WWW.IJRPR.COM

**International Journal of Research Publication and Reviews**

Journal homepage: www.ijrpr.com ISSN 2582-7421

# EnteroMix: A Next-Generation Cancer Vaccine Combining Oncolytic Viruses and mRNA Platforms

***Bharathi. D[1*],Deepa.N[2], Benita. E[3], Janani. P[4], Kirubakaran. A[5], Shahana. S.[6]***

[1]Faculty of Pharmacy,BIHER, SBMCH, Department of Pharmaceutical Chemistry, Chromepet
Corresponding author:
bharathi.madhavan3@gmail.com

**ABSTRACT :**

*EnteroMix* is a novel therapeutic cancer vaccine that combines an *oncolytic viral platform* with a *personalized mRNA vaccine* strategy to induce robust anti-tumour immunity. The oncolytic virus selectively infects and lyses tumour cells, releasing tumour-associated antigens and activating innate immune pathways through pathogen- and damage-associated molecular patterns. Concurrently, the personalized mRNA vaccine—derived from tumour RNA—encodes patient-specific neoantigens, enabling antigen-presenting cells to stimulate $CD8^+$ cytotoxic and $CD4^+$ helper T-cell responses. This dual approach synergistically converts the tumour into an immunogenic environment while enhancing systemic adaptive immunity, thereby promoting tumour regression and long-term immune memory. Early reports suggest favourable safety and promising efficacy signals in colorectal and other cancers; however, peer-reviewed clinical data remain limited, and larger randomized trials are essential for validation. EnteroMix represents a mechanistically rational and potentially transformative step in cancer immunotherapy, bridging innate and adaptive immune activation for durable tumour control.

**Keywords**: *EnteroMix, mRNA ,* T-cell, anti-tumour, $CD8^+$ cytotoxic and $CD4^+$, neoantigens, oncolytic virus

## 1.Introduction

Cancer remains one of the leading causes of morbidity and mortality worldwide, and despite advances in surgery, chemotherapy, radiotherapy, and targeted therapies, many patients experience poor long-term outcomes. In recent decades, *cancer immunotherapy* has emerged as a transformative approach, leveraging the body's own immune system to recognize and eliminate malignant cells. Among these strategies, *cancer vaccines*—both therapeutic and prophylactic—have gained significant interest, particularly with the advent of *mRNA platforms* and *oncolytic virotherapy*.

*EnteroMix* represents a novel therapeutic cancer vaccine developed in Russia that integrates *two complementary mechanisms*: (i) an *oncolytic enterovirus* engineered to selectively infect and lyse tumour cells, thereby releasing tumour antigens and danger signals that stimulate innate immunity, and (ii) a *personalized mRNA vaccine*, designed from patient-derived tumour RNA, which encodes specific tumour-associated neoantigens to activate adaptive immune responses. This dual approach is intended to convert immunologically "cold" tumours into "hot" ones, enhancing antigen presentation, breaking tumour immune tolerance, and generating durable T-cell–mediated antitumour immunity.

Early preclinical and preliminary clinical reports suggest that EnteroMix exhibits strong tumour regression potential and a favourable safety profile in patients with advanced malignancies, including colorectal cancer. However, as of now, most information originates from institutional announcements and media coverage, with peer-reviewed clinical trial data yet to be published. The scientific rationale, nonetheless, positions EnteroMix at the intersection of *oncolytic virotherapy* and *mRNA vaccine technology*, offering a potentially powerful next-generation immunotherapeutic strategy.

The platform is reported to use a multi-viral ("four harmless viruses") oncolytic component alongside mRNA derived from a patient's own tumour, with the goal of generating immune responses that are both broad (via tumour cell lysis, antigen release) and specific (via neoantigen presentation).Early trial reports involving approximately 48 colorectal cancer patients suggest the vaccine is well-tolerated, with no severe adverse effects, and shows tumour shrinkage or slowed tumour growth in ~60-80% of cases[1].Some claims go further, stating "100% immune response activation" in these early cohorts[2].

