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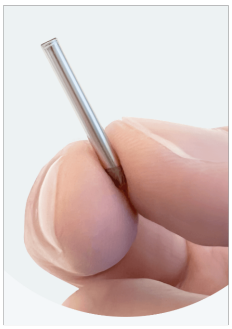


NanoPortal™

Based on public information

Developer(s)

Vivani Medical

Originator

https://vivani.com/

United States

Vivani Medical, Inc., headquartered in Alameda, California, develops biopharmaceutical implants leveraging their proprietary NanoPortal™ platform. The company focuses on creating long-term drug delivery solutions to address chronic diseases such as type 2 diabetes and chronic weight management. Vivani was formed from the merger of Nano Precision Medical, Inc. and Second Sight Medical Products, Inc

Sponsor(s)

No sponsor indicated

Partnerships

NanoPrecision Medical

https://www.linkedin.com/company/nanoprecision-medical/

Technology information

Type of technology

Titanium implant

Administration route

Subcutaneous, Intraocular

Development state and regulatory approval

Active Pharmaceutical Ingredient (API)

Exenatide

Development Stage

Phase I

Regulatory Approval

Not provided

Description

The NanoPortal implant device technology are customizable drug delivery system according to the desired drug release rate, implant duration, and various other factors specific to the target product profile. NanoPortal holds significant potential to improve tolerability by addressing common issues associated with the API and its variable drug release patterns. Smaller nanotube pore size and fewer exposed nanotubes produces slower drug release rates.

Technology highlight

• Space-Efficient Design • No pumps or electronic devices • Subdermal Administration • Incorporation of different concentrations of API • Vertical nanotubes (40 micrometers in length) attached to titanium substrate • The content of the tubes are customizable depending on the desired delivery rate of the API • Pore is only slightly larger than the API molecule, you can achieve a near constant steady rate of medication deliver

Technology main components

The NanoPortal implant typically consists of • A housing (Capsule) • Titania (TiO2) nanotube membrane • Obturator • Pressure reducer • Connector for transport of fluid • Reservoir for biocompatible fluid

Information on the raw materials sourcing, availability and anticipated price

Not provided

Delivery device(s)

NanoPortal Implantable drug delivery system: Titanium-based subcutaneous implant with nanopore membrane for drug delivery

APIs compatibility profile

API desired features

Water-soluble molecules

Water-insoluble molecules

Small molecules

Therapeutic agents of type 2 diabetes, high blood pressure, heart disease, stroke, joint problems, liver disease, gallstones, some types of cancer, and sleep & pulmonary diseases are targeted for NanoPortal Implant drug delivery system.

Proteins

NanoPortal has the potential to deliver large hydrophilic molecules, such as peptides and proteins, potentially enabling a broader range of therapeutic applications.

Additional solubility data

Not provided

Additional stability data

Not provided

API loading: Maximum drug quantity to be loaded

Not provided

API co-administration

Not provided

LogP

Not provided

Scale-up and manufacturing prospects

Scale-up prospects

Not provided

Tentative equipment list for manufacturing

• Plasma treatment system • Uv-ozone treatment unit • Chemical activation bath • Dip-coating machine • Spin-coating device • Spray-coating equipment • Layer-by-layer assembly setup • Thermal curing ovens • Chemical curing stations • Annealing furnaces • Controlled atmosphere chambers

Manufacturing

ISO Class 5 to ISO Class 8 with HEPA filters Process of manufacturing includes: • Preparation of Nanoporous Substrate: Create nanopores in polycarbonate using ion track etching/ anodization/ phase inversion • Surface Treatment and Coating Preparation: Enhance adhesion with plasma treatment or chemical activation; prepare the coating solution with desired materials and additives • Application and Curing of Coating: Apply the coating via dip-coating or spray-coating, then dry and cure using thermal treatment, UV irradiation, or chemical curing • Post-Treatment and Characterization using SEM.

