LAPaL
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

Developed by

medicines patent pool

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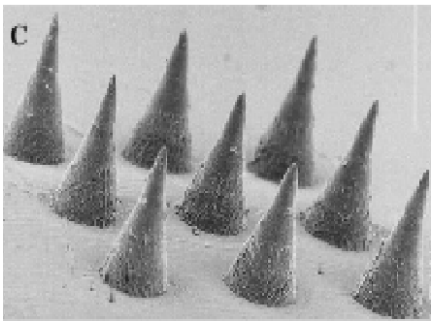

Dissolving microarray patches

Verified by the innovator, on Sep 2021

Developer(s)

Queen's University Belfast

Originator

https://www.qub.ac.uk/schools/SchoolofPharmacy/

Ireland

Currently focusing on research in the field of microneedles/microarray patches, minimally-invasive patient monitoring/diagnosis, transdermal drug delivery, including biomolecules, vaccine delivery, photodynamic therapy, nanomedicine delivery, HIV treatment and prevention, delivery of therapeutics for tropical diseases and rare conditions.

Sponsor(s)

EPSRC

https://epsrc.ukri.org/

USAID

https://www.usaid.gov/

Partnerships

PATH

https://www.path.org/

Technology information

Type of technology

Polymer-based particles, In-situ forming gel/implant, Aqueous drug particle suspension, Transdermal patch

Administration route

Intradermal delivery of long-acting drug formulations

Development state and regulatory approval

Active Pharmaceutical Ingredient (API)

Cabotegravir (CAB)

Development Stage

Pre-clinical

Regulatory Approval

N/A

Description

Biocompatible polymeric microneedle system that painlessly and without drawing blood penetrates the skin's stratum corneum barrier and then dissolves to deposit long-acting drug formulations in the viable skin layers. This technology could be a replacement for long-acting intramuscular injections

Technology highlight

Avoids needle stick injuries, no cold chain required, high-dose delivery system, easy to use by patients at home, self-disabling system, with specialist disposal not required

Technology main components

Microneedles composed of FDA-approved biocompatible polymers

Information on the raw materials sourcing, availability and anticipated price

PVA and PVP, the typical dissolving polymers, are inexpensive and can readily be obtained by pharmaceutical excipient manufacturers. Sometimes, PLGA will be required to sustain release of more water soluble molecules. PLGA is more expensive, but Ashland and Evonik offer many different products with controllable biodegradation properties that are suitable for injectable products.

Delivery device(s)

No delivery device

APIs compatibility profile

API desired features

Water-soluble molecules

Unit: mg/mL
Microneedles are suitable for a wide range of therapeutic classes. Formulation can be readily adjusted as required

Water-insoluble molecules

Unit: mg/mL
Both soluble (e.g. tenofovir alafenamide fumarate) and poorly soluble (e.g. rilpivirine, cabotegravir) can be delivered. Formulations can be adjusted as needed to obtain the delivery rate desired

Small molecules

Rilpivirine, cabotegravir, tenofovir alafenamide fumarate, etravirine

Nucleic acids

DNA and RNA vaccines

Proteins

Therapeutic antibodies and single domain antibodies, protein vaccines and peptides (e.g. insulin, exenatide)

Additional solubility data

N/A

Additional stability data

N/A

API loading: Maximum drug quantity to be loaded

75-90 wt%

API co-administration

2 different APIs : At least two

LogP

Not provided

Scale-up and manufacturing prospects

Scale-up prospects

Microneedle products can now be made at scale by a number of manufacturers to GMP conditions - For example, by LTS Lohmann - https://ltslohmann.de/en/micro-array-patches/

Tentative equipment list for manufacturing

Confidential. Each manufacturer is unlikely to disclose such details without a CDA

Manufacturing

It is likely a low bioburden product will be required

Specific analytical instrument required for characterization of formulation

HPLC-MS, XRD, DSC, TGA, FT-IR, texture profile analysis, optical coherence tomography

Clinical trials

Not provided

Excipients

Proprietary excipients used

PVA, PVP and, when needed, PLGA

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

No novel excipient or existing excipient used

Residual solvents used

No residual solvent used

Additional features

Other features of the technology

- Drug-eluting
- At least 1 year shelf life

Release properties

Sustained release enabled by the drug formulation - the microneedles act as a tool to place the long-acting system in the viable skin layers

Injectability

Applied to the skin and the needles penetrate the stratum corneum, then dissolve and deposit the long-acting drug formulation in the viable skin layers

Safety

No needle stick injuries. no specialised disposal required, as the microneedles dissolve in skin

Stability

Not provided

Storage conditions and cold-chain related features

No cold chain needed, as the system is dry-state and so very stable

Potential application(s)

Therapeutic area(s)

HIV

Disease agnostic

Use case(s)

Pre-Exposure Prophylaxis (PrEP)

Post-Exposure Prophylaxis (PEP)