However, several important caveats remain. To date, EnteroMix is not yet documented in peer-reviewed scientific journals; trial protocols, detailed adverse-event logs, randomized controlled comparisons, long-term follow-up, and raw immunologic data have not been publicly released[3].Moreover, experts urge caution given past examples where early immunogenicity or tumour shrinkage did not translate into durable survival benefit.[4]

The first indicated use of EnteroMix is for *colorectal cancer*, with development also underway for *glioblastoma* and *melanoma* (including ocular melanoma).[5] Regulatory documentation reportedly has been submitted for registration in Russia; the vaccine is expected to be made free to patients once approved.[6]

## 2.MECHANISAM OF ACTION

### *2.*1 Oncolytic Virus Action

EnteroMix contains an engineered oncolytic enterovirus.
It selectively infects tumour cells, sparing normal tissues.
Inside tumour cells, the virus replicates → cell lysis (oncolysis).
This releases tumour-associated antigens (TAAs), neoantigens, and danger signals (DAMPs, PAMPs).

### *2.2* Innate Immune Activation

Dendritic cells (DCs), macrophages, and NK cells are recruited.
Pattern recognition receptors (e.g., TLRs, RIG-I) detect viral RNA and danger signals.
Production of Type I interferons**, TNF-α, IL-12**, etc. creates an immunostimulatory tumour microenvironment.

### *2.3* Personalized mRNA Vaccine

Tumour RNA is extracted from each patient → used to design an mRNA vaccine encoding patient-specific neoantigens.
The mRNA vaccine is taken up by APCs → antigens are translated and displayed on MHC I and II molecules.

### *2.4* Adaptive Immunity

$CD8^+$ cytotoxic T lymphocytes (CTLs) are primed → directly kill tumour cells.
$CD4^+$ helper T cells provide cytokine support, sustain CTL activity, and generate memory.
Long-term immune memory reduces recurrence risk.

### *2.5* Overall Synergy

Oncolytic virus = breaks tolerance, releases broad antigens, activates innate immunity.
*mRNA vaccine* = focuses adaptive immunity on patient-specific neoantigens.
Together = *robust systemic anti-tumour response* → tumour regression + memory.

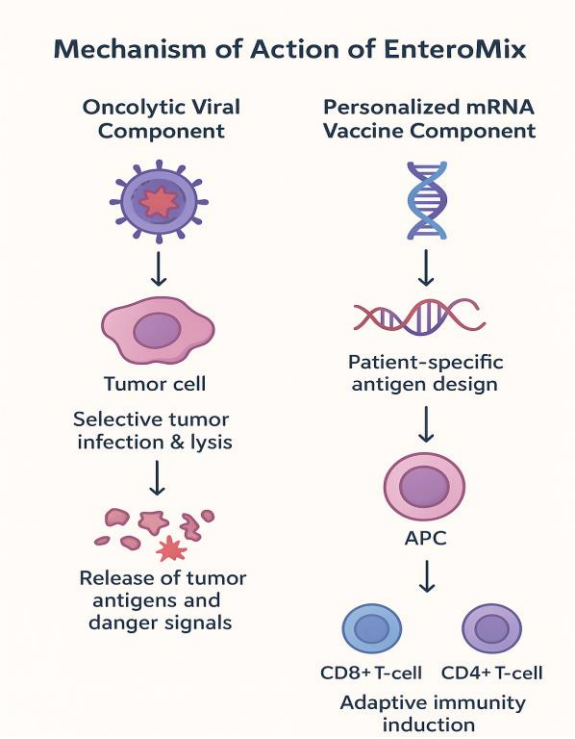


**Fig.**

**1 – Mechanism of action**

**1.Reported Outcomes of EnteroMix**

| Outcome | What has been claimed | Source(s) / Context | Caveats |
|---|---|---|---|
| Preclinical (animal / model) tumour response | Tumour shrinkage / regression of 60-80%; in some cases, "eliminated" tumours; improved survival in animal models. | FMBA announcements; media reporting of preclinical trials. | Exact models (species, tumour types), numbers, controls, follow-up, and statistical significance not disclosed. |
| Safety in preclinical studies | Safe with repeated dosing; no significant toxicity reported in animal studies. | Media/FMBA statements. | Without published toxicology or pathology data, or peer-review, claims are unverified. |
| Phase I / early human trial enrolment | A Phase I trial has begun (or has begun recruitment) in Russia with ~48 volunteers. | Announced by the National Medical Research Radiology Center during forums in 2025. | At least as of reports, results (beyond safety) not published; endpoints (immune response, tumour response, survival) not clearly defined or peer-reviewed. |
| Efficacy in humans (initial / claimed) | Reports claim tumour shrinkage / slowed tumour growth by ~60-80%; in some cases claimed "100% efficacy" (often used loosely to mean immune response activation or absence of severe side effects) in early trials. | These are media reports, quoting FMBA or institutional announcements. | The meaning of "100% efficacy" is vague — probably refers to "all trial participants showed some measurable immune activation / response / tolerated vaccine," not necessarily complete tumour elimination or long-term survival. |

