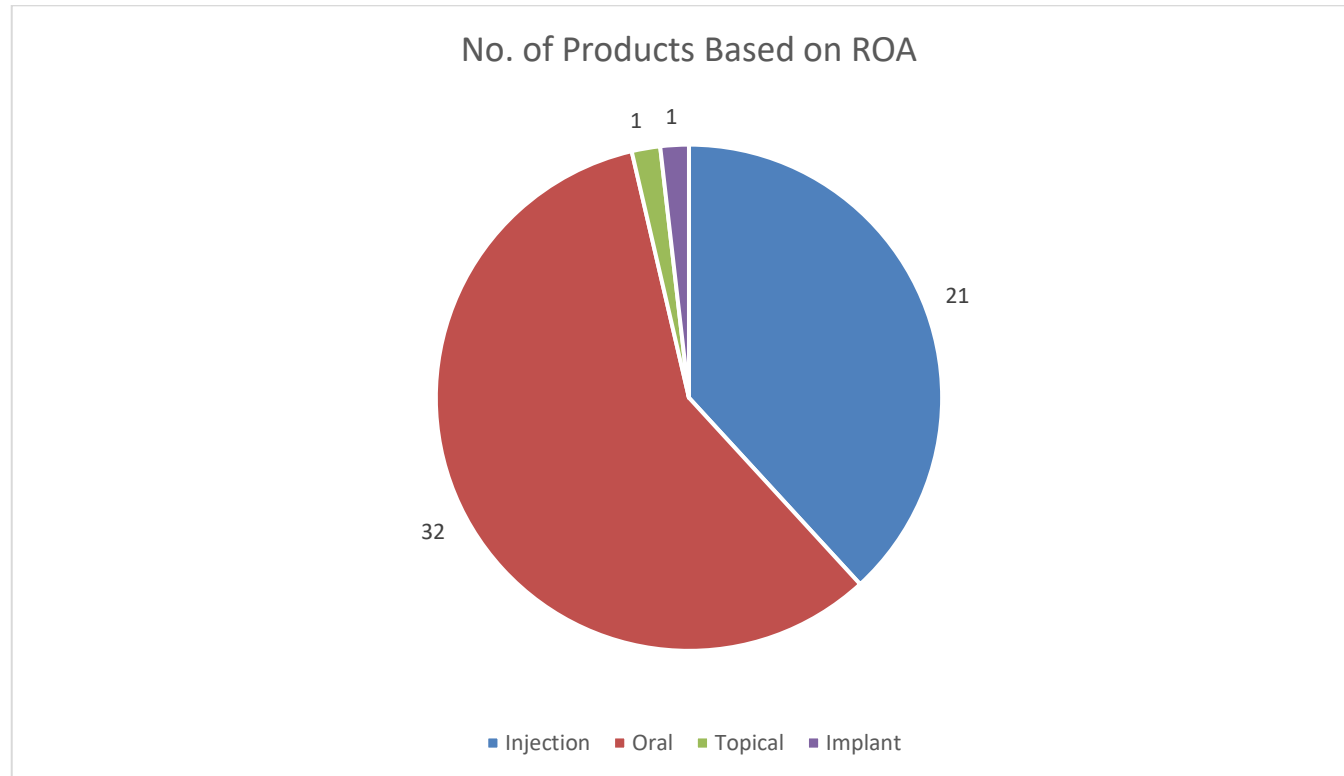
We all are aware that the first day of Para IV filing on any NDA is exactly one year before the NCE exclusivity of the NDA expires. In other words, NCE – 1 expiry of an NDA is the day on which a first Para IV filing can happen.

As a result, NCE – 1 is actively tracked by all the generic companies for all the new NDAs. However, no one knows about the name of generic companies targeting specific NDAs for Para IV filing.

This report brings you the names of those generic companies that are targeting NDAs whose NCE – 1 is expiring between October 2024 and December 2025 (NCE expires between October 2025 and December 2026). These are those generic companies who we believe are at some stage of generic development of their respective NDA (Generic developer cos). Kindly note the below:

1. Total 55 NDAs will lose it's exclusivity between October 204 and December 2025.
2. Generic developer list includes only those companies which are developing products only in India.
3. This list also includes CRO (Contract Research Organization) who may be developing product for other Generic companies. ANDA filing may happen in the name of Generic company and not on CRO name.
4. The Generic developer developing a product may target a Para IV or a Para III filing.