Treatment

Use of technology

Ease of administration

- Self-administered

Frequency of administration

Weekly, Monthly

User acceptance

Many studies have been conducted in this area - Freely available in the literature

Targeted user groups

Age Cohort

- Children
- Adolescents
- Adults
- Older Adults
- Neonates

Genders

- All

Pregnant individuals

Unspecified

Lactating individuals

Unspecified

Healthy individuals

Unspecified

Comment

People in their own homes, including children

Potential associated API(s)

Rilpivirine (RPV)

Class(es)

anti-retroviral

Development stage

Pre-clinical

Clinical trial number(s)

N/A

Foreseen/approved indication(s)

HIV prevention and treatment

Foreseen user group

HIV patients and PreP patients

Foreseen duration between application(s)

1 week to 1 month

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

N/A

Cabotegravir (CAB)

Class(es)

anti-retroviral

Development stage

Pre-clinical

Clinical trial number(s)

N/A

Foreseen/approved indication(s)

HIV treatment and prevention

Foreseen user group

HIV patients and PreP patients

Foreseen duration between application(s)

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Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

N/A

Tenofovir alafenamide (TAF)

Class(es)

Antiviral (NRTI)

Development stage

Pre-clinical

Clinical trial number(s)

Not provided

Foreseen/approved indication(s)

Not provided

Foreseen user group

Not provided

Foreseen duration between application(s)

Not provided

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Not provided

Patent info

There are either no relevant patents or these were not yet submitted to LAPaL

Supporting material

Publications

There are no publication

Additional documents

No documents were uploaded

Useful links

- Link to QUB Microneedles publications

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

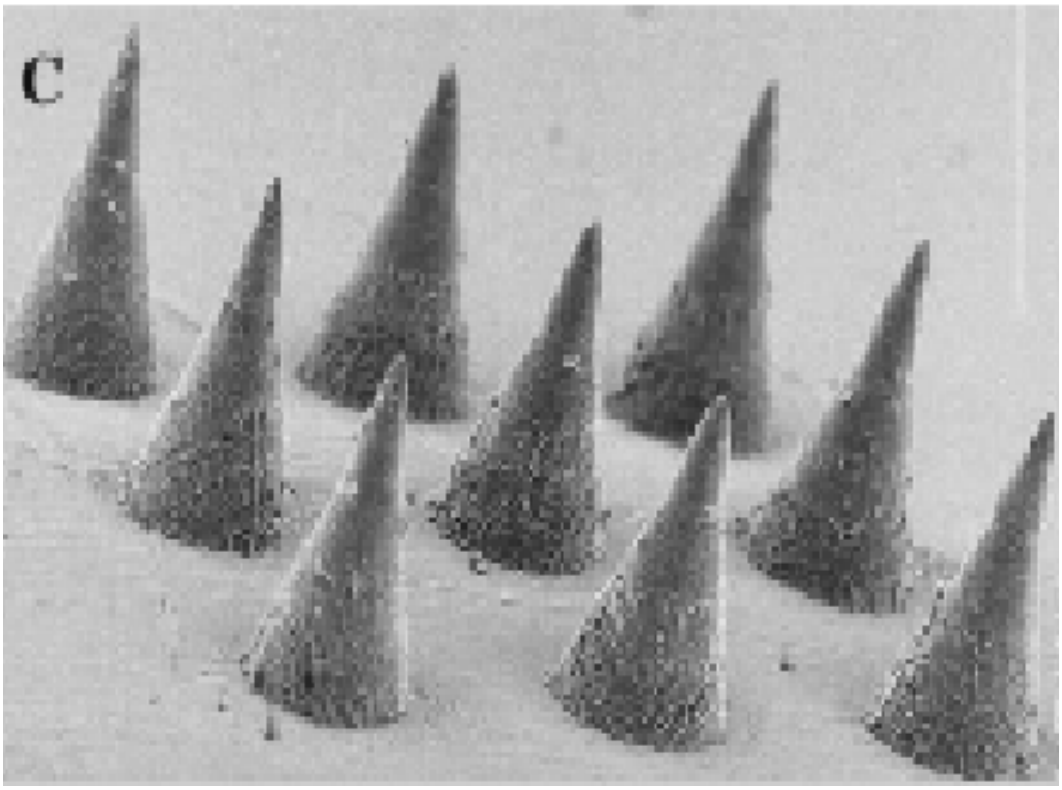
In the event that a product using the referred to long-acting technology is successfully developed, the technology IP holder(s) will work with the Medicines Patent Pool towards putting in place the most appropriate strategy for timely and affordable access in low and middle-income countries, including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

Not provided

Comment & Information

Microneedles aim to take the hypodermic needle out of the equation in the delivery of high-dose, long-acting drug formulations. Conditions to be managed include HIV, malaria, tuberculosis, schizophrenia and many others

Illustrations



Microneedles

Queen's University Belfast