BCIL Biotech Consortium India Limited

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Accelerating Technology Translation

Nanomicelles based Effective Drug Delivery System

TECHNOLOGY AVAILABLE FOR TRANSFER

UNMET NEED

Drug delivery strategies have a major role in converting promising therapeutics into successful therapies. Drug delivery technologies have empowered many pharmaceutical product developments for improving patient health by enhancing the delivery of a therapeutic to its target site, minimizing off-target accumulation and facilitating patient compliance. Existing drug delivery systems pose the following drawbacks.

- Low drug encapsulation capacity and high excipient to drug ratio, as well as low stability in bio-media leading to low bioavailability.
- Physical encapsulation of drugs in the carrier, often leads to an initial burst release of drug in the circulation.
- These drawbacks are prominently observed in anticancer Drug formulations. Whereas water-soluble anticancer drug formulations are challenging because of their solubility and poor absorption by the body, the water-insoluble anticancer drugs pose even more challenging risks. Water-insoluble hydrophobic anticancer drugs such as Taxanes and Camptothecin lead to hypersensitivity reactions, haematological problems and hepatotoxicity due to which sensitive patients may succumb to death. Commercially available parenteral formulations of the hydrophobic drugs e.g Docetaxel (DTX) use high amounts of surfactants that upon intravenous administration lead to a spectrum of systemic toxicities including fatal hypersensitivity reactions.

Therefore there is a need for development of effective administrable drug delivery system with steady bio-availability. Lipid-based drug delivery systems offer promise in the development of such drug formulations with steady bioavailability and other added features.

TECHNOLOGY

The present invention is a Bile acid-drug conjugate nanoparticle which can be used as an effective drug delivery platform.

This drug delivery platform has been tested using anti-cancer drug either in encapsulated or conjugated pattern in nano-particle form. The lipid-based nanoparticle drug formulation was aggregated in supra molecular form to attain different structural assemblies which was found useful in target-specific drug delivery. The invention addressed the problem of delivery, toxic nature, and insufficient retention time of hydrophobic and hydrophilic cancer drugs using a lipid-based formulation.

This platform technology has been tested for delivery of commonly used hydrophobic water-insoluble drug Docetaxel using nanomicelles. This invention used pro-drug strategy for sustained release of the DTX with increased accumulation at the tumor site without any free drug in the plasma, in comparison to commercial drug formulations.

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VALIDATION

The efficacy of the drug delivery platform has been tested by comparing it with the available marketed drug for which:

- Antitumor activity has been established in murine models and found effective.
- In-depth toxicology and pharmacokinetic studies in murine and non-human primates have been performed to confirm its effectiveness.

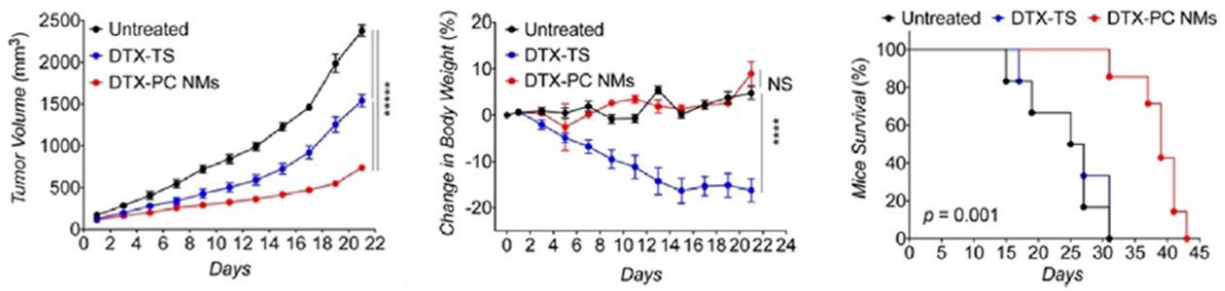

Fig. Graphical representation of the comparative efficiency data of developed formulation of docetaxel (DTX-PC NMs) with Taxotere (DTX-TS), the FDA-approved formulation of DTX.

APPLICATIONS

- Efficient delivery of existing drugs for effective treatment of diseases particularly chronic diseases such as cancer, bacterial infection, fungal infection, diabetes, and inflammatory diseases.
- Delivery of drugs in Cancer patients diagnosed with breast cancer, non-small cell lung cancer, gastric cancer, prostate cancer, or head, neck cancer etc.

UNIQUE SELLING PROPOSITION

Following are the highlights of the drug delivery system validated with an anti-cancer drug-Docetaxel. This drug delivery platform is expected to have many more USPs when treated with other drugs-

- Up to 3.5-fold increase in drug biodistribution compared to results from the commercial formulation (DTX-TS) in mice.
- Three times higher free drug accumulation at the tumor site
- Two times reduction in mean tumor volume in mice after 21 days.
- Do not affect the body weight and cause any systemic toxicity
- Decelerate tumor progression and increase survivability.
- Targeted drug delivery at tumor sight.

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• Unique sub-100 nm sized NMs provide increased systemic circulation leading to enhanced permeation and retention (EPR) in leaky and highly vascularized tumor tissue.
• Enhanced drug entrapment efficacy.
• Simple and easy steps in nanoparticle preparation.

OPPORTUNITY

- The global pharmaceutical drug delivery market is projected to reach USD 2,206.5 billion by 2026, at a CAGR of 5.9% from 2022 - 2026.
- Whereas global Drug Delivery Cancer Market alone was estimated at USD 1400.1 Million in 2019 and expected to grow at a CAGR of 7.1 % from 2020 - 2026.
- The increasing prevalence of cancer across the globe is a major factor driving the growth of the global drug delivery in cancer market.
- Additionally increasing old age population, advanced diagnostic technologies, high cost to develop new drugs and problems with current drug delivery systems demand for novel effective and safer drug delivery approaches.

STAGE OF TECHNOLOGY

- This has been validated and is ready for industrial scale-up for the production of drug delivery molecules. Further, the molecule can be modified for their easy application and convenience as per the interest area of application.

LICENSING OPPORTUNITY

BCIL is looking for a suitable industrial partner for the development and commercialization of Nanomicelles-based Effective Drug Delivery System.

CONTACT:

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