

BROAD-SPECTRUM THERAPEUTICS FOR VIRAL DISEASES: A MEDICAL COUNTERMEASURE PLATFORM FOR EMERGING THREATS

MedinCell®: Developing Long-acting Injectables Of Small Molecule Drugs To Biologics, Targeting Systemic Or Local Delivery, Aiming To Provide Optimal Sustained Drug Exposure From A Single Injection.

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MedinCell® is a pharmaceutical company specializing in formulating long-acting in-situ forming depot injectables using its proprietary technology, BEPO®. Long-acting injectables (LAIs) are now recognized as key pillars of the treatment armamentarium in several therapeutic areas, most notably in infectious disease prophylaxis and CNS. Recurrent dosing requirements lead to adherence challenges which may ultimately lead to the risk of sub-efficacious concentrations and viral drug resistance. Beyond compliance, LAIs may bring additional clinical benefits such as improved safety and tolerability with the potential for enhanced treatment efficacy.

What makes BEPO® an innovative and versatile platform perfect for DTRA's mission is its ability to be combined with a wide array of compounds (small molecules, peptides, and proteins) for local or systemic release, and can be developed as prefilled and ready-to-inject dosage forms. Our LAIs require a much lower dose than oral formulations to reach clinical efficacy, can be stored at room temperature in harsh climatic conditions, and are straightforward to manufacture at an affordable cost. Furthermore, our platform can also accommodate the combined sustained delivery of at least two drugs, which could be a significant advantage in polypharmacy.

MedinCell has two manufacturing sites (US & EU) for the BEPO® technology polymers, each with commercial-scale capability, greatly decreasing the risk of supply blocks. Thanks to the affordable cost of manufacturing and versatility of our technology, Unitaid and BMGF have partnered with us for the development of two global health programs.

We are seeking to provide the DoD with access to our technology platform with the aim of developing new LAIs to combat the emerging threats facing our warfighters from biologics, chemicals, and any identified vulnerabilities for DTRA missions. Covid-19 was a wake-up call to the world of how important medical countermeasure platforms are for viral diseases. BEPO® can protect warfighters from biological and/or chemical threats for prolonged periods with one quick and easy subcutaneous injection. MedinCell® can achieve similar reformulations of many other drugs, having a range of therapeutic effects from weeks up to a year depending on the desired timeframe.

The applications of BEPO® can be expanded into other areas and can potentially address the full spectrum of a warfighter's needs at home or on the battlefield, especially in CNS indications. Our lead asset, under regulatory review for market authorization by the FDA, is a subcutaneous extended-release reformulation of Risperidone to treat Schizophrenia. Another example is our 3-month intra-articular injection of celecoxib to treat the pain and inflammation of post-total knee replacement surgery. Since it is a local injection, it has little to no systemic exposure, providing an improved safety profile than the oral equivalent (better cardio and gastrointestinal-toxicity profiles). Another benefit to a sustained local release of an NSAID is the decreased need of opioids to relieve pain.

We look forward to presenting the full spectrum of applications that our technology can address, and the unmet medical needs our unique LAIs can solve.

I would like to thank every person at MedinCell® who helped complete this abstract, and BMGF and UNITAID for financially supporting our efforts in the global health initiatives. We at MedinCell® are truly excited and motivated to share our technology with the DoD and to develop medicine to better protect our warfighters on the field and at home.