

Creating value through Research & Development

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#### SVP R&D Orion from June 2020



MD, PhD (immunology), University of Helsinki

Professor of Immunology, LiU, Sweden, 2001

Research Professor, THL, 2004-2014

EMA Permanent External Expert 2005-2014

VP Research, AZ/Medimmune 2014-2019

VP Oncology Research Orion 2019-2020



## Agenda





1. RD renewal



2. Research focus areas



3. Clinical pipeline





Renewal of Orion R&D



## 1. Re-newal of Orion R&D - starting point





#### **AREAS TO DEVELOP**



Hormonal cancer drug discovery



Parkinson's disease drug discovery



ALS Ph3 program in neurological rare diseases area



Investments 2017-2020

- Large molecules
- Digital medicine /AI



Orion has a solid financial basis to support RD



Build a balanced pipeline with continuous feed of clinical projects



Increase success rate and speed



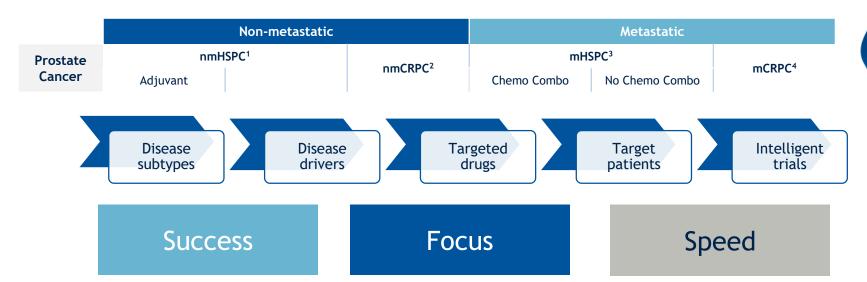
• Science & Data driven organisation

 Focused strategy in Oncology and Neurological Diseases





## We follow the patient's journey and transform science into life-changing medicines



<sup>1)</sup> nmHSPC = non-metastatic hormone-sensitive prostate cancer 2) nmCRPC = non-metastatic castration-resistant prostate cancer



<sup>3)</sup> mHSPC = metastatic hormone-sensitive prostate cancer 4) mCRPC = metastatic castration-resistant prostate cancer

## Key changes in Orion R&D

Research strengthened to drive target identification and validation

Resources reallocated for the prioritised projects



**Focused** clinical trials on biomarker selected patients

Support pipeline with in-licensing and partnering

Boosting generics development

Microbiome research in **Animal Health** 





## Research focus areas



#### Research Areas in Orion's R&D







#### **Neurological Disorders**

- Pain
- Neurodegenerative Proteinopathy
- Neurological Genetic Disorders

### Oncology Research

- Immuno-oncology
- Cancer Genomics and Signalling
- Antibody Drug Conjugates

#### **Discovery Sciences**

- New Therapies
- Microbiome
- Discovery Technologies



## **Neurological Disorders Research**

#### Research Areas



Pain - Ion channels and neuro-immune interaction



Neurodegenerative Proteinopathy - Pathological protein aggregation and clearance

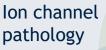


Neurological Genetic Disorders - Rare lysosomal storage disorders and epilepsies









Impaired protein homeostasis



















## **Oncology Research**

#### Research Areas



Immuno-Oncology

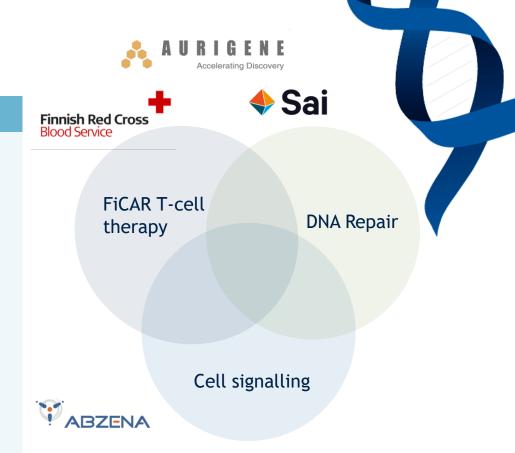
- FiCAR T-cell therapy
- 2<sup>nd</sup> generation immunecheckpoint inhibitors



