CTN 'CT-2019-CTN-04139-1 v4' - Completed.

CT-2019-CTN-04139-1 v4: UpdateDetails

Is Active Version:	1
Contact Name:	s22 [redacted]
Contact Phone Number:	s22 [redacted]
Contact Email:	s22 [redacted]@xaludthera.com
Protocol Number:	XT-150-2-0204
Potential Use of Restricted Goods:	No
Title of Study:	A Double-Blind, Placebo-Controlled Assessment of the Tolerability and Efficacy of XT-150 for the Treatment of Moderate to Severe Pain Due to Osteoarthritis of the Knee
This Trial:	Involves the use of a Medicine Has relevant preceding trials Is a multicentre trial in Australia Involves gene therapy Is being conducted in other countries Is placebo controlled
Trial Type:	Phase 2
Brief Description of Trial:	2 doses of XT-150 s47 [redacted] to treat pain due to osteoarthritis of the knee. Placebo controlled comparison.
Expected Trial Start Date:	2020-01-06
Expected Completion Date:	2022-05-31
Total number of participants to be enrolled in the Trial:	201-500
Therapeutic Area:	Musculoskeletal System
Genetically Modified Organism:	
Nanoparticles:	
Details of Gene Therapy:	s47 [redacted]
This Trial is also being conducted in the following Countries:	Australia United States Of America

CT-2019-CTN-04139-1 v4: Medicine

Is Active Version:	1
Trade/Product/Code Name:	XT-150
Is this a combination product:	No
Is this a cannabis product:	No
Type of Container:	glass vial
Dosage Form:	Injection
Route of Administration:	Intraarticular

Formulations:

Ingredient Name	Quantity	Unit
s47 [redacted]		

Indication:	Pain due to Osteoarthritis of the knee
Dosage and Frequency:	Single dose
Intended Use:	Investigational Medicinal Product
Is the medicine manufactured in Australia?:	No
Manufacturer:	VGXI, 2700 Research Forest Drive, The Woodlands, TX, 77381, USA
GMP licence/clearance number or relevant exemption:	

CT-2019-CTN-04139-1 v4: Placebo

Is Active Version:	1
Product Name:	Sterile Phosphate Buffered Saline (PBS) for injection
Route of Administration:	IARTIC
Description (if required):	Sterile PBS

CT-2019-CTN-04139-1 v4: Site

Is Active Version:	1
Site Name:	Alfred Hospital (Alfred Health)
Site Address:	55 Commercial Road, Melbourne VIC 3004
Site State:	Victoria
Expected Trial Start Date:	03/04/2020
Principal Investigator Name:	s22 [redacted]
Contact Phone Number:	[redacted]
Contact Email:	s22 [redacted]@monash.edu
HREC Contact Officer:	Central Adelaide Local Health Network HREC
HREC Code:	EC00192
Position:	s22 [redacted]
Contact Phone:	s22 [redacted]
Contact Email:	Health.CALHNResearchEthics@sa.gov.au
Approving Authority Name:	Alfred Health
Approving Authority Contact Officer:	s22 [redacted]
Position:	s22 [redacted]
Contact Phone:	s22 [redacted]
Contact Email:	research@alfred.org.au

CT-2019-CTN-04139-1 v4: Site

Is Active Version:	1
Site Name:	CMAX Clinical Research Pty Ltd in collaboration with UoA
Site Address:	Level 5, 18a /UofA - Adelaide Health & Medical Sciences Building, North Terrace
Site State:	South Australia
Expected Trial Start Date:	06/01/2020
Principal Investigator Name:	s22 [redacted]
Contact Phone Number:	s22 [redacted]
Contact Email:	s22 [redacted]@me.com
HREC Contact Officer:	Central Adelaide Local Heath Network HREC
HREC Code:	EC00192
Position:	s22 [redacted]
Contact Phone:	s22 [redacted]
Contact Email:	Health.CALHNReseachEthics@sa.gov.au
Approving Authority Name:	CMAX Clinical Research Pty Ltd
Approving Authority Contact Officer:	s22 [redacted]
Position:	s22 [redacted]
Contact Phone:	
Contact Email:	s22 [redacted]@cmax.com.au

CT-2019-CTN-04139-1 v4: Site

Is Active Version:	1
Site Name:	University of Adelaide, Adelaide Health & Medical Sciences Building
Site Address:	North Terrace, Adelaide
Site State:	South Australia
Expected Trial Start Date:	06/01/2020
Principal Investigator Name:	s22 [redacted]
Contact Phone Number:	[redacted]
Contact Email:	s22 [redacted]@me.com
HREC Contact Officer:	Central Adelaide Local Health Network HREC
HREC Code:	EC00192
Position:	s22 [redacted]
Contact Phone:	s22 [redacted]
Contact Email:	Health.CALHNReseachEthics@sa.gov.au
Approving Authority Name:	University of Adelaide
Approving Authority Contact Officer:	s22 [redacted]
Position:	s22 [redacted]
Contact Phone:	[redacted]
Contact Email:	s22 [redacted]@adelaide.edu.au

CT-2019-CTN-04139-1 v4: TrialConductedInCountry

Is Active Version:	1
Trial Conducted in Country Code:	AU
Trial Conducted in Country Label:	Australia

CT-2019-CTN-04139-1 v4: TrialConductedInCountry

Is Active Version:	1
Trial Conducted in Country Code:	USA
Trial Conducted in Country Label:	United States Of America

CT-2019-CTN-04139-1 v4: Completion

Is Active Version:	1
Contact Name:	s22 [redacted]
Contact Phone Number:	[redacted]
Contact Email:	s22 [redacted]@xaludthera.com
Date Trial Completed:	2022-11-22
Completion Reason:	Concluded Normally

CTN - CT-2016-CTN-02978-1 v2 – Completed.

