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DOSTARLIMAB - A RISING HOPE IN THE TREATMENT OF COLORECTAL CANCER

Ms. Fatima Nooha, Mr. Noor Muhammed Sinan*

Introduction:

Of the 19 million cancer cases reported worldwide in 2020, colorectal cancer (CRC) has a 10% prevalence and 9.4% mortality. A critical lack of cancer treatment facilities was observed in certain countries with a high prevalence of CRC. The five FDA-approved drugs used for CRC therapy (Durvalumab, Atezolizumab, Nivolumab, Pembrolizumab, and Avelumab) have been associated with a high occurrence of grade 3–4 adverse side effects.[1] In a recent clinical trial, Dostarlimab, which was previously approved for endometrial cancer, has proved to cure 100% of CRC patients.[2]

The Basics of Dostarlimab:

Dostarlimab is a humanized monoclonal antibody that binds PD-1 on T cells and blocks interactions with its ligands PD-L1 and PD-L2, activating immune responses and enhancing overall immunity.[1]Dostarlimab is an immunotherapy that aids the body's natural anti-tumour immune response during cancer treatment. It is given via intravenous infusion for over 30 minutes every three to six weeks, depending on the cycle.[2,3]

Dostarlimab has gained swift approval by the Food and Drug Administration (FDA) for the treatment of adults with deficient mismatch repair (dMMR) recurring or advanced endometrial cancer and solid tumours. [3] This drug has been used for multiple cancers and has been considered safe with substantial survival rates for patients.[1,3]

Ongoing clinical trials for Dostarlimab:

June 2022 saw a revolutionary discovery in the field of cancer treatment. For the very first time in science, a drug under clinical trial showed complete eradication of a tumour with no reoccurrence.[4] Dostarlimab was characterised by a variety of in vitro and in vivo experiments and preclinical actions that enabled it to become an investigational new drug. Dostarlimab has no cross-reactivity with the mouse orthologue, and it does not cause considerable cytokine stimulation when used alone.[5] These findings show that Dostarlimab is a strong anti-PD-1 receptor antagonist with features that warrant further clinical testing in cancer patients.[4,5]

A prospective phase 2 study was initiated in patients with stage II or III rectal adenocarcinomas who were mismatch repair-deficient. They were administered with Dostarlimab every 3 weeks for 6 months. Although this treatment is supposed to be followed with standard surgery and chemoradiotherapy, the patients who show a clinically complete response following dostarlimab therapy would not undergo chemotherapy, radiotherapy, or surgery. This is also the primary endpoint for the study. Interim results were obtained from the study completed on a total of 12 patients that had completed treatment with Dostarlimab and had also undergone a minimum of 6 months of follow-up. It was demonstrated that all 12 patients (100%; 95% confidence interval, 74 to 100) had a complete clinical response and no form of existing tumour, progression or recurrence was noticed in 18F-fluorodeoxyglucose–positron emission tomography, magnetic resonance imaging, biopsy, digital rectal examination or endoscopic evaluation. Moreover, no adverse events of grade 3 or higher were reported.[3]

Conclusion:

The study showed that a single agent PD1 was highly sensitive to mismatch repair deficient, locally advanced rectal cancer and could bring about positive results. However, a longer follow-up study still needs to be performed to validate this point. [3] On the other hand, the drug is yet to go through clinical trials and it could take approximately 3–4 years for the drug to get approved and perhaps even longer for it to become commonplace in oncologic management plans. Drugs with a similar profile usually undergo extensive testing and randomised controlled trials before finally getting approval. However, considering the ground-breaking effects of Dostarlimab on rectal cancer patients in the phase 2 trial, it is safe to assume this drug might not take long for approval.[4,5]

References:

