Pharmaceutical Licensing Opportunity

UNIVERSITY OF SASKATCHEWAN

Novel formulation for sustained mycophenolate mofetil release after organ transplants

Market need

There is a need for a novel drug formulation that enhances maintenance therapy in solid organ transplant patients and prevents organ rejection.

Mycophenolate mofetil (MMF) is an immunosuppressant that significantly reduces acute rejection rates; however, it is rapidly excreted from the body. The need for a sustained post-transplant MMF formulation is critical for maintaining the health and improving the quality of life in organ transplant patients.

Our solution

We offer a novel modified release formulation for oral delivery of MMF, comprising polymeric nanoparticles (PNPs) coated with a muco-adhesive polymer. The nanoparticles comprise MMF encapsulated in poly(lactic) acid (PLA) at the ratio of 1:7 of MMF to PLA, and the composition is encapsulated in medium molecular weight (MMWC) chitosan.

MMF: PLA: MMWC= 1:7:7 offers the optimal formulation ratio maximizing the sustained release of the MMF up to 24 hours and minimizes the burst release of MMF and its undesirable diffusion and degradation in the system.

Benefits of our approach

- Eliminates the main drawback of high dose medications
- Increases likelihood of being used by patients as the formulation is convenient and less aggressive
- Provides alternative or supplementary treatment to patients who currently address symptoms via lifestyle changes.
- Expands treatment options for life-time use of immunosuppressive medications in organ transplant patient
- It is based on known compounds combined into a convenient delivery mechanism that is safe and effective
- The IP-protected novel formulation of existing ingredients reduces time to market, as all ingredients are known compounds with extensive clinical histories.
- benefits any type of organ transplant

Publications

- Development and in vitro characterization of chitosan-coated polymeric nanoparticles for oral delivery and sustained release of the immunosuppressant drug mycophenolate mofetil. Mohammed M, Mansell H, Shoker A, Wasan KM, Wasan EK. Drug Dev Ind Pharm. 2019 Jan;45(1):76-87. doi: 10.1080/03639045.2018.1518455. PMID: 30169982

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Background

Organ transplant patients take 11 pills/day on average for immunosuppressive and supportive drugs. These drugs are critical to prevent the body from fighting off the transplanted organ and avoid the underlying conditions such as organ rejection.

Complexities associated with the use of several drugs on a daily basis coupled with the rising need for patients ease throughout life after transplant, are some of the key factors fueling the growth of the global organ transplant market.

Current treatment options

Immunosuppressant drugs are prescribed for post-transplantation. Mycophenolate mofetil (MMF) is an immunosuppressant pro-drug prescribed in organ transplant patients. MMF converts to MPA (mycophenolic acid) in the liver and intestinal wall that rapidly clears from the body by defecation.

Challenges of the current treatments

- Very high oral dose (up to 2g daily) is required to compensate for the rapid clearance of the drug
- The high dose of the drug causes gastrointestinal toxicity and diarrhea
- To avoid toxicity, the total MMF dose is recommended in 2-4 doses daily
- Taking the required dose is crucial and missing the required dose may cause organ impairment / rejection and increase mortality

Inventor: Dr. Ellen Wasan

Patents/applications: US patent application 16/291,269: "MODIFIED RELEASE FORMULATIONS OF MYCOPHENOLATE MOFETIL" (priority date Mar 2018)

Reference: 17-017

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