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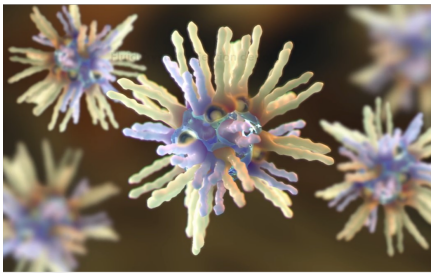


FluidCrystal®

Based on public information

Developer(s)

Camurus AB

Originator

https://www.camurus.com

Sweden

Camurus AB is a biopharmaceutical company that creates long-acting treatments for serious and chronic diseases. This company originated in 1991. Camurus, based on scientific understanding, aims to enhance patient outcomes through innovative therapies. They specialise in pharmaceutical commercialization and have a portfolio that includes clinical trial products as well as two FDA-approved drugs.

Sponsor(s)

No sponsor indicated

Partnerships

Braeburn Pharmaceuticals

https://braeburnrx.com/

Rhythm Pharmaceuticals

https://rhythmtx.com/

NewBridge Pharmaceuticals

https://www.nbpharma.com/

Novartis

https://www.novartis.com/

Technology information

Type of technology

Based on other organic particles, Amphiphile-based

Administration route

Subcutaneous, Intravenous, Optical

Development state and regulatory approval

Active Pharmaceutical Ingredient (API)

Buprenorphine

Development Stage

Marketed

Regulatory Approval

Buprenorphine long acting is approved under the brand name - Brixadi by US FDA and as Buvidal by EMA for Opoid Dependence.

Description

FluidCrystal Technology is an advanced injectable formulation utilizing endogenous lipids, characterized by low viscosity and long-acting properties. This technology enables the administration of active pharmaceutical ingredients (APIs) with controlled release durations ranging from days to months. The mechanism underlying this system involves reversed non-lamellar liquid crystalline phases, which facilitate the efficient encapsulation of APIs. These phases ensure a sustained and steady-state release of the API into the bloodstream, thereby enhancing therapeutic efficacy.

Technology highlight

• Self assembling lipids forms a nanostructure reversed-phase nonlamellar liquid crystal around the API in an aqueous environment • Easy and convenient administration • High treatment adherence • Adapted to prefilled syringes and pen injection devices • Small injection volume with a thin needle.

Technology main components

The level of each component varies based on the physiological and chemical properties of the API a) One or more neutral diacyl lipids and / or at least one tocopherol b) One or more 5–90% phospholipids c) One or more biocompatible , oxygen-containing, or low-viscosity organic solvents d) At least one bioactive agent is dissolved or dispersed in the low-viscosity mixture e) One or more oxygen-containing solvent selected from alcohols , ketones , esters , ethers , amides and sulfoxide

Information on the raw materials sourcing, availability and anticipated price

The price of Brixadi (FDA approved FluidCrystal drug) is 459.13 USD. Camurus obtains commercially available, high-quality sources of key components for FluidCrystal formulation.

Delivery device(s)

No delivery device

APIs compatibility profile

API desired features

Water-soluble molecules

Water-insoluble molecules

Small molecules

Small molecules that are targeted for FluidCrystal Technology are Opioids, local analgesics, hormones, anti-emetics, local antibiotics, and prostacyclins

Proteins

Peptides & proteins that are targeted for FluidCrystal Technology are somatostatin & analogues, LHRH agonists, Glucagon & insulin, GLP-1 & analogues, MC4 agonists, and antibody fragments

Additional solubility data

Not provided

Additional stability data

Not provided

API loading: Maximum drug quantity to be loaded

< 10 wt%

API co-administration

Not provided

LogP

Not provided

Scale-up and manufacturing prospects

Scale-up prospects

In 2022, 830,000 doses were manufactured

Tentative equipment list for manufacturing

Not provided

Manufacturing

Manufacturing and distribution of Camurus’ products is based on a multi-stage supply chain with several participants involved. Braeburn Pharmaceuticals overlooks the manufacturing of the FDA approved drugs of FluidCrystal in liaison with a third party manufacturer. The manufacturing process includes: - Compounding - Filtration - Filing The aim of the manufacturing process setup is to reduce product manufacturing waste by 20% and to increase the use of packaging material originating from sustainable sources to at least 50%.