1. Hussain HU, Burney MH, Rehan ST, Hasan MM. Dostarlimab: A breakthrough in the field of oncology. Ann Med Surg (Lond).2022;80:104046.
2. Costa B, Vale N. Dostarlimab: A Review. Biomolecules. 2022;12(8):1031.
3. Singh V, Sheikh A, Abourehab MAS, Kesharwani P. Dostarlimab as a miracle drug: rising hope against cancer treatment. Biosensors. 2022;12(8):617.
4. Ali E, Ellahi A, Adil M, Shaikh A, Huda Z. Jemperli (Dostarlimab-gxly): An unprecedented cancer trial. Annals of Medicine and Surgery. 2022;79:104047.
5. Cercek A, Lumish M, Sinopoli J, Weiss J, Shia J, Lamendola-Essel M, et al. PD-1 Blockade in Mismatch Repair–Deficient, Locally Advanced Rectal Cancer. New England Journal of Medicine. 2022;386(25):2363-2376.

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POMPE DISEASE: A REVIEW

Sagara M K*

Pompe disease (PD), or glycogen storage disease type II is a rare (1 in every 40,000 births), genetic and sometimes deadly disease which is caused by mutations in a gene that makes an enzyme called acid alpha-glycosidase (GAA) .[1] 1 in every 40,000 births and 5000-10,000 people are affected world widely. [2] GAA also known as α-1, 4-glucosidase and acid maltase, is an enzyme that aids in the breakdown of glycogen in the lysosome. It functions similarly to the glycogen debranching enzyme but is found on a different chromosome, undergoes cellular processing in a different way, and is found in the lysosome rather than the cytosol .[3]

Clinically, PD encompasses a highly variable range of phenotypes that differ in the age of onset, extent of organ involvement, and rate of progression. 300 different mutations in the GAA gene that cause the symptoms of Pompe disease were identified which can vary widely in terms of age of onset and severity. The main type of mutations which will results in PD are intronic mutations (genetic variants falling more than 100bp away from the closest exon-intron boundary and Dutch mutation.[4]

There are mainly two types of Pompe disease, Early onset and Late onset Pompe Disease. Early onset, often known as the infantile form, is brought on by a complete or almost complete GAA deficiency. Feeding issues, slow weight gain, muscular weakness, floppiness, and head lag are the early signs of the condition. Lung infections can make respiratory issues worse. The heart has an enormous growth. The heart has an enormous growth and the tongues of many new-borns with Pompe disease are swollen. The majority of infant deaths are caused by cardiac or respiratory issues before they turn one.

A partial GAA deficiency leads to late (juvenile or adult) Pompe disease, which has a late start. The first decade of infancy or the sixth decade of adulthood might both mark the beginning of the condition. The main symptom is muscular weakness, which progresses to respiratory weakening and eventually results in death from respiratory failure following a several-year course. Usually, the heart is unaffected. By checking for the prevalent genetic mutations or assessing the amount of GAA enzyme activity in a blood sample, a diagnosis of PD can be established.

Depending on when the condition manifests itself, symptoms may vary slightly. Breathing issues, muscular weakness, hearing issues, infections, etc. are some of the typical symptoms.[5]

The measurement of an enzyme in the blood is part of the diagnosis, and DNA testing is used to confirm it. Other tests include taking a thorough medical and family history, pulmonary function tests, electromyography (a test that evaluates how well the muscles function), MRIs, heart studies like X-rays, electrocardiograms, and echocardiograms, sleep studies, and a prenatal diagnosis may be performed for at-risk pregnant women. [6]

All Pompe patients may get the authorised medication known as enzyme replacement therapy (ERT) [Table1]. Alglucosidase alfa is a medication that is administered intravenously (via the patient's vein). It is a genetically modified enzyme that functions similarly to the acid alpha glucosidase enzyme that occurs naturally. For patients with Pompe disease, specialised teams (including cardiologists, respiratory therapists, neurologists, etc.) can treat symptoms and provide supportive care. Inquire with your physicians about specifics for each unique instance.[7]

Infants with Pompe illness will die if untreated. The majority of those who have Pompe disease suffer from muscular weakness, cardiac issues, and respiratory (breathing) issues. Most individuals will eventually need to use wheelchairs and oxygen.