CT-2016-CTN-02978-1 v2: UpdateDetails

Is Active Version:	1
Contact Name:	s22 [redacted]
Contact Phone Number:	
Contact Email:	s22 [redacted]@cmax.com.au
Protocol Number:	IDP-001
Potential Use of Restricted Goods:	Yes
Title of Study:	A Phase I/IIa Study of DVC1-0101 in Subjects with Intermittent Claudication or Critical Limb Ischaemia Secondary to Peripheral Artery Disease
This Trial:	Involves the use of a Medicine Involves a Genetically Modified Organism Involves gene therapy Is placebo controlled
Trial Type:	Phase 1
Brief Description of Trial:	This study will evaluate the safety and tolerability of DVC1-0101 in patients with intermittent claudication or critical limb ischaemia. It aims to evaluate the efficacy of DVC1-0101 in improving absolute claudication distance measured by treadmill.
Expected Trial Start Date:	2016-08-23
Expected Completion Date:	2023-01-31
Total number of participants to be enrolled in the Trial:	1-20
Therapeutic Area:	Other
Genetically Modified Organism:	DVC1-0101: s47 [redacted]
Nanoparticles:	
Details of Gene Therapy:	s47 [redacted] s47 [redacted] It has been reviewed and approved by the OGTR under a DNIR
This Trial is also being conducted in the following Countries:	

CT-2016-CTN-02978-1 v2: Medicine

Is Active Version:	1
Trade/Product/Code Name:	DVC1-0101
Is this a combination product:	No
Is this a cannabis product:	
Type of Container:	glass vial
Dosage Form:	Injection
Route of Administration:	Intramuscular
Formulations:	s47 [redacted]
Indication:	Intermittent Claudication or Criticial Limb Ischaemia Secondary to Peripheral Artery Disease
Dosage and Frequency:	Dosed once with 30 injections (0.5 mL per injection). Extension study available where the participants may receive an additional dose.
Intended Use:	Investigational Medicinal Product
Is the medicine manufactured in Australia?:	No
Manufacturer:	IDP Pharma Co Pty Ltd, 6 Ohkubo Tsukaba, Ibaraki, 300-2611, Japan
GMP licence/clearance number or relevant exemption:	

Ingredient Name	Quantity	Unit
s47 [redacted]		

CT-2016-CTN-02978-1 v2: Medicine

Is Active Version:	1
Trade/Product/Code Name:	DVC1-0101
Is this a combination product:	No
Is this a cannabis product:	
Type of Container:	glass vial
Dosage Form:	Injection
Route of Administration:	Intramuscular

Formulations:

Ingredient Name	Quantity	Unit
s47 [redacted]		

Indication:	Intermittent Claudication or Critical Limb Ischaemia Secondary to Peripheral Artery Disease
Dosage and Frequency:	Dosed once with 30 injections (0.5 mL per injection) into the leg. Extension study available where the participants may receive an additional dose
Intended Use:	Investigational Medicinal Product
Is the medicine manufactured in Australia?:	No
Manufacturer:	IDP Pharma Co Ltd, 6 Ohkubo Tsukuba, Ibaraki, 300-2611 Japan
GMP licence/clearance number or relevant exemption:	

CT-2016-CTN-02978-1 v2: Placebo

Is Active Version:	1
Product Name:	Placebo: Dulbecco’s phosphate buffered saline solution (DPBS)
Route of Administration:	IMUSC
Description (if required):	Participant will receive 30 x 0.5mL of active drug or placebo in their leg

CT-2016-CTN-02978-1 v2: Site

Is Active Version:	1
Site Name:	CMAX Clinical Research Pty Ltd
Site Address:	Level 5 and Level 6, 18a North Tce, Adelaide
Site State:	South Australia
Expected Trial Start Date:	23/08/2016
Principal Investigator Name:	s22 [redacted]
Contact Phone Number:	s22 [redacted]
Contact Email:	s22 [redacted]@sahmri.com
HREC Contact Officer:	Royal Adelaide Hospital HREC
HREC Code:	15/RAH/278
Position:	s22 [redacted]
Contact Phone:	s22 [redacted]
Contact Email:	Health.CALHNResearchEthics@sa.gov.au
Approving Authority Name:	Royal Adelaide Hospital HREC
Approving Authority Contact Officer:	s22 [redacted]
Position:	s22 [redacted]
Contact Phone:	s22 [redacted]
Contact Email:	Health.CALHNResearchEthics@sa.gov.au

CT-2016-CTN-02978-1 v2: Site

Is Active Version:	1
Site Name:	Sir Charles Gairdner Hospital
Site Address:	Hospital Avenue, Nedlands 6009
Site State:	Western Australia
Expected Trial Start Date:	01/07/2020
Principal Investigator Name:	s22 [redacted]
Contact Phone Number:	[redacted]
Contact Email:	s22 [redacted]@health.wa.gov.au
HREC Contact Officer:	Royal Adelaide Hospital Human Research Ethics Comm
HREC Code:	EC00192
Position:	s22 [redacted]
Contact Phone:	s22 [redacted]
Contact Email:	Health.CALHNResearchEthics@sa.gov.au
Approving Authority Name:	North Metropolitan Health Service
Approving Authority Contact Officer:	s22 [redacted]
Position:	[redacted]
Contact Phone:	[redacted]
Contact Email:	s22 [redacted]@health.wa.gov.au

CT-2016-CTN-02978-1 v2: Completion	
Is Active Version:	1
Contact Name:	s22 [redacted]
Contact Phone Number:	
Contact Email:	s22 [redacted]@cmax.com.au
Date Trial Completed:	2022-04-29
Completion Reason:	Insufficient Recruits