Specific analytical instrument required for characterization of formulation

The listed analytical instrument used was HPLC with UV detection

Clinical trials

CAM2038

Identifier

NCT02946073

Link

https://clinicaltrials.gov/study/NCT02946073

Phase

Phase III

Status

Completed

Sponsor

Braeburn Pharmaceuticals

More details

This is a Phase III, placebo-controlled, multicenter study with an enriched-enrollment withdrawal (EEW) design to evaluate the efficacy and safety of CAM2038 in opioid-experienced subjects with moderate to severe CLBP that requires continuous, around-the-clock (ATC) opioid treatment ≥ 40 mg morphine equivalent dose (MED). The study includes 5 phases: A Screening Phase (up to 2 weeks), a Transition Phase (up to 2 weeks), an Open-Label Titration Phase (up to 10 weeks), a Double-Blind Treatment Phase including a Final Study Visit (12 weeks), and a Follow-up Phase (4 weeks). The overall duration of participation in the core phase of the study (randomized Double-Blind Phase) is up to 30 weeks, from the Screening Phase through the Follow-up Phase.

Subjects who complete the Double-Blind Treatment

Purpose

Buprenorphine (CAM2038) in Subjects With a Recent History of Moderate to Severe Chronic Low Back Pain

Interventions

Intervention 1

buprenorphine

Intervention 2

Placebo

Countries

United States of America

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2016-09-01

Anticipated Date of Last Follow-up

2021-09-20

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2018-05-01

Actual Completion Date

2019-02-01

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: 1. Written informed consent provided prior to the conduct of any study-related procedures. 2. Male or non-pregnant, non-lactating female subject, greater than or equal to 18 years old. 3. Body mass index (BMI) between 18 and 38 kg/m2, inclusive. 4. Treated with daily opioids for moderate to severe CLBP for a minimum of 3 months prior to Screening. 5. On a stable dose of ≥40 mg/day of oral morphine or MED during the 14 days prior to Screening. 6. Systolic blood pressure ≥100 mmHg and diastolic blood pressure ≥60 mmHg. 7. Female subject of

childbearing potential who is willing to use a reliable method of contraception during the entire study (Screening Visit to final Follow-up). To be considered not of childbearing potential, female subjects must be surgically sterile.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

1053

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Not provided

Frequency of administration

Weekly

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Subcutaneous

Use case

Treatment

Key resources

Not provided

ACROINNOVA 1

Identifier

NCT04076462

Link

https://clinicaltrials.gov/study/NCT04076462

Phase

Phase III

Status

Completed

Sponsor

Camurus AB

More details

The purpose of this trial is to assess the efficacy and safety of CAM2029 in patients with acromegaly. Patients will be randomized to either CAM2029 or placebo administered subcutaneously once monthly during 6 months.

Purpose

A Trial to Assess Efficacy and Safety of Octreotide Subcutaneous Depot in Patients With Acromegaly

Interventions

Intervention 1

CAM2029 (octreotide subcutaneous depot)

Intervention 2

Matching placebo

Countries

United States of America

Germany

Greece

Hungary

Italy

Poland

Russian Federation

Spain

United Kingdom

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2019-08-19

Anticipated Date of Last Follow-up

2024-04-24

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2023-05-02

Actual Completion Date

2023-05-02

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: * Male or female patients, ≥18 years at screening * Able to provide written informed consent to participate in the trial prior to any trial related procedures are performed * Diagnosis of acromegaly by historical evidence of (persistent or recurrent) acromegaly * Treatment with a stable dose of octreotide LAR or lanreotide ATG for at least 3 months as monotherapy prior to screening * IGF-1 levels ≤1xULN at screening * Adequate liver, pancreatic, renal and bone marrow functions * Normal ECG Exclusion Criteria: * GH ≥2.5 µg/L at screening (cycle) * Have received medical treatment for acromegaly with pasireotide (within 6 months prior to screening), pegvisomant (within 3 months prior to screening), dopamine agonists (within 3 months prior to screening).

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

72

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Triple-blind masking

Masking description

Not provided

Frequency of administration

Monthly

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Subcutaneous

Use case

Treatment

Key resources

Not provided

HS-12-455

Identifier

NCT02299089

Link

https://clinicaltrials.gov/study/NCT02299089

Phase

Phase II

Status

Completed

Sponsor

Camurus AB

More details

This is a Phase II, open-label multicentre, randomised study to assess the PK, PD, efficacy, and safety of two dosing regimens of CAM2029 in adult patients with acromegaly or a functional, well-differentiated NET, with carcinoid symptoms.