This condition cannot presently be prevented since it is inherited. There are services and therapy options for support. With early discovery and treatment, patients with any kind of infantile-onset Pompe disease may experience a longer lifespan. But both of these forms of Pompe disease frequently result in death. Rarely do patients with the typical infantile-onset type live past the age of one. Patients with the uncommon infantile-onset form may survive into their early years. Due to the disease's slower progression in children with late-onset forms of Pompe disease, they can survive longer.

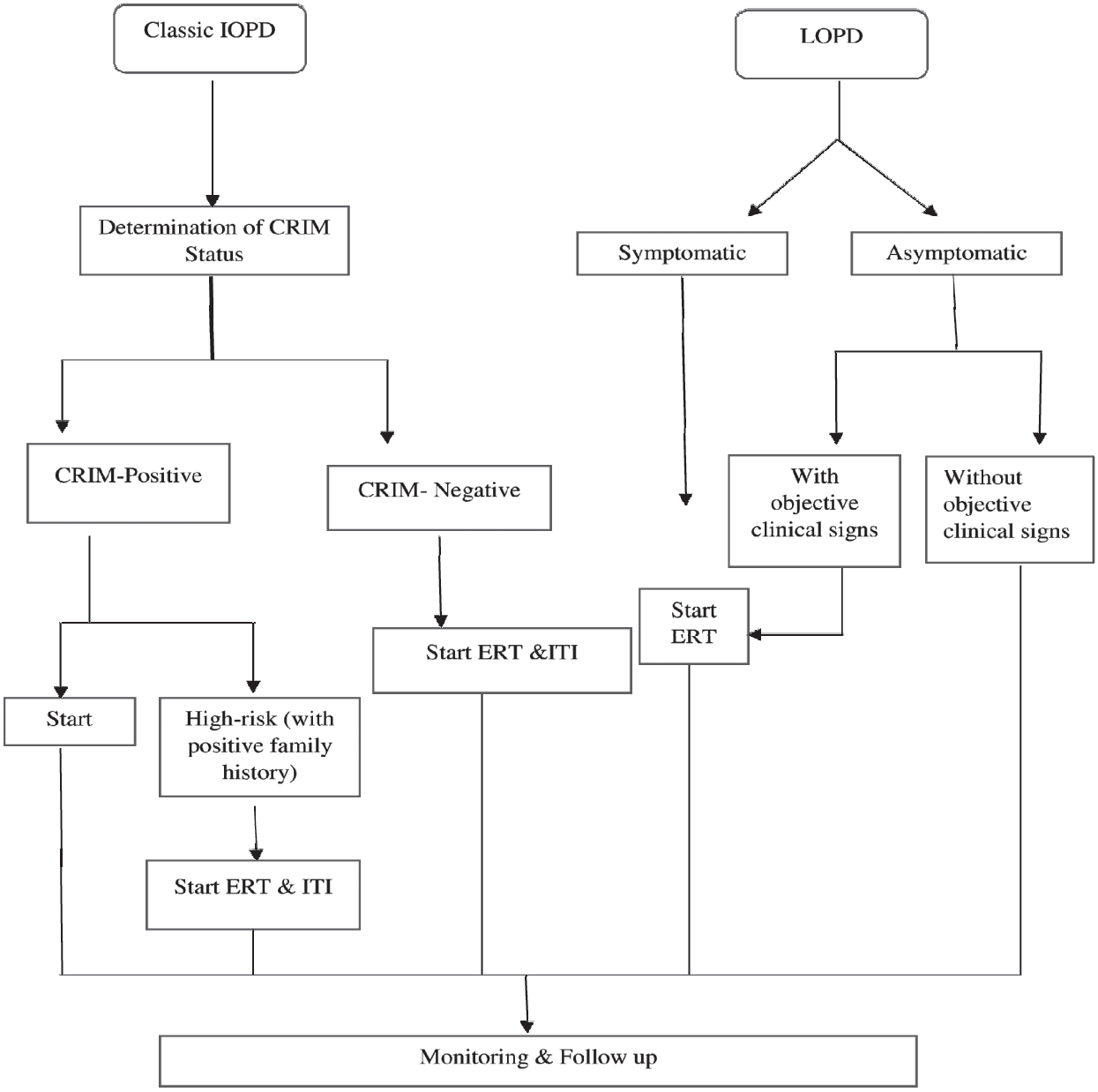

Table1-Enzyme Replacement Therapy (ERT) of Pompe Disease (CRIM -Cross-Reactive Immunologic Material CRIM, ITI-Immune Tolerance Induction).[7]

REFERENCES

1. Fukuda, T., Roberts, A., Plotz, P. H., & Raben, N. Acid alpha-glucosidase deficiency (Pompe disease). Current neurology and neuroscience reports, 2007.7(1):71–77.
2. American Association of Neuromuscular & Electrodiagnostic Medicine. Diagnostic criteria for late-onset (childhood and adult) Pompedisease. Muscle Nerve. 2009; 40(1):149-160.
3. Güngör D, Reuser AJ. How to describe the clinical spectrum in Pompe disease? Am J Med Genet A 2013; 161 (A):399-400.
4. Martiniuk F, Bodkin M, Tzall S, et al. Isolation and partial characterization of the structural gene for human acid alpha glucosidase. DNA Cell Biol 1991; 10:283-92.
5. Chien, Y. H., Lee, N. C., Thurberg, B. L., Chiang, S. C., Zhang, X. K., Keutzer, J., Huang, A. C., Wu, M. H., Huang, P. H., Tsai, F. J., Chen, Y. T., &Hwu, W. L. (2009). Pompe disease in infants: improving the prognosis by newborn screening and early treatment. Pediatrics, 2008;124(6):e1116–e1125.