**Chart-I**  
**Upcoming NCE -1 Expiries**  
**Product Breakup based on Route of Administration (ROA)**



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# Generic Developers of Upcoming NCE-1



Chart-II  
Upcoming NCE -1 Expiries  
Company Wise Generic Products Under Development

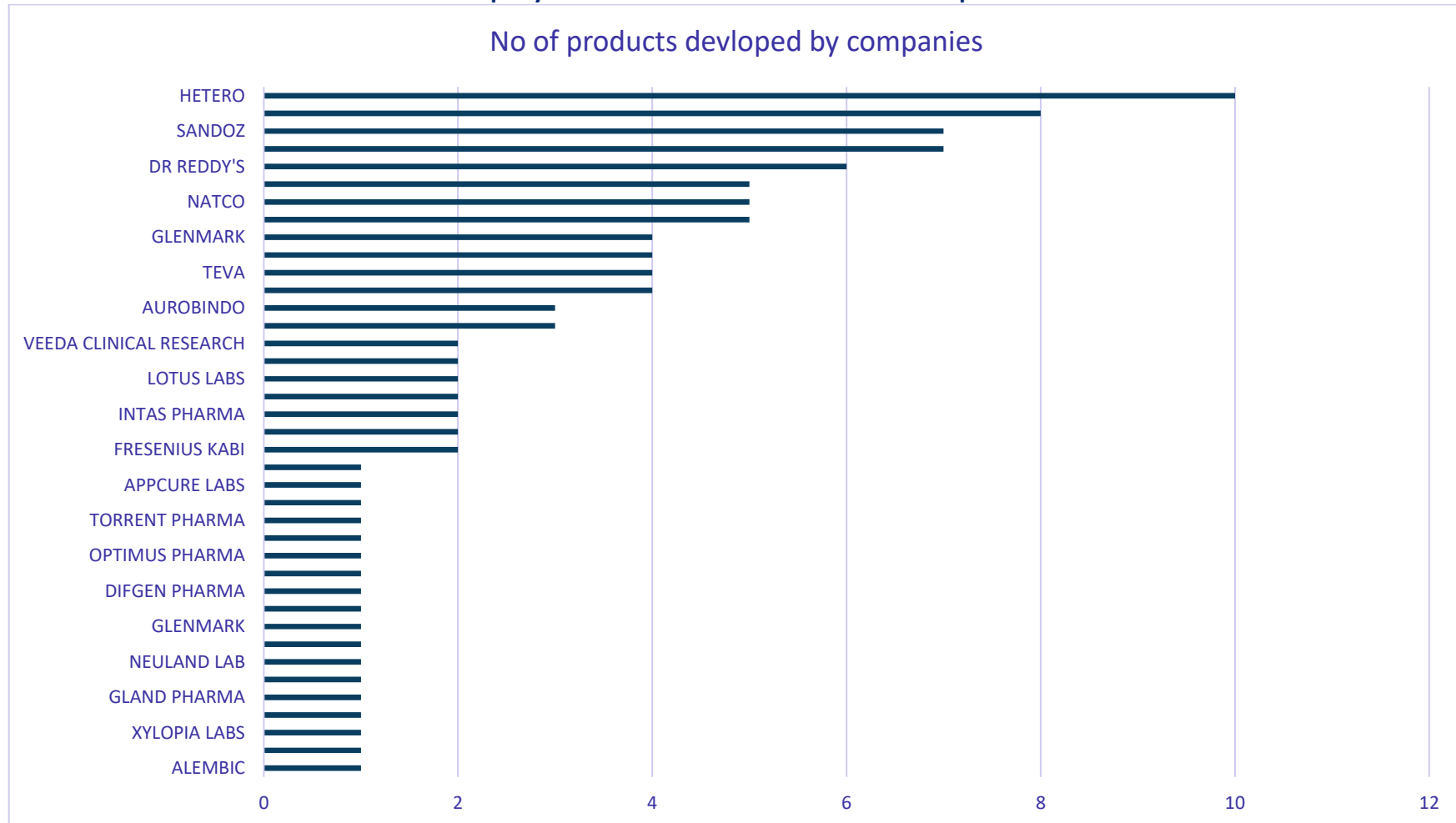


Table-I

**Research Delta Advisors**

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# Generic Developers of Upcoming NCE-1