Specific analytical instrument required for characterization of formulation

• Scanning Electron Microscopy (SEM) • Atomic Force Microscopy (AFM) • Fourier Transform Infrared Spectroscopy (FTIR) • Raman spectroscopy • Differential Scanning Calorimetry (DSC) • Thermogravimetric Analysis (TGA) • Tensile testing • Nanoindentation • Gas Adsorption (BET Analysis) • Mercury Intrusion Porosimetry • High-Performance Liquid Chromatography (HPLC) • Mass Spectrometry (MS) • X-ray Photoelectron Spectroscopy (XPS)

Clinical trials

LIBERATE-1

Identifier

NCT05670379

Link

https://clinicaltrials.gov/study/NCT05670379

Phase

Phase I

Status

Not yet recruiting

Sponsor

Vivani Medical, Inc

More details

The purpose of this study is to evaluate the safety, tolerability and drug levels of an exenatide implant (NPM-119) for the treatment of type 2 diabetes

Purpose

Assessment of Safety, Tolerability and Drug Levels of NPM-119 in Participants With Type 2 Diabetes

Interventions

Intervention 1

NPM-119 (exenatide implant)

Intervention 2

Bydureon BCise (exenatide extended release)

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

2024-03-01

Actual Start Date

Not provided

Anticipated Date of Last Follow-up

2023-11-27

Estimated Primary Completion Date

2025-01-01

Estimated Completion Date

2025-01-01

Actual Primary Completion Date

Not provided

Actual Completion Date

Not provided

Studied populations

Age Cohort

- Adults
- Older Adults

Genders

- All

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Inclusion Criteria: * Type 2 diabetes * BMI up to 40 kg/m\^2 * Estimated glomerular filtration rate (eGFR) \>60 mL/min/1.73 m\^2 * HbA1c \<8.5 * Treated with a stable regimen of a GLP-1receptor agonist other than exenatide-containing drugs for a minimum of 3 months Exclusion Criteria: * Has a clinically significant medical condition that could potentially affect study participation and/or personal well-being * History of, or currently has, acute or chronic pancreatitis or has triglyceride concentrations ≥500 mg/dL * Has medullary thyroid carcinoma (MTC) or multiple endocrine neoplasia (MEN II) or a family history of MTC or MEN II * Current or past exposure to exenatide * Sulfonylurea (SU) use within the prior 3 months * Alpha-glucosidase inhibitor, meglitinide, nateglinide.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

16

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Other : "Every 12 weeks "

Studied LA-formulation(s)

Implant

Studied route(s) of administration

Subcutaneous

Use case

Treatment

Key resources

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

No novel excipient or existing excipient used

Residual solvents used

No residual solvent used

Additional features

Other features of the technology

- Drug-eluting
- Removable
- Single-use
- Reservoir-type

Release properties

Minimally fluctuating drug release profile were observed in pre-clinical studies.

Injectability

Insertion using smaller 11-gauge needle

Safety

Phase I (LIBERATE-1) safety and efficacy studies of NPM-115 are ongoing.

Stability

Not provided

Storage conditions and cold-chain related features

Not provided

Potential application(s)

Therapeutic area(s)

Diabetes

Other(s) : "Hypertension, Coronary Heart Disease, Stroke, Arthritis, Liver disease, Gallstones, and Sleep & Pulmonary diseases"

Oncology

Use case(s)

Not provided

Use of technology

Ease of administration

- Administered by a community health worker
- Administered by a nurse
- Administered by a specialty health worker

Frequency of administration

Weekly, Monthly, Every 12 weeks

User acceptance

Not provided

Targeted user groups

Age Cohort

- Adults
- Older Adults

Genders

- All

Pregnant individuals

Unspecified

Lactating individuals

Unspecified

Healthy individuals

Unspecified

Comment

Not provided

Potential associated API(s)

Exenatide

Class(es)

GLP-1 agonist

Development stage

Phase I

Clinical trial number(s)

NCT05670379

Foreseen/approved indication(s)

Obesity, Type II Diabetes Mellitus, Feline Pre-Diabetes & Diabetes

Foreseen user group

Not provided

Foreseen duration between application(s)

Once every 12 weeks

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Not provided

Semaglutide

Class(es)