Purpose

Phase II Study of Subcutaneous Inj. Depot of Octreotide in Patients With Acromegaly and Neuroendocrine Tumours (NETs)

Interventions

Intervention 1

Octreotide FluidCrystal® injection depot

Countries

Not provided

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2015-01-01

Anticipated Date of Last Follow-up

2017-05-16

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2016-05-01

Actual Completion Date

2016-06-01

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: Acromegaly: * Male or female patients ≥18 years of age * Acromegaly currently treated with Sandostatin LAR NET: * Male or female patients ≥18 years of age * Functional, well-differentiated (Grade 1 or Grade 2) NET with symptoms of carcinoid syndrome (number of bowel movements and/or flushing) * Currently treated with Sandostatin LAR for symptom control Exclusion Criteria: Acromegaly: * Inadequate bone marrow function * Abnormal coagulation or chronic treatment with warfarin or coumarin derivates * Impaired liver, cardiac and/or renal function * Known gallbladder, bile duct disease or pancreatitis * Diabetes with poorly controlled blood glucose levels despite adequate therapy * Hypothyroidisms not adequately treated.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

12

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Monthly
Other : "Once two weekly "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Subcutaneous

Use case

Treatment

Key resources

Not provided

SORENTO

Identifier

NCT05050942

Link

https://clinicaltrials.gov/study/NCT05050942

Phase

Phase III

Status

Not provided

Sponsor

Camurus AB

More details

The purpose of this study is to compare the effectiveness and safety of CAM2029 to octreotide LAR or lanreotide ATG in patients with advanced, well-differentiated GEP-NET. Patients who experience progressive disease in the randomized part of the study may proceed to an open-label extension part with intensified treatment with CAM2029.

Purpose

A Trial to Assess Efficacy and Safety of Octreotide Subcutaneous Depot in Patients With GEP-NET

Interventions

Intervention 1

CAM2029

Intervention 2

Octreotide LAR

Intervention 3

Lanreotide ATG

Countries

United States of America
Australia
Belgium
Canada
France
Germany
Hungary
Israel
Italy
Netherlands
Romania
Spain

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2021-10-22

Anticipated Date of Last Follow-up

2024-01-25

Estimated Primary Completion Date

2024-12-01

Estimated Completion Date

2026-12-01

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: * Male or female patient ≥18 years old * Histologically confirmed, advanced (unresectable and/or metastatic), and well-differentiated NET of GEP or presumed GEP origin * At least 1 measurable, somatostatin receptor-positive lesion according to RECIST 1.1 determined by multiphasic CT or MRI (performed within 28

days before randomization) * ECOG performance status of 0 to 2 Exclusion Criteria: * Documented evidence of disease progression while on treatment (including SSAs) for locally advanced unresectable or metastatic disease * Known central nervous system metastases * Consecutive treatment with long-acting SSAs for more than 6 months before randomization * Carcinoid symptoms that are refractory to treatment (according to the Investigator's judgement) with convention.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

332

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Monthly

Other : "Once two weekly "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Subcutaneous

Use case

Treatment

Key resources

Not provided

HS-19-647

Identifier

NCT04125836

Link

https://clinicaltrials.gov/study/NCT04125836

Phase

Phase III

Status

Not provided

Sponsor

Camurus AB

More details

The purpose of this trial is to assess the long-term safety and efficacy of CAM2029 in patients with acromegaly. Patients will be administered CAM2029 subcutaneously once monthly during 12 months. Patients fulfilling trial NCT04076462 will be offered to continue with open-label treatment week 24-52 in this trial. Patients completing the main part of the trial will be offered 52 weeks continued open-label treatment in an extension part.