6. Kishnani PS, Steiner RD, Bali D, Berger K, Byrne BJ, Case LE, Crowley JF, Downs S, Howell RR, Kravitz RM, Mackey J, Marsden D, Martins AM, Millington DS, Nicolino M, O'Grady G, Patterson MC, Rapoport DM, Slonim A, Spencer CT, Tifft CJ, Watson MS. Pompe disease diagnosis and management guideline. Genet Med. 2006; 8 (1):267-288.
7. Kazi ZB, Desai AK, Berrier KL, et al. Sustained immune tolerance induction in enzyme replacement therapy-treated CRIM-negative patients with infantile Pompe disease. JCI Insight. 2017; 2(16):93-128.

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ADVERSE DRUG REACTIONS REPORTED TO AMC
(JULY - SEPTEMBER 2022)

Suspected Drug	Adverse Drug Reaction	Number (%) n=61
Linezolid	Fever	1(1.64)
ATT Regimen		1(1.64)
Tramadol	Constipation	2(3.28)
Ferrous ascorbate+ Folic acid		2(3.28)
Ondansetron		1(1.64)
Diclofenac		1(1.64)
Tramadol + Acetaminophen		1(1.64)
Clonidine		1(1.64)
Trihexyphenidyl		2(3.28)
Olanzapine		1(1.64)
Cariprazine	Tremors	1(1.64)
Risperidone		1(1.64)
Olanzapine		1(1.64)
Heparin	Thrombocytopenia	1(1.64)
Pantoprazole		1(1.64)
Ceftriaxone	Vomiting	1(1.64)
Tramadol		1(1.64)
Lorazepam	Hyponatremia	1(1.64)
Naproxen		1(1.64)
Pantoprazole	Hypokalemia	1(1.64)
Amphotericin		1(1.64)
Etophylline + Theophylline	Tachycardia	1(1.64
Ambroxol + Levosalbutamol + Guaifenesin		1(1.64)
Risperidone	Hyperglycemia	1(1.64)
Dexamethasone		1(1.64)
Betamethasone		1(1.64)
Torsemide	Hyponatremia & Hypouricemia	1(1.64)
Tramadol	Dyspepsia	1(1.64)
Quetiapine	Drowsiness	2(3.28)
Sodium Valproate		1(1.64)

