

Celex Oncology Innovations Ltd



From invasive to benign tumour

February, 2021



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CELEX – A Major Opportunity



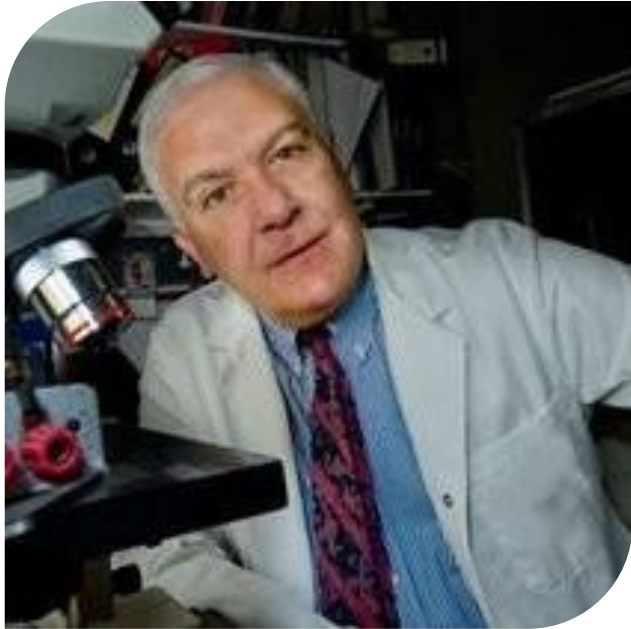
- Celex inhibits metastasis in several major cancers.
- Our strategy is to prove the concept in-man through a 'repurposed' drug, Ranolazine, and then go to market with our patented combination drug and antibody solutions.
- This represents the biggest breakthrough in understanding and treating cancer in 50 years.



The
SCIENCE &
INTELLECTUAL PROPERTY



Ground-breaking Scientist-led



Mustafa Djamgoz: The first person to discover that electrical excitability of cancer cells drives metastasis

Professor Mustafa Djamgoz

Holder of two Professorships - Neurobiology, then Cancer Biology, at Imperial College London. Currently, Emeritus Professor and acting CEO.

Published 4 books and over 200 primary research papers; Co-editor in Chief of *Bioelectricity*.

Winner of the Huxley Memorial Medal, The Japanese Government Research Award for Foreign Specialist and awarded The Freedom of the City of London.

As a neurobiologist, Professor Djamgoz studied the electrical signals in brain for more than 20 years. As a cancer biologist, he applied this knowledge and experience to tumours to discover that cancer cells become electrically excitable in order to become aggressively invasive and malignant.