Purpose

A Trial to Assess the Long-term Safety of Octreotide Subcutaneous Depot in Patients With Acromegaly

Interventions

Intervention 1

CAM2029 (octreotide subcutaneous depot)

Countries

United States of America

Germany

Greece

Hungary

Italy

Poland

Russian Federation

Serbia

Spain

United Kingdom

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2019-10-10

Anticipated Date of Last Follow-up

2024-04-10

Estimated Primary Completion Date

2025-06-01

Estimated Completion Date

2025-06-01

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: * Male or female patients, ≥18 years at screening * Able to provide written informed consent to participate in the trial * Diagnosis of acromegaly by historical evidence of (persistent or recurrent) acromegaly * Treatment with a stable dose of octreotide LAR or lanreotide ATG for at least 3 months as monotherapy prior to screening * IGF-1 levels ˃1xULN and ≤2.0xULN at screening or IGF-1 levels ≤1xULN at screening with or without prior pituitary radiotherapy * Adequate liver, pancreatic, renal and bone marrow functions * Normal ECG Exclusion Criteria: For Roll-over Patients from NCT04076462: * Unresolved, drug-related serious adverse event (SAE) from the preceding trial.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

135

Allocation

Not provided

Intervention model

Single group assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Monthly

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Subcutaneous

Use case

Treatment

Key resources

Not provided

POSITANO

Identifier

NCT05281328

Link

https://clinicaltrials.gov/study/NCT05281328

Phase

Phase II/III

Status

Not provided

Sponsor

Camurus AB

More details

The purpose of the trial is to compare the effectiveness and safety of 2 treatment regimens of CAM2029 (given weekly or every 2 weeks) to placebo in participants with symptomatic PLD, either isolated as in autosomal dominant PLD (ADPLD) or associated with autosomal dominant polycystic kidney disease (ADPKD). In the Treatment Period of the trial, participants will be allocated at random to 1 of the 3 treatment arms in a 1:1:1 ratio. After completing the Treatment Period (53 weeks) participants may proceed to a 24-week open-label extension part of the trial and then only receive the same CAM2029 treatment. The active ingredient in CAM2029, octreotide, is administered as a subcutaneous depot using Camurus' FluidCrystal® technology.

Purpose

A Trial to Assess the Efficacy and Safety of Octreotide Subcutaneous Depot in Patients

With PLD

Interventions

Intervention 1

CAM2029

Intervention 2

Placebo

Countries

United States of America

Belgium

Germany

Netherlands

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2022-06-28

Anticipated Date of Last Follow-up

2024-02-13

Estimated Primary Completion Date

2025-02-01

Estimated Completion Date

2025-08-01

Actual Primary Completion Date

2011-05-01

Actual Completion Date

2011-06-01

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: * Male or female patient, ≥18 years at screening * Diagnosis of PLD (associated with ADPKD or isolated as in ADPLD) as defined by htTLV ≥1800 mL/m at screening * Presence of at least 1 of the following PLD-related symptoms within 2 weeks before screening: bloating, fullness in abdomen, lack of appetite, feeling full quickly after beginning to eat, acid reflux, nausea, rib cage pain or pressure, pain in side, abdominal pain, back pain, shortness of breath after physical exertion, limited in mobility, concern about abdomen getting larger, dissatisfied by the size of abdomen * Not a candidate for, or not willing to undergo, surgical intervention for hepatic cysts during the trial.

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

71

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Quadruple-blind masking

Masking description

Not provided

Frequency of administration

Weekly
Other : "Once two weekly "

Studied LA-formulation(s)

Injectable

Studied route(s) of administration

Subcutaneous

Use case

Treatment

Key resources

Not provided

HS-12-460

Identifier

NCT02212197

Link

https://clinicaltrials.gov/study/NCT02212197

Phase

Phase II

Status

Completed

Sponsor

Camurus AB

More details

The purpose of this study is to assess the pharmacokinetics, pharmacodynamics, efficacy and safety of CAM2032 versus Eligard, in patients with prostate cancer. All patients will receive leuprolide acetate administered subcutaneously once monthly during 3 months.

Purpose

Phase II Study of Subcutaneous Injection Depot of Leuprolide Acetate in Patient With Prostate Cancer