GLP-1 Analogues

Development stage

Pre-clinical

Clinical trial number(s)

Not provided

Foreseen/approved indication(s)

Obesity

Foreseen user group

Not provided

Foreseen duration between application(s)

Not provided

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Not provided

Patent info

Description

Implant Delivery System with Hydration Promotor Capability

Brief description

The application pertains to apparatuses, means and methods to promote uptake of biocompatible fluids into a reservoir of an implantable drug delivery system though a porous membrane. Examples of the application promote fluid uptake by creating a pressure differential between the reservoir of the drug delivery device and the biocompatible fluid outside the device.

Representative patent

WO2018067535

Category

Medical Device

Patent holder

Nano Precision Medical, Inc.

Exclusivity

Not provided

Expiration date

October 7, 2037

Status

Not provided

Description

Apparatus and Method for Promoting Fluid Uptake into an Implant

Brief description

The invention pertains to apparatuses, means and methods to promote uptake of fluids into a reservoir of an implantable drug delivery system though a porous membrane. Embodiments of the invention promote fluid uptake by creating a pressure differential between the reservoir of the drug delivery device and the environment of the device after implantation, for instance a subcutaneous pocket.

Representative patent

WO2016123027

Category

Medical Device

Patent holder

Nano Precision Medical, Inc.

Exclusivity

Not provided

Expiration date

January 26, 2036

Status

Not provided

Description

Implant Device for Drug Delivery

Brief description

The present invention provides a method for controlling the internal diameter of nanopores to afford nanopore membranes with a zero-order rate of release of a therapeutic agent.

Representative patent

WO2015112811A1

Category

Medical Device

Patent holder

Nano Precision Medical, Inc.