## 3.Critical Evaluation & Uncertainties

*No peer-reviewed publication yet*: The detailed methods, raw data, endpoints (PFS, OS, immune biomarkers), and statistical analyses are not yet available in scientific journals.[7]

*Small human sample size*: ~48 volunteers in Phase I — adequate for safety signals, but not powered for strong efficacy conclusions.[8]

*Ambiguity in "100% efficacy"*: Likely refers to immune activation or minor tumour response rather than full remission. Media uses this phrase loosely.[9]

*Duration of follow-up unknown*: How long responses last, whether tumour regression translates into improved survival or lower recurrence, is not disclosed.[10, 11]

*Variability in tumour biology*: Colorectal cancer, glioblastoma, melanoma are very different; success in one does not guarantee success in others.[12,13]

## 4.Conclusion

EnteroMix represents a *novel dual-platform cancer vaccine* that combines the oncolytic properties of engineered enteroviruses with the precision of personalized mRNA vaccination. By simultaneously inducing tumour cell lysis, releasing endogenous tumour antigens, and priming adaptive immunity against patient-specific neoantigens, the vaccine aims to generate a comprehensive and durable anti-tumour immune response.

Preclinical findings and early human trial announcements suggest *favourable safety* and *encouraging signals of efficacy*, particularly in colorectal cancer, with future applications proposed for glioblastoma and melanoma. Reports of "100% efficacy" should, however, be interpreted cautiously, as these claims currently stem from institutional and media sources without peer-reviewed validation.

At present, the greatest strengths of EnteroMix lie in its *innovative mechanism* and its potential to bridge innate and adaptive immunity. Its limitations include the *absence of peer-reviewed clinical data*, the *small scale of reported trials*, and uncertainty regarding *long-term outcomes* such as overall survival and recurrence rates.

Overall, EnteroMix is a *promising candidate* in the field of cancer immunotherapy, but its ultimate value will depend on the outcomes of *rigorous, large-scale, and transparently reported clinical trials*. Until such evidence becomes available, enthusiasm should be balanced with scientific caution.

***Acknowledgements***

The authors wish to thank Faculty of Pharmacy,BIHER,SBMCH Campus, Department of Pharmaceutical Chemistry, for providing the necessary facilities and support to carry out this work. We are also grateful to our guide, for their valuable insights and encouragement throughout the study.

**REFERENCES**

1. NIH Research Matters. An mRNA vaccine to treat pancreatic cancer created a strong anti-tumor immune response in half the participants in a small study. NIH; 2023. National Institutes of Health (NIH)
2. India Today. "Russia's Enteromix cancer vaccine: Scientific breakthrough or global hype?" India Today; 2025 Sep 8. India Today
3. Business Today. "Major victory against cancer? Russia's mRNA cancer vaccine Enteromix raises global hope after stunning trial results." Business Today; 2025 Sep 7. Business Today
4. Business Standard. "Enteromix Cancer Vaccine: Cancer breakthrough? Russia's mRNA vaccine shows 100% early success." Business Standard; 2025. Business Standard

5. ETHealthWorld. "Russia's mRNA Cancer Vaccine: Big Claim, Bigger Questions—Experts Urge Need for Rigorous Data." ETHealthWorld; 2025. ETHealthworld.com
6. One.uz. "New mRNA vaccine for cancer is being registered in Russia." Society Today; 2025.
7. https://www.onlymyhealth.com/author/sushmita-sharma-1591456751
8. https://www.thenews.com.pk/latest/1342048-russias-enteromix-cancer-vaccine-aces-preclinical-trials?utm_source=chatgpt.com
9. Federal Medical-Biological Agency of Russia. *Press Release on EnteroMix Clinical Trial Launch.* Moscow; 2025.
10. "Russia's EnteroMix Cancer Vaccine Shows 100% Efficacy in Early Trials." NDTV Health. September 2025.
11. "Russian Scientists Say Cancer Vaccine EnteroMix Ready for Use." India Today. September 2025.
12. "EnteroMix: Cancer Vaccine Aces Preclinical Trials." The News International. July 2025.
13. Plenglish.com. *Russia Begins Clinical Trials of New Cancer Vaccine.* June 2025.