## Upcoming NCE Expiries

Sr. No.	Drug Name	Generic Name	Dosage	Innovator	Last Patent Expiry	NCE Excl Expiry	Drug Complexity	Probable Generic Developers
1	OLINVYK	OLICERIDINE	SOLUTION INTRAVENOUS	TREVENA	23-Mar-32	30-Oct-25	Premium Content	
2	QELBREE	VILOXAZINE HYDROCHLORIDE	CAPSULE ER	SUPERNUS PHARMACEUTICALS	07-Feb-33	02-Apr-26		
3	BYFAVO	REMIMAZOLAM BESYLATE	POWDER INTRAVENOUS	ACADIA PHARMS INC	13-Jan-34	06-Oct-25		
4	VOCABRIA	CABOTEGRAVIR SODIUM	TABLET	VIIV HLTHCARE	28-Apr-26	21-Jan-26		
5	CABENUVA KIT	CABOTEGRAVIR; RILPIVIRINE	SUSPENSION ER, INTRAMUSCULAR	VIIV HLTHCARE	15-Sep-31	21-Jan-26		
6	FOTIVDA	TIVOZANIB HYDROCHLORIDE	CAPSULE	AVEO PHARMS	05-Nov-39	10-Mar-26		

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7	AZSTARYS	DEXMETHYLPHENIDATE HYDROCHLORIDE; SERDEXMETHYLPHENIDATE CHLORIDE	CAPSULE	COMMAVE THERAP	09-Dec-37	07-May-26	Premium Content	
8	GEMTESA	VIBEGRON	TABLET	UROVANT	01-Dec-30	23-Dec-25		
9	AMONDYS 45	CASIMERSEN	SOLUTION INTRAVENOUS	SAREPTA THERAPS INC	12-Nov-30	25-Feb-26		
10	UKONIQ	UMBRALISIB TOSYLATE	TABLET	TG THERAPS	26-May-35	05-Feb-26		
11	KLISYRI	TIRBANIBULIN	OINTMENT	ALMIRALL	07-Sep-38	14-Dec-25		

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12	LYBALVI	OLANZAPINE; SAMIDORPHAN L-MALATE	TABLET	ALKERMES INC	12-Nov-41	28-May-26	Premium Content	
13	PONVORY	PONESIMOD	TABLET	VANDA PHARMS INC	10-Oct-42	18-Mar-26		
14	LUPKYNIS	VOCLOSPORIN	CAPSULE	AURINIA	07-Dec-37	22-Jan-26		
15	IMCIVREE	SETMELANOTIDE ACETATE	SOLUTION SUBCUTANEOUS	RHYTHM	04-Jul-34	25-Nov-25		
16	ZOKINVY	LONAFARNIB	CAPSULE	SENTYNL THERAPS INC	17-Oct-24	20-Nov-25		
17	NULIBRY	FOSDENOPTERIN HYDROBROMIDE	POWDER INTRAVENOUS	SENTYNL THERAPS INC	31-Jan-25	26-Feb-26		

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18	ORLADEYO	BEROTRALSTAT HYDROCHLORIDE	CAPSULE	BIOCRYS	01-Nov-39	03-Dec-25	Premium Content	
19	TEPMETKO	TEPOTINIB HYDROCHLORIDE	TABLET	EMD SERONO	19-Mar-30	03-Feb-26		
20	OXLUMO	LUMASIRAN SODIUM	SOLUTION SUBCUTANEOUS	ALNYLAM PHARMACEUTICALS INC.	20-Nov-38	23-Nov-25		
21	NEXTSTELLIS	DROSPIRENONE; ESTETROL	TABLET	MAYNE PHARMA	17-Jun-36	15-Apr-26		
22	COSELA	TRILACICLIB DIHYDROCHLORIDE	POWDER INTRAVENOUS	G1 THERAP	23-Jul-39	12-Feb-26		

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23	ZEGALOGUE	DASIGLUCAGON HYDROCHLORIDE	SOLUTION SUBCUTANEOUS	ZEALAND PHARMA	03-Feb-35	22-Mar-26	Premium Content	
24	ZEGALOGUE (AUTOINJECTOR)	DASIGLUCAGON HYDROCHLORIDE	SOLUTION SUBCUTANEOUS	ZEALAND PHARMA	03-Feb-35	22-Mar-26		
25	VERQUVO	VERICIGUAT	TABLET	MERCK	26-Nov-32	19-Jan-26		
26	FEXINIDAZOLE	FEXINIDAZOLE	TABLET	SANOFI	Expired	16-Jul-26		

