BEPO®

Verified by the innovator, on Feb 2022
MedinCell® is a pharmaceutical company at premarketing stage that develops innovative long-acting injectable medicines in many therapeutic areas. Products of our portfolio are based on our BEPO® technology and aim to ensure patient compliance, improve the effectiveness and accessibility of treatments, and reduce their environmental footprint.
Sponsor(s)

No sponsor indicated
Partnerships

TEVA Pharmaceuticals
www.tevapharm.com

Arthritis Innovation Corporation (AIC)
www.aic.com/about-us

UNITAID
www.unitaid.org

The Bill and Melinda Gates Foundation
www.gatesfoundation.org

CORBION
www.corbion.com
Technology information

**Type of technology**
In-situ forming gel/implant

**Administration route**
Subcutaneous, Intra-articular

**Development state and regulatory approval**

**Active Pharmaceutical Ingredient (API)**
Risperidone

**Development Stage**
Phase III

**Regulatory Approval**
NDA pending approval at the FDA (2022)
Description

BEPO® is a simple yet flexible technology based on MedinCell®'s custom proprietary copolymers, which forms a fully bioresorbable depot once injected. BEPO® technology has the potential to control regular delivery of an API at an optimal therapeutic dose for several days, weeks or months. BEPO® can be administered subcutaneously for systemic exposure of APIs or locally for targeted treatments.

Technology highlight

From systemic to local delivery, BEPO® is a clinically advanced proprietary long acting injectable technology that enables the controlled delivery of various active ingredients, to address a broad range of therapeutic needs.
Technology main components

Three core components: a- Two block copolymers, bioresorbable, made of Polyethylene glycol and poly(Lactic acid). They are functional excipients, ensuring the controlled drug release. b- A pharmaceutically acceptable organic solvent, e.g. DMSO, to dissolve the copolymers and make the entire system injectable. c- An API to ensure pharmacological activity. The API can be a small molecule, a peptide or a therapeutic protein.

Information on the raw materials sourcing, availability and anticipated price

The core functional copolymer excipients are exclusively manufactured and supplied through a joint Venture made between Medincell and Corbion, called CMB. Corbion manufactures the copolymers with the appropriate quality standards and scale to ensure sufficient availability.

Delivery device(s)

No delivery device
APIs compatibility profile

API desired features

Small molecules

Small molecules are best suited for formulating. Compatibility needs to be determined on a case-by-case basis.

Proteins

Case by case basis. Complex biomacromolecules like therapeutic proteins have inherent challenges that need to be tackled specifically during formulation development.

Additional solubility data

Not provided

Additional stability data

Not provided

API loading: Maximum drug quantity to be loaded

0.1-60%

API co-administration

Not provided
Scale-up and manufacturing prospects

Scale-up prospects
Not provided

Tentative equipment list for manufacturing
Not provided

Manufacturing
Not provided

Specific analytical instrument required for characterization of formulation
Not provided
Clinical trials

Not provided
Excipients

**Proprietary excipients used**

No proprietary excipient used

**Novel excipients or existing excipients at a concentration above Inactive Ingredients Database (IID) for the specified route of administration**

Confidential information

**Residual solvents used**

No residual solvent used
Additional features

**Other features of the technology**

- Biodegradable
- Room temperature storage
- At least 1 year shelf life
- Drug-eluting

**Release properties**

BEPO® technology has the potential to control regular delivery of an API at an optimal therapeutic dose for several days, weeks or months. The technology can provide a sustained release profile of an API with low initial burst.

**Injectability**

BEPO® drug products are liquid and can be injected using standard injection device with standard 21 gauge needle or even thinner depending on the formulation characteristics.

**Safety**

We currently have 3 clinically advanced drug products based on BEPO® technology, including one at NDA stage with TEVA pharmaceuticals. The RISE clinical phase III study completed in November 2020 did not raise any safety signals that were inconsistent with the known safety profile of other risperidone formulations.

**Stability**

Our technology may allow long-term storage at room temperature with shelf life well above 1 year.
Storage conditions and cold-chain related features

Room Temperature storage possible. Cold chain is not mandatory, except in instances where the drug substance requires refrigeration for long term storage.
Potential application(s)

Therapeutic area(s)
Malaria
Contraception

Use case(s)
Not provided

Use of technology

Ease of administration
- Administered by a nurse
- Administered by a specialty health worker
- To be determined

Frequency of administration
Depending on product, once weekly up to once annually, Weekly, Monthly, Bi-yearly, Yearly, Once every 8 weeks

User acceptance
Not provided
Targeted user groups

Age Cohort

- Adults
- Older Adults

Genders

- All
- Male
- Female
- Cisgender female
- Cisgender male
- Transgender female
- Transgender male
- Intersex
- Gender non-binary

Pregnant individuals
Unspecified

Lactating individuals
Unspecified

Healthy individuals
Unspecified

Comment
Not provided
Potential associated API(s)

Risperidone

Class(es)
antipsychotic

Development stage
Phase III

Clinical trial number(s)
Not provided

Foreseen/approved indication(s)
Schizophrenia

Foreseen user group
Not provided

Foreseen duration between application(s)
1 or 2 months

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals
NDA pending approval at the FDA (2022)
Celecoxib

Class(es)
anti inflammatory

Development stage
Phase II

Clinical trial number(s)
Not provided

Foreseen/approved indication(s)
post-operative pain and inflammation

Foreseen user group
Not provided

Foreseen duration between application(s)
Once every 12 weeks

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals
Not provided
**Ivermectin**