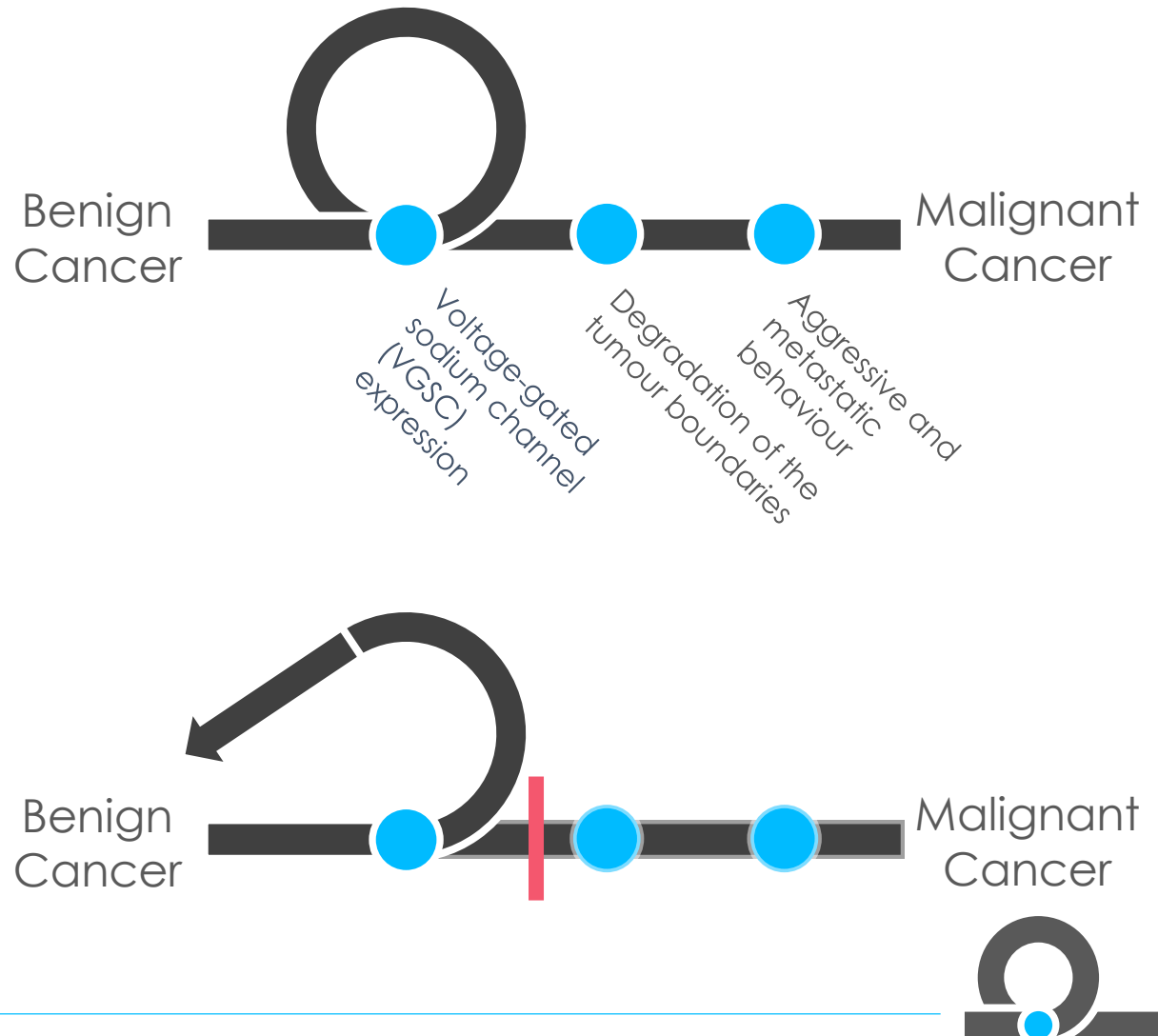
The Celex Concept is Simple

CELEX

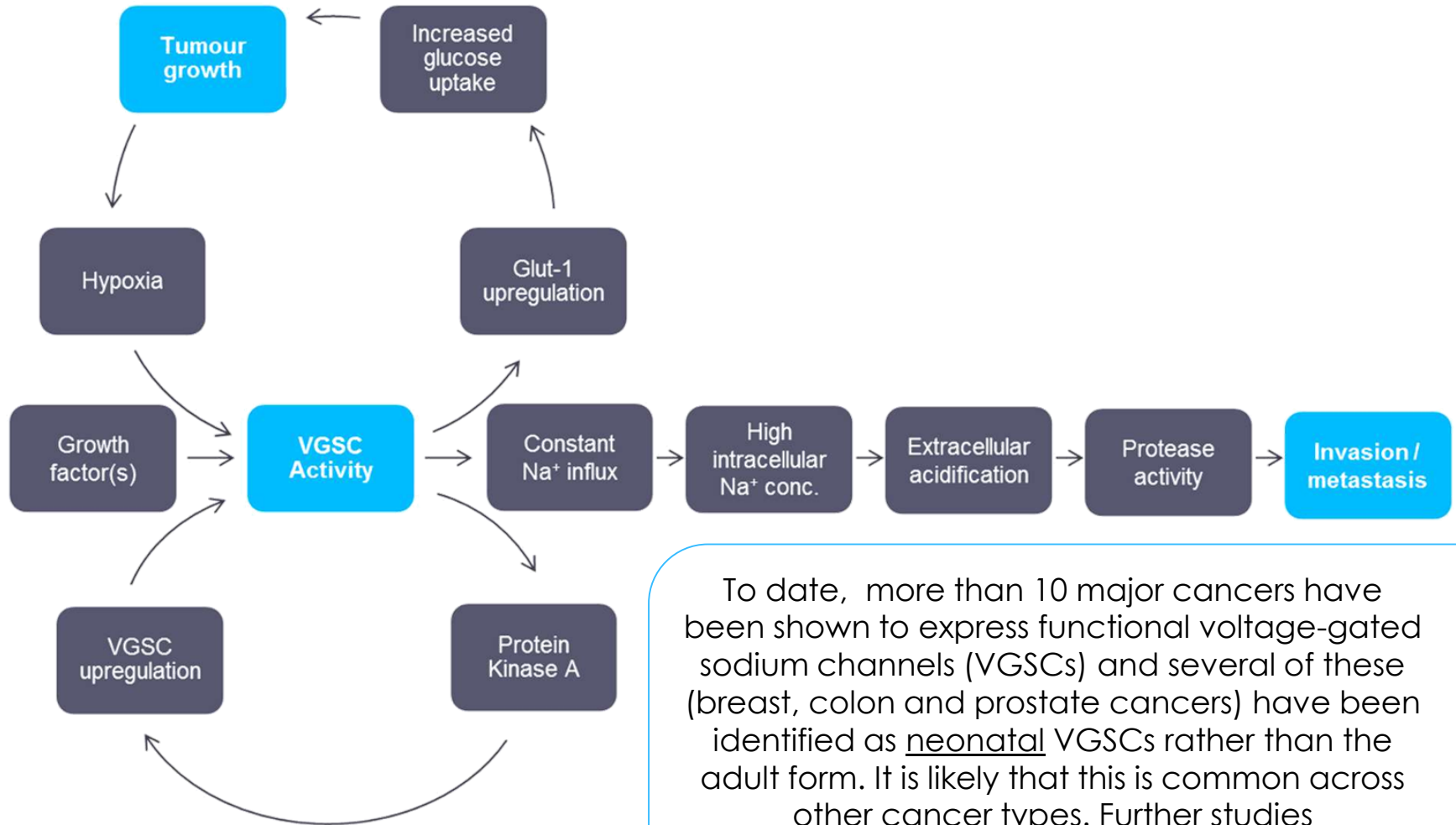
Cellular Excitability

First described in
Djamgoz, J Clin Exp
Oncol 2014, S1

Malignant tumours have the potential to metastasise. Metastasis is the main cause of cancer death. If this mechanism can be blocked, tumours could be prevented from metastasising, turning cancer into a chronic condition that can be managed.
= A paradigm shift in the treatment of cancer.



The Celex Mechanism is fully integrated



To date, more than 10 major cancers have been shown to express functional voltage-gated sodium channels (VGSCs) and several of these (breast, colon and prostate cancers) have been identified as neonatal VGSCs rather than the adult form. It is likely that this is common across other cancer types. Further studies are on-going to verify these.



Key Characteristics of the cancer VGSC

- The cancer VGSC has 2 independent, complementary characteristics (both discovered and patented by us) that make it amenable for immediate therapeutic exploitation:
 1. Expression as **neonatal splice variant** (approachable by monoclonal antibody – one already produced and sequenced); and
 2. Component of **persistent current** that develops under the hypoxic conditions of growing tumours (approachable by VGSC blocker drugs including Ranolazine and novel drug combinations).
- Our findings are supported by independent international research and has stood the test of time since inception.