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27	TAVNEOS	AVACOPAN	CAPSULE	CHEMOCENTRYX	29-May-41	07-Oct-26	Premium Content	
28	ORGOVYX	RELUGOLIX	TABLET	SUMITOMO PHARMA CO.	29-Sep-37	18-Dec-25		
29	TRUSELTIQ	INFIGRATINIB PHOSPHATE	CAPSULE	HELSINN	11-Dec-34	28-May-26		
30	LIVMARLI	MARALIXIBAT CHLORIDE	SOLUTION	MIRUM	12-Feb-40	29-Sep-26		
31	LUMAKRAS	SOTORASIB	TABLET	AMGEN	15-Sep-40	28-May-26		
32	REZUROCK	BELUMOSUDIL MESYLATE	TABLET	KADMON PHARMS LLC	09-Apr-35	16-Jul-26		
33	VEKLURY	REMDESIVIR	POWDER INTRAVENOUS	GILEAD	28-Nov-41	22-Oct-25		

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34	VEKLURY	REMDESIVIR	SOLUTION INTRAVENOUS	GILEAD	28-Nov-41	22-Oct-25	Premium Content	
35	PYLARIFY	PIFLUFOLASTAT F-18	SOLUTION INTRAVENOUS	PROGENICS PHARMS INC	09-Jun-37	26-May-26		
36	MYFEMBREE	ESTRADIOL; NORETHINDRONE ACETATE; RELUGOLIX	TABLET	SUMITOMO PHARMA CO.	03-May-38	18-Dec-25		
37	BREXAFEMME	IBREXAFUNGERP CITRATE	TABLET	SCYNEXIS	10-Jun-39	01-Jun-26		
38	KORSUVA	DIFELIKEFALIN ACETATE	SOLUTION INTRAVENOUS	CARA THERAP	12-Nov-27	23-Aug-26		

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39	EMPAVELI	PEGCETACOPLAN	SOLUTION SUBCUTANEOUS	APELLIS PHARMACEUTICALS, INC.	09-Dec-38	14-May-26	Premium Content	
40	QULIPTA	ATOGEANT	TABLET	ABBVIE	30-Jan-35	28-Sep-26		
41	EXKIVITY	MOBOCERTINIB SUCCINATE	CAPSULE	TAKEDA	13-May-35	15-Sep-26		
42	KERENDIA	FINERENONE	TABLET	BAYER	29-Jul-35	09-Jul-26		

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43	SCEMBLIX	ASCIMINIB HYDROCHLORIDE	TABLET	NOVARTIS	14-May-40	29-Oct-26	Premium Content	
44	WELIREG	BELZUTIFAN	TABLET	MERCK	05-Sep-34	13-Aug-26		
45	BYLVAY	ODEVIXIBAT	CAPSULE, PELLETS	IPSEN	12-Nov-41	20-Jul-26		
46	BYLVAY	ODEVIXIBAT	CAPSULE	IPSEN	12-Nov-41	20-Jul-26		
47	LEQVIO	INCLISIRAN SODIUM	SOLUTION SUBCUTANEOUS	NOVARTIS	25-Aug-36	22-Dec-26		
48	CYTALUX	PAFOLACIANINE SODIUM	SOLUTION INTRAVENOUS	ON TARGET LABS	04-Oct-33	29-Nov-26		

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49	VOXZOGO	VOSORITIDE	POWDER SUBCUTANEOUS	BIOMARIN PHARMA	01-Aug-36	19-Nov-26	Premium Content	
50	SCEMBLIX	ASCIMINIB HYDROCHLORIDE	TABLET	NOVARTIS	14-May-40	29-Oct-26		
51	APRETUDE	CABOTEGRAVIR	SUSPENSION ER, INTRAMUSCULAR	VIIV HLTHCARE	15-Sep-31	21-Jan-26		
52	LIVTENCITY	MARIBAVIR	TABLET	TAKEDA	04-Jan-32	23-Nov-26		
53	GALLIUM GA 68 GOZETOTIDE	GALLIUM GA-68 GOZETOTIDE	SOLUTION INTRAVENOUS	UNIV CA LOS ANGELES	Expired	2025-12-01		

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54	GALLIUM GA 68 GOZETOTIDE	GALLIUM GA-68 GOZETOTIDE	SOLUTION INTRAVENOUS	UNIV OF CA SAN FRAN	Expired	01-Dec-25	Premium Content	
55	SYFOVRE	PEGCETACOPLAN	SOLUTION INTRAVITREAL	APELLIS PHARMACEUTICALS, INC.	22-Feb-37	14-May-26		

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