Exclusivity

Not provided

Expiration date

January 23, 2035

Status

Not provided

Supporting material

Publications

There are no publication

Additional documents

- 2024 Investor Presentation

Useful links

- NanoPortal Official Website

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

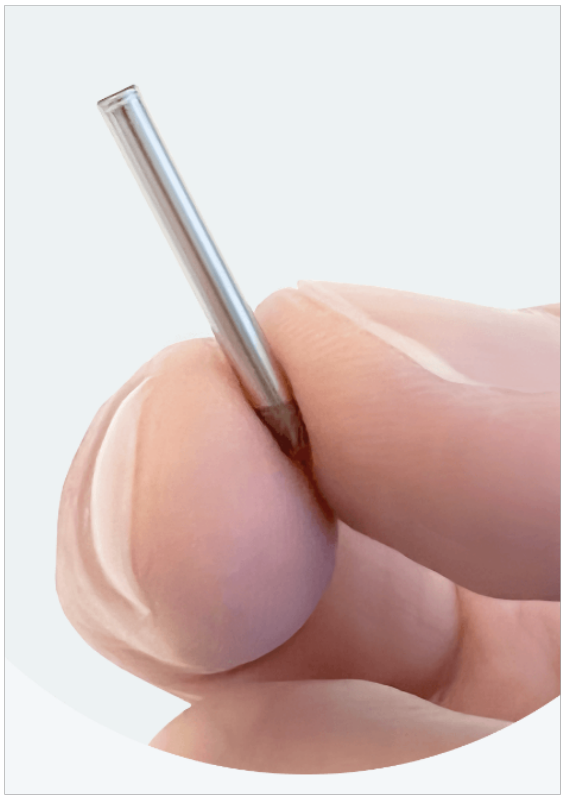
Work with MPP to expand access in LMICs

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

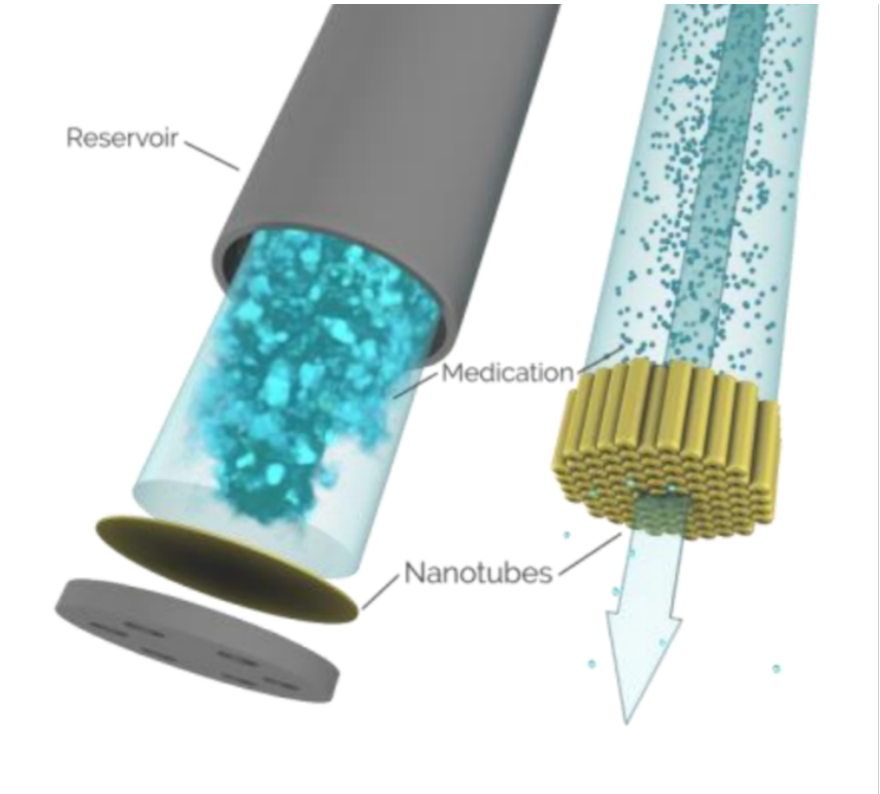
Comment & Information

Illustrations



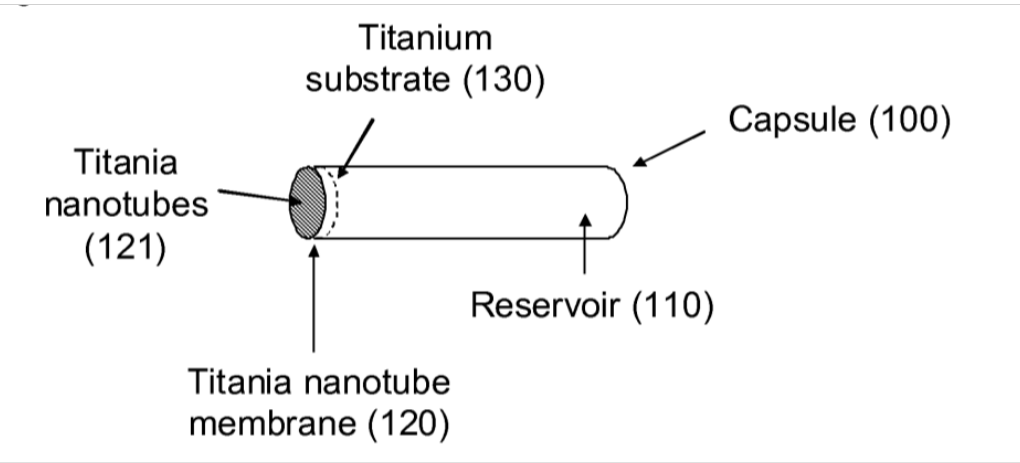
NanoPortal Implant

NanoPortal (2024) Vivani. Available at: https://vivani.com/ (Accessed: 09 July 2024).



Graphical illustration of different parts of the NanoPortal

Vivani Medical. (2024, May 13). Vivani investor presentation May 2024. Retrieved from https://d1io3yog0oux5.cloudfront.net/_2ec16443bfa8ea8ed92ef0a0a7e08196/vivanimedical/



Different parts of the NanoPortal

Young, P., & Borde, B. (2015). System and method for facilitating development of a cellular therapy (WO2015112811A1). World Intellectual Property Organization. Retrieved from https://patents.google.co