Cancer genomics and Cell signalling



Antibody drug conjugates





### **Discovery Sciences**

#### **Research Areas**









#### **New Therapies**

· Cell and Gene Therapy



Microbiome



**Discovery Technologies** 







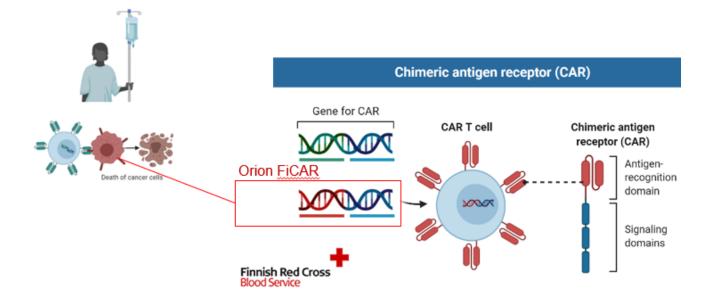






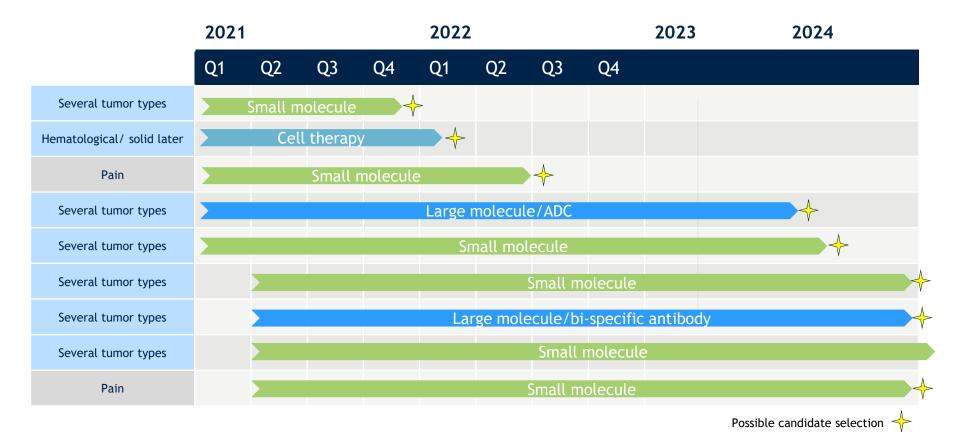


## We have initiated CAR T-cell therapy research project in collaboration with The Finnish Red Cross





## R&D research pipeline in May 2021



26 May 2021



Key clinical pipeline



Key clinical development pipeline		Phase complete	d Phase	ongoing	
Project/compound	Indication	Phase I	Phase II	Phase III	Registration
ARASENS / darolutamide <sup>1</sup>	Prostate cancer (mHSPC)	Phase I	Phase II	Phase III	
ARANOTE / darolutamide <sup>1</sup>	Prostate cancer (mHSPC)	Phase I	Phase II	Phase III	
ODM-208	Prostate cancer (CRPC)	Phase I	Phase II		
ODM-209	Prostate cancer (CRPC), breast cancer				

Oncology

Respiratory

<sup>1)</sup> In collaboration with Bayer

## Nubeqa®: Clinical trials ongoing to expand indication to patients with metastatic hormone sensitive prostate cancer

	Non-metastatic		Metastatic				
Prostate Cancer	nml	nHSPC¹		mHSPC <sup>3</sup>		mCRPC⁴	
Prostate Cancer	Adjuvant		milett C	Chemo Combo	No Chemo Combo	HICKEC	
NUBEQA° (darolutamide) ﷺ	DASL-HiCaP		approved	ARASENS	ARANOTE		
enzalutamide			approved		approved	approved	
apalutamide			approved		approved		
abiraterone acetate					approved	approved	





<sup>1)</sup> nmHSPC = non-metastatic hormone-sensitive prostate cancer 2) nmCRPC = non-metastatic castration-resistant prostate cancer

<sup>3)</sup> mHSPC = metastatic hormone-sensitive prostate cancer 4) mCRPC = metastatic castration-resistant prostate cancer

## ARASENS & ARANOTE trials aiming to expand the indication of darolutamide to metastatic hormone-sensitive prostate cancer

Trial on-going	Target Patients	Treatment Combo	Primary End-point	Present Status
ARASENS	mHSPC	Darolutamide + ADT + Docetaxel	Overall survival	Fully recruited
ARANOTE	mHSPC	Darolutamide + ADT	Radiological progression-free survival	Recruitment started



Key clinical development pipeline		Phase completed Phase ongoing			
Project/compound	Indication	Phase I	Phase II	Phase III	Registration
ARASENS / darolutamide <sup>1</sup>	Prostate cancer (mHSPC)	Phase I	Phase II	Phase III	
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ODM-209	Prostate cancer (CRPC), breast cancer	Phase I			
Oncology Respirator	у				