Interventions

Intervention 1

leuprolide acetate FluidCrystal® injection depot

Intervention 2

leuprolide acetate

Countries

Finland

Hungary

Sites / Institutions

Not provided

Trials dates

Anticipated Start Date

Not provided

Actual Start Date

2014-09-01

Anticipated Date of Last Follow-up

2017-03-15

Estimated Primary Completion Date

Not provided

Estimated Completion Date

Not provided

Actual Primary Completion Date

2015-11-01

Actual Completion Date

2016-03-01

Studied populations

Age Cohort

Adults

- Older Adults

Genders

- Male

Accepts pregnant individuals

Unspecified

Accepts lactating individuals

Unspecified

Accepts healthy individuals

No

Comments about the studied populations

Inclusion Criteria: * Men ≥40 and ≤85 years of age * Histological or cytological proven adenocarcinoma of the prostate requiring hormone therapy * Life expectancy over 12 months * World Health Organisation/ The Eastern Cooperative Oncology Group (WHO/ECOG) performance status of 0, 1 or 2 * Adequate and stable renal function * Adequate and stable hepatic function Exclusion Criteria: * Evidence of brain metastasis, spinal cord compression, or urinary tract obstruction * Serum Testosterone levels below 150 ng/dL at Screening visit * Medical or radiological prostate cancer treatments within 2 months prior to the Screening visit * Surgical treatment of prostate cancer within 2 weeks prior to the Screening visit * Prior orchiectomy, hypophysectomy, or adrenalectomy * Prior use of LHRH agonist

Health status

Not provided

Study type

Interventional (clinical trial)

Enrollment

51

Allocation

Randomized

Intervention model

Parallel Assignment

Intervention model description

Not provided

Masking

Open label

Masking description

Not provided

Frequency of administration

Monthly

Studied LA-formulation(s)

Injectable

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

- Biodegradable
- Drug-eluting
- Monolithic

Release properties

Upon administration of the FluidCrystal SC injection, lamellar liquid crystal nanoparticles are formed by phospholipids in conjunction with the active pharmaceutical ingredient (API). This structural formation results in an initial burst release of the API into the fatty tissue environment. Subsequently, the plasma concentration of the API gradually decreases, yielding a near dose-proportional drug release over a target period of four weeks. Furthermore, repeated weekly administrations of the FluidCrystal product demonstrate smaller and less frequent fluctuations in the plasma concentration.

Injectability

Use a 23 to 25 gauge, 5/8-inch needle for the subcutaneous FluidCrystal injection. Clean the injection site and inject into the subcutaneous tissue of the abdomen, upper arm, or thigh, rotating sites each time.

Safety

A recent study aimed to evaluate the safety and efficacy of Buprenorphine administered via weekly or monthly subcutaneous (SC) injection using the FluidCrystal technology, compared to the traditional daily sublingual administration. Among the 215 patients assigned to receive SC Buprenorphine, 128 reported experiencing at least one adverse effect. The most frequently observed adverse events included injection-site pain, headache, constipation, nausea, as well as injection-site pruritus and erythema.

Stability

Not provided

Storage conditions and cold-chain related features

FluidCrystal formulations are should be stored at room temperature, specifically between 20ºC to 25ºC . Within the range of 15°C to 30°C, fluctuations are allowed. In case of unexpected temperature variations, products should have a fall-back at refrigerated storage conditions.

Potential application(s)

Therapeutic area(s)

Other(s) : "Acromegaly, Polycystic liver disease, Genetic obesity disorders, Raynaud's phenomenon, Pulmonary arterial hypertension, Chemotherapy-induced nausea and vomiting, Endocrine disorders"
Pain management
Oncology
Substance use disorders

Use case(s)

Treatment

Use of technology

Ease of administration

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

Frequency of administration

Weekly, Monthly

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)

Buprenorphine

Class(es)

Analgesics

Development stage

Marketed

Clinical trial number(s)

NCT02651584

Foreseen/approved indication(s)

Opoid Dependence and Chronic Pain Management

Foreseen user group

All genders above the age of 18 years

Foreseen duration between application(s)

Once weekly (8mg, 16mg, 24mg and 32mg) and Once monthly injections (64mg, 96mg and 128mg)

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

Buprenorphine long acting is approved under the brand name - Brixadi by US FDA and as Buvidal by EMA for Opoid Dependence.

Pituitary and hypothalamic hormones and analogues

Class(es)

Synthetic Stomatostatin

Development stage

Phase III

Clinical trial number(s)

NCT04076462

Foreseen/approved indication(s)

Acromegaly, Gastroenteropancreatic neuroendocrine tumors and Polycystic liver disease

Foreseen user group

Not provided

Foreseen duration between application(s)

Once monthly

Applications to Stringent Regulatory Authorities (SRA) / regulatory approvals

holds Orphan Drug Designation in the EU for CAM2029 for the treatment of acromegaly

Patent info

Description

Lipid Depot Formulations

Brief description

The invention relates to pre-formulations made from low viscosity, non-liquid crystalline mixtures of a neutral diacyl lipid, tocopherol, phospholipid, and a biocompatible organic solvent. The bioactive agent is dissolved in the mixture, and the pre-formulation forms a liquid crystalline phase structure upon contact with an aqueous fluid. These preformulations are suitable for generating depot compositions for sustained release of active agents. The invention also relates to methods of delivery, treatment, and the use of preformulations in the manufacture of a medicament.