ADVERSE DRUG REACTIONS REPORTED TO AMC
(JULY - SEPTEMBER 2022)

Suspected Drug	Adverse Drug Reaction	Number (%) n=61
Tramadol	Nausea	1(1.64)
Doxophylline	Irritability	1(1.64)
Tranexamic Acid	Headache & Blurred Vision	1(1.64)
Ceftriaxone	Induration at the injection site	1(1.64)
Pantoprazole	Rashes	1(1.64)
Ceftriaxone	Skin rash	1(1.64)
Voriconazole	QT Prolongation	1(1.64)
Cisplatin	Anaemia	1(1.64)
Ferrous ascorbate+ Folic acid	Gastric Irritation	1(1.64)
Iopromide	Edema	1(1.64)
(Risperidone + Trihexyphenidyl) + Sodium Valproate	Generalized Edema	1(1.64)
Sodium Valproate	Increase appetite	1(1.64)
Vancomycin	Red Man Syndrome	1(1.64)
Labetalol	Nasal Congestion & Headache	1(1.64)
Fluconazole	Blisters	1(1.64)
Acamprosate	Tingling Sensation	1(1.64)
Haloperidol	Rigidity	1(1.64)
Clozapine	Decreased neutrophil count	1(1.64)
Heparin	Hematemesis	1(1.64)
Doxycycline	Gastritis	1(1.64)
Cefixime	Diarrhoea	1(1.64)
Pancreatin	Eosinophilia	1(1.64)
Insulin	Hypoglycemia	2(3.28)
Metformin		1(1.64)
Dexamethasone	Itching	1(1.64)
Cilostazol	Anaemia	1(1.64)

NEW DRUGS APPROVED BY CENTRAL DRUGS STANDARD CONTROL ORGANISATION (CDSCO)

(JULY - SEPTEMBER 2022)

Musammil. A*

Sl. No.	Name of Drug	Uses	Date of Issue
1.	Tepotinibe film-coated tablet 250 mg	Each film-coated tablet contains Tepotinibe hydrochloride hydrate 250 mg equivalent to Tepotinibe 225 mg	12-08-2022

Reference:

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODg5Ng[Last accessed on 30 September 2022]

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NEW DRUGS APPROVED BY U.S. FOOD AND DRUG ADMINISTRATION (FDA)

(JULY - SEPTEMBER 2022)

Athulya K*

Brand Name	Generic Name	Uses	Approved On
Xenpozyme	Olipudase alfa	Acid Sphingomyelinase Deficiency	August 2022
Spevigo	Spesolimab-sbzo	Generalized pustular psoriasis flares	September 2022
Daxxify	DaxibotulinumtoxinA-lanm	Moderate-to-severe glabellar lines associated with corrugator and/or procerus muscle activity	September 2022
Sotyktu	Deucravacitinib	Moderate-to-severe plaque psoriasis	September 2022
Rolvedon	Eflapegrastim	Decrease the incidence of infection in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia	
Terlivaz	Terlipressin	Improve kidney function in adults with hepatorenal syndrome with a rapid reduction in kidney function	September 2022
Elucirem	Gadopiclenol	Detect and visualize lesions with abnormal vascularity in the central nervous system and the body	September 2022
Omlonti	Oomidenepag isopropyl ophthalmic solution	Reduce elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	September 2022
Relyvrio	Sodiumphenylbutyrate / taurursodiol	Amyotrophic lateral sclerosis (ALS)	September 2022
Lytgobi	Futibatinib	Intrahepatic cholangiocarcinoma harbouring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements	September 2022

Reference:

https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022 [Last assessed on 30 September 2022]

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DEPARTMENT OF PHARMACY PRACTICE NEWS