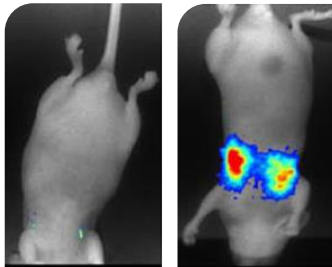
Animal studies support the Celex mechanism

Mice implanted with human breast cancer¹

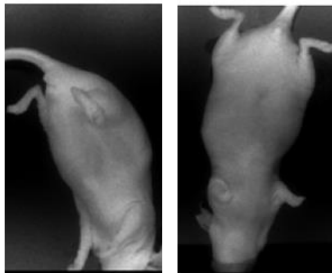
Bright regions indicate tumour growth

Start 8 weeks

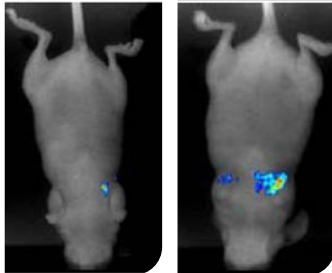
Control mouse



Mouse with VGSC gene silenced

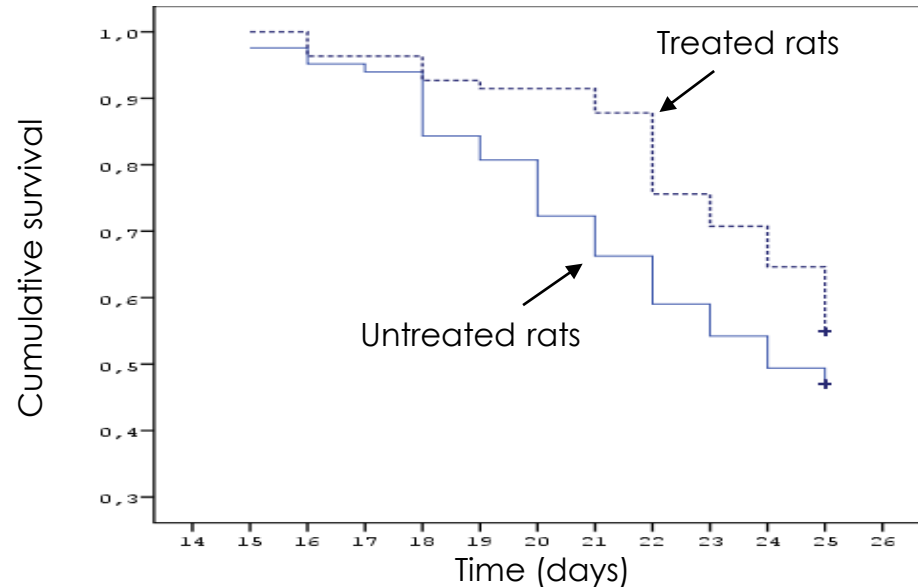


Mouse treated with ranolazine to block VGSC persistent current



Inhibition of VGSC expression and activity in tumours has been shown to suppress metastasis and prolong survival in animal studies

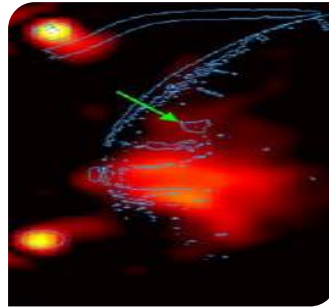
Rats with prostate cancer²



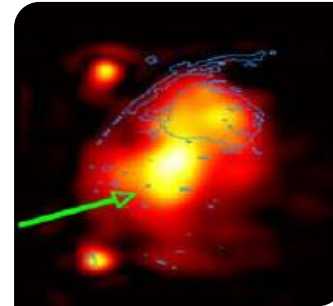
There was a significantly improved survival in rats treated with tetrodotoxin, which blocks VGSCs in the tumour and stops it from spreading

Evidence for VGSCs in Human Cancers

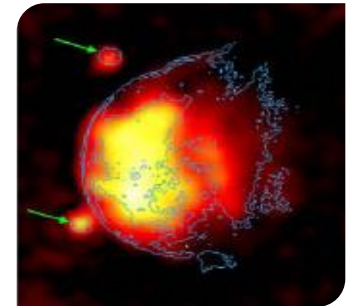
Increased sodium can be seen in advanced cancer on a clinical 23-sodium MRI scan. These are scans of human breast cancer. The increased sodium level in tumours (resulting from persistent VGSC activity) leads to metastasis via the Celex mechanism.