<sup>1)</sup> In collaboration with Bayer

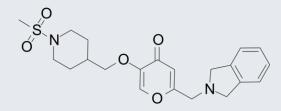
## CYP11A1 inhibitors (ODM-208 & ODM-209) to treat the patients with metastatic castration-resistant prostate cancer (mCRPC)

	Non-metastatic		Metastatic			
Prostate Cancer	nmF Adjuvant	ISPC <sup>1</sup>	nmCRPC <sup>2</sup>	mH!	SPC <sup>3</sup> No Chemo Combo	mCRPC⁴
NUBEQA° (darolutamide) ﷺ	DASL-HiCaP		approved	ARASENS	ARANOTE	ODM-208/ ODM-209



## ODM-208 (& ODM-209): CYP11A1 inhibitor to treat the patients with metastatic castration-resistant prostate cancer (mCRPC)

#### **ODM-208**



 First-in-class oral molecule to inhibit the synthesis of all steroid hormones and precursors, which could mediate androgen receptor signalling and tumor growth

#### **Target Patients**



Target patients with prostate cancer that has become resistant to the standard hormonal treatments.

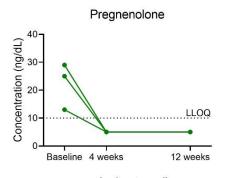


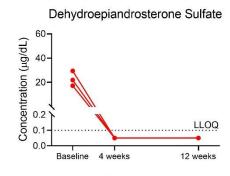
Potential indications beyond prostate cancer: breast cancer, endometrial uterus cancer

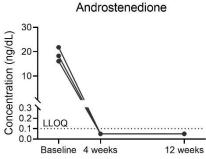


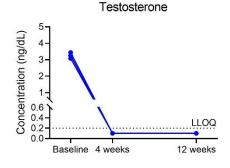
## ODM-208 reduces the serum steroids below the detection limit in the patients with mCRPC and ongoing ADT

#### Steroid decrease in three patients dosed in CYPIDES Ph1

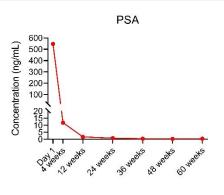


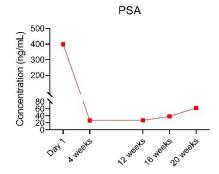






#### PSA decrease in two responders







# CYPIDES and STESIDES studies to select the best molecule for the patients with metastatic castrate-resistant prostate cancer (progressed during one or more novel hormonal therapy and chemotherapy)

Trial on-going	Target Patients	Treatment	Primary end-point	Present Status
CYPIDES	mCRPC	ODM-208 + glucocorticoid and mineralocorticoid replacement therapy	Safety Efficacy (steroids + PSA decrease)	Ph2 on-going
STESIDES	mCRPC Breast Cancer	ODM-209 + glucocorticoid and mineralocorticoid replacement therapy	Safety Efficacy (steroids + PSA decrease)	Ph1 on-going



Key clinical deve	lopment pipeline	Phase completed	Phase	ongoing	
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Easyhaler® tiotropium	COPD	Bioequ	ivalence st	udy	
New dry-powder inhaler / indacaterol-glycopyrronium	COPD	Bioequivalence study			
Oncology Respirator	y				

<sup>1)</sup> In collaboration with Bayer

26 May 2021

## Patient centric portfolio for Asthma & COPD

**Current portfolio** 



Clinical development projects aiming to expand the offering



**FORMOTEROL** 

**FLUTICASONE** 

Tiotropium Easyhaler®



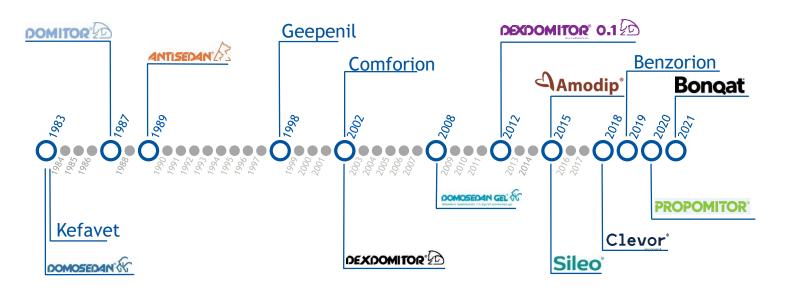
Connected Easyhaler®



Indacaterol-glycopyrronium New dry-powder inhaler



## Main Orion Animal Health Marketing Authorisations



In registration phase

A novel alpha-2 adrenoceptor agonist, alleviates acute anxiety and fear associated with travel and separation anxiety in dogs

Highlight from research

Several activities in microbiome field - different species such as chicken, dogs, cats and swine



**Orion Corporation Capital Markets Day** 