WORLD PATIENT SAFETY DAY AND SECOND NATIONAL PHARMACOVIGILANCE WEEK CELEBRATION

The Adverse Drug Reaction Monitoring Centre (AMC), Justice K S Hegde Charitable Hospital, NGSM Institute of Pharmaceutical Sciences, KSHEMA, Nitte (Deemed to be University), Mangalore celebrated the **World Patient Safety Day** on 17th September 2022 and **2nd National Pharmacovigilance Week** between 17th - 23rd September 2022 under the theme of **"*Encouraging Reporting of ADR by Patients*".** During this week, the AMC organised a quiz competition, skit competition, and oral presentation as a part of the week-long event.

Furthermore, on 22nd September 2022, an **Invited Lecture** on **Adverse Drug Reactions Reporting** was organized and Dr. Ashok Shenoy, Professor, Dept. of Pharmacology, AMC Coordinator of Kasturba Medical College, Mangalore delivered the talk.

NGSM Institute of Pharmaceutical Sciences

Nitte Institutions

Health Science Institutions, Hospitals and Research Centres

1. K.S. Hegde Medical Academy, Mangaluru
2. A.B. Shetty Memorial Institute of Dental Sciences, Mangaluru
3. Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences, Mangaluru
4. Nitte Usha Institute of Nursing Sciences, Mangaluru
5. Nitte Institute of Physiotherapy, Mangaluru
6. Nitte Institute of Medical Laboratory Sciences, Mangaluru
7. Nitte Institute of Speech and Hearing, Mangaluru
8. Justice K. S. Hegde Charitable Hospital, Mangaluru
9. Nitte Meenakshi Institute of Craniofacial Surgery, Mangaluru
10. Leela Narayana Shetty Memorial Cancer Institute, Mangaluru
11. Nitte-Gajria Hospital, Karkala
12. Kshema-IVF: Fertillity & Reproductive Medicine Centre, Mangaluru
13. Nitte Rural Psychiatry Centre, Nitte.
14. Kowdoor Gopal Hegde & Smt. Manorama Hegde Hospital, Bailur.
15. Nitte University Centre for Science Education & Research (NUCSER), Mangaluru
16. Nitte University Centre for Animal Research & Experimentation (NUCARE), Mangaluru
17. Nitte University Centre for Stemcell Research & Regenerative Medicine (NUCSReM), Mangaluru

Engineering Institutions

18. Nitte Mahalinga Adyanthaya Memorial Institute of Technology, Nitte
19. Nitte Meenakshi Institute of Technology, Bengaluru
20. Nitte Institute of Architecture, Mangaluru

Management Institutions

21. Justice K. S. Hegde Institute of Management (Dept. of Nitte Management Studies, NMAMIT, Nitte)
22. Nitte School of Management, Bengaluru
23. Sarosh Institute of Hotel Administration, Mangaluru
24. Nitte Institute of Banking & Finance, Mangaluru
25. Nitte Institute Communication, Mangaluru

Technical Instituions

26. Nitte Rukmini Adyanthaya Memorial Polytechnic, Nitte
27. Mulki Ramakrishna Punja Industrial Training Institute, Thokur

Science and Commerce Institutions

28. Dr. Nitte Shankara Adyanthaya Memorial First Grade College, Nitte
29. Dr. Nitte Shankara Adyanthaya Memorial First Grade College, Bengaluru
30. Dr. Nitte Shankara Adyanthaya Memorial Pre-University College, Nitte
31. Dr. Nitte Shankara Adyanthaya Memorial Pre-University College, Mangaluru
32. Dr. Nitte Shankara Adyanthaya Memorial Pre-University College, Bengaluru

Schools

33. Dr. Nitte Shankara Adyanthaya Memorial Senior Secondary School, Nitte
34. Dr. Mundkur Ramanna Shetty Memorial English Medium High School, Thokur
35. Nitte International School, Bengaluru
36. Dr. Nitte Shankara Adyanthaya Memorial Higher Primary School, Bolakodi

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