Representative patent

WO2005117830

Category

formulation

Patent holder

Camurus AB

Exclusivity

Not provided

Expiration date

June 6, 2035

Status

Granted in : AU, BR, CA, CN, IL, JP, KR, MX, NZ, RU, ZA, UA, EP (GB, DK, FR, DE, IS, IE, IT, NL, PL, ES, SE, CH, TR,) SG, US

Description

Depot precursor formulation comprising buprenorphine

Brief description

Depot precursor formulation comprising buprenorphine and its salts, controlled release matrix and organic solvent; administration for the sustained delivery of buprenorphine, for treatment of pain or opioid dependence etc

Representative patent

WO2014016428

Category

formulation

Patent holder

Camurus AB

Exclusivity

Not provided

Expiration date

July 26, 2033

Status

Pending in: AR, BR, IL, MY, KR, EP, HK, TH Granted in: AU, CA, CL, CN, CO, IN, ID, JP, MX, NZ, PE, SG, ZA, TH, US, EA (AM, AZ ,BY, KZ, RU, TJ, TM), EP

Description

Composition for the delayed delivery of a peptide active agent

Brief description

A composition for the delayed delivery of a peptide active agent comprising; i) a salt of said peptide active agent comprising at least one positively charged peptide ion and at least one negatively charged counter-ion ii) a sustained-release delivery vehicle. Wherein said at least one negatively charged counter-ion is a halide ion, preferably a chloride or bromide ion.

Representative patent

WO2008152401

Category

formulation

Patent holder

Camurus AB

Exclusivity

Not provided

Expiration date

June 13, 2028

Status

Not provided

Supporting material

Publications

** Albayaty, M., Linden, M., Olsson, H., Johnsson, M., Strandgården, K., & Tiberg, F. (2017). Pharmacokinetic Evaluation of Once-Weekly and Once-Monthly Buprenorphine Subcutaneous Injection Depots (CAM2038) Versus Intravenous and Sublingual Buprenorphine in Healthy Volunteers Under Naltrexone Blockade: An Open-Label Phase 1 Study. Advances in therapy, 34(2), 560–575. https://doi.org/10.1007/s12325-016-0472-9 **

A study involving 89 healthy volunteers was conducted to evaluate the effectiveness of a new treatment for buprenorphine. The participants were divided into five groups: intravenous buprenorphine 600 µg, sublingual buprenorphine 8, 16, or 24 mg daily for 7 days, or four repeated weekly doses of CAM2038 q1w 16 mg. All subjects received daily naltrexone. The mean duration of buprenorphine release after CAM2038 q4w was 4-10 hours, with a mean terminal half-life of 19-25 days. Both CAM2038 formulations showed complete absolute bioavailability of buprenorphine, with 5.7- to 7.7-fold greater bioavailability compared to sublingual buprenorphine. Both CAM2038 q1w and q4w were well tolerated, with higher acceptance rates for CAM2038 than sublingual buprenorphine 1 hour post-dose.

** Chang, D. P., Barauskas, J., Dabkowska, A. P., Wadsäter, M., Tiberg, F., & Nylander, T. (2015). Non-lamellar lipid liquid crystalline structures at interfaces. Advances in colloid and interface science, 222, 135-147.**

https://doi.org/10.1016/j.cis.2014.11.003</p>

Non-lamellar interfacial layer: from the organization of the adsorbed layer to the characterization of the internal structure. The self-assembly of lipids results in the formation of various nano-structures, including non-lamellar liquid crystalline structures like cubic, hexagonal, and sponge phases. These non-lamellar phases are crucial for living systems, providing compartmentalization and acting as biological activity regulators. They are of interest for pharmaceutical, food, and cosmetic applications due to their compartmentalizing nature. Understanding how these structures interact with different interfaces is essential for their use in biomedical devices for drug delivery and analysis. These non-lamellar interfacial layers can entrap functional biomolecules that respond to lipid curvature and confinement.