**Class(es)**
Not provided

**Development stage**
Not provided

**Clinical trial number(s)**
Not provided

**Foreseen/approved indication(s)**
Malaria Transmission prevention

**Foreseen user group**
Not provided

**Foreseen duration between application(s)**
Single intervention per year (3 months action duration)

**Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals**
Not provided
Patent info
## Patents

### Patent information

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<tbody>
<tr>
<td>Biodegradable drug delivery composition covering BEPO® technology</td>
<td>WO2012090070</td>
<td>Long-acting platform</td>
<td>Medincell</td>
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A biodegradable drug delivery compositions comprising a triblock copolymer containing a polyester and a polyethylene glycol and a diblock copolymer containing a polyester and an end-capped polyethylene glycol, as well as a pharmaceutically active principle is disclosed.

### Patent status

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<th>High income</th>
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<tr>
<td>Granted</td>
<td>Brazil, China, Russian Federation, Kazakhstan, Bulgaria, Türkiye, Mexico, Malaysia, Ukraine, South Africa, India, Indonesia, Viet Nam</td>
<td>Australia, Canada, Chile, Liechtenstein, Italy, Norway, Denmark, Belgium, United Kingdom, Greece, Netherlands, Hungary, Croatia, Switzerland, Spain, Slovenia, Austria, Romania, Iceland, Cyprus, Finland, France, Slovakia, Poland, Latvia, Ireland, Estonia, Germany, Luxembourg, Portugal, Czechia, Lithuania, Sweden, Israel, Japan, Korea, Republic of, New Zealand, Singapore, United States of America, Hong Kong</td>
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<td>Filed</td>
<td>Bulgaria, Türkiye, North Macedonia, Thailand</td>
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<td>World Intellectual Property Organization (WIPO), Liechtenstein, Norway, Malta, Denmark, Belgium, Greece, Hungary, Croatia, Switzerland, San Marino, Slovenia, Austria, Romania, Iceland, Cyprus, Finland, Slovakia, Latvia, Ireland, Estonia, Luxembourg, Portugal, Czechia, Lithuania, Monaco, Sweden, United States of America, United Arab Emirates, Qatar, Brunei Darussalam</td>
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**MPP Licence(s)**

**MPP/MedinCell licence on a long-acting formulation of ivermectin developed using BEPO® technology**

https://medicinespatentpool.org/licence-post/long-acting-technology-for-malaria-vector-control
Biodegradable drug delivery composition comprising triblock polymer and diblock polymer

Expiry date: 2033-06-27

A biodegradable drug delivery compositions comprising a triblock copolymer containing a polyester and a polyethylene glycol and a diblock copolymer containing a polyester and an end-capped polyethylene glycol, as well as at least one pharmaceutically active principle or hydrophobic active principle such as medroxyprogesterone acetate, levonorgestrel, cyclosporine, progesterone or bupivacaine is disclosed.

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<td>WO2014001904</td>
<td>Composition</td>
<td>Medincell</td>
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<tr>
<td>Method for morselizing and/or targeting pharmaceutically active principles to synovial tissue</td>
<td>WO2017085561</td>
<td>Process</td>
<td>Medincell</td>
<td>Yes</td>
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A method of targeting to the synovial tissue biodegradable drug delivery compositions or morselizing biodegradable drug delivery compositions are described. The biodegradable drug composition comprises a triblock copolymer containing a polyester and a polyethylene glycol and a diblock copolymer containing a polyester and an end-capped polyethylene glycol, as well as at least one pharmaceutically active principle is disclosed.

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This article presents BEPO®, an in situ forming depot (ISFD) technology mediated by a solvent-exchange mechanism. The matrix of the in situ formed drug delivery depot is composed of the combination of a diblock (DB) and a triblock (TB) polyethylene glycol-polyester copolymer. This combination offers a broad capability to tune the release of a wide variety of drugs to the desired pharmacokinetics. The work described in the present article demonstrates that the delivery rate and profile can be adjusted by changing the composition of either TB or DB or the relative ratio between them, among other parameters. It has been shown that the polymeric composition of the formulation has a substantial impact on the solvent exchange rate between the organic solvent and the surrounding aqueous medium which subsequently determines the internal structure of the resulting depot and the delivery of the therapeutic cargo. This has been demonstrated studying the in vitro release of two model molecules: bupivacaine and ivermectin.

Formulations releasing these drugs have been administered to animal models to show the possibility of delivering therapeutics from weeks to months by using BEPO® technology.
Additional documents

No documents were uploaded

Useful links

- Video presenting BEPO technology
Access principles

Collaborate for development

Consider on a case by case basis, collaborating on developing long acting products with potential significant public health impact, especially for low- and middle-income countries (LMICs), utilising the referred to long-acting technology

Not provided

Share technical information for match-making assessment

Provide necessary technical information to a potential partner, under confidentiality agreement, to enable preliminary assessment of whether specific medicines of public health importance in LMICs might be compatible with the referred to long-acting technology to achieve a public health benefit

Not provided

Work with MPP to expand access in LMICs

In the event that a product using the referred to long-acting technology is successfully developed, the technology IP holder(s) will work with the Medicines Patent Pool towards putting in place the most appropriate strategy for timely and affordable access in low and middle-income countries, including through licensing

Not provided
Comment & Information

More information available at: https://www.medincell.com/en/
To be determined

To be determined