Additional documents

- Corporate Presentation

Useful links

There are no additional links

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

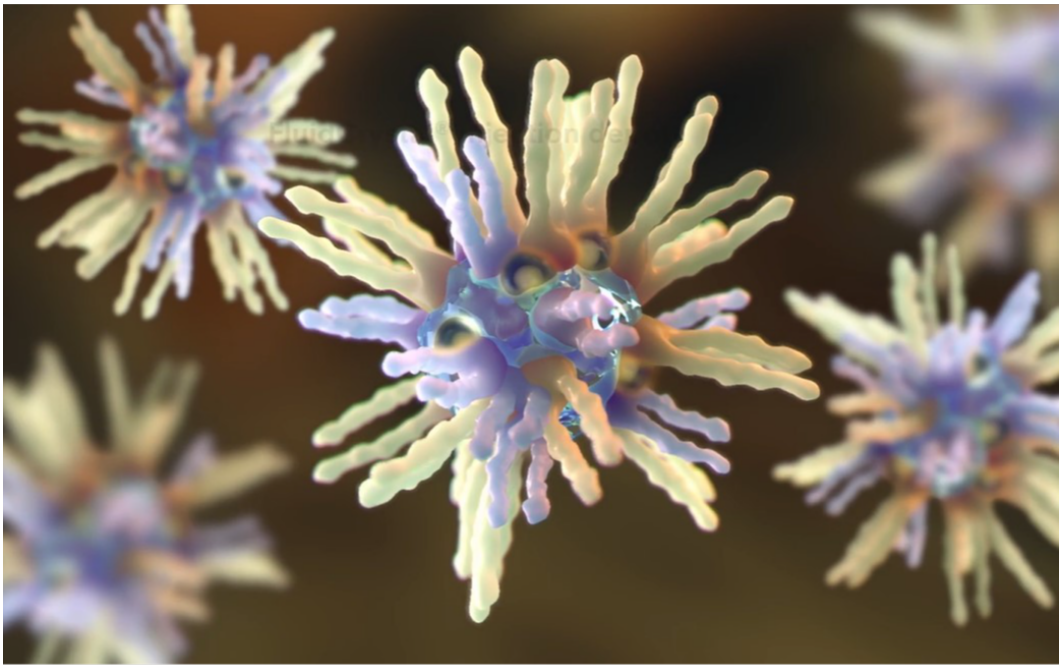
Work with MPP to expand access in LMICs

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

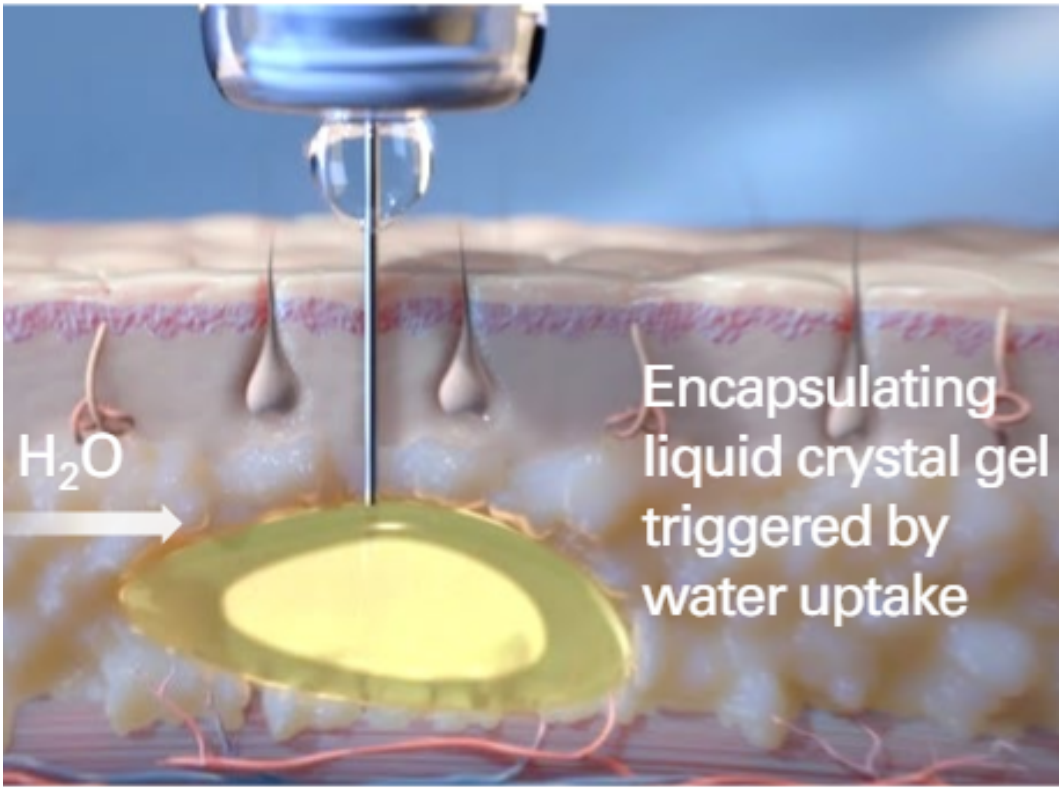
Comment & Information

Illustrations



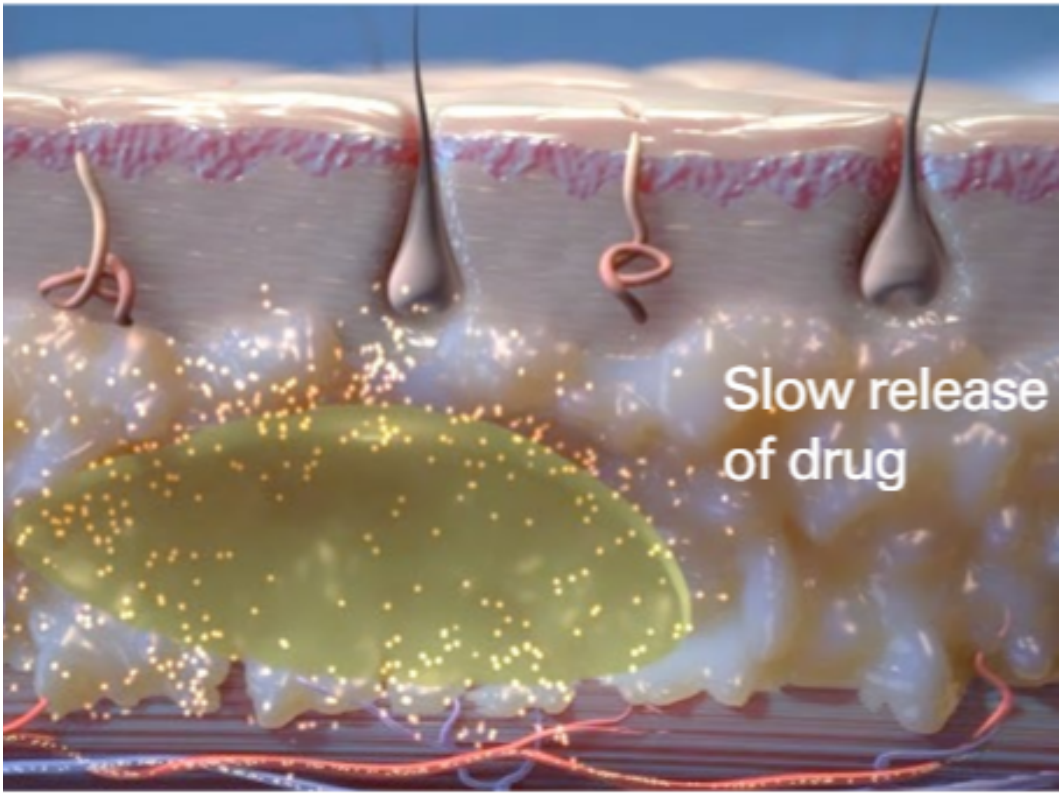
Self-assembled functional reversed-phase nonlamellar liquid crystal gel formed around API molecules by the phospholipids

Camurus. (n.d.). Technology. Retrieved June 20, 2024, from https://www.camurus.com/science/technology/.



Subcutaneous Administration of FluidCrystal prefilled Injection and the initiation of the encapsulation

Camurus. (2023). Camurus Annual Report 2023. Retrieved from https://www.camurus.com/files/Main/13456/3952729/camurus-annual-report-2023.pdf



Initial Burst of the API into the body from the FluidCrystal lipid lamellar structure

Camurus. (2023). Camurus Annual Report 2023. Retrieved from https://www.camurus.com/files/Main/13456/3952729/camurus-annual-report-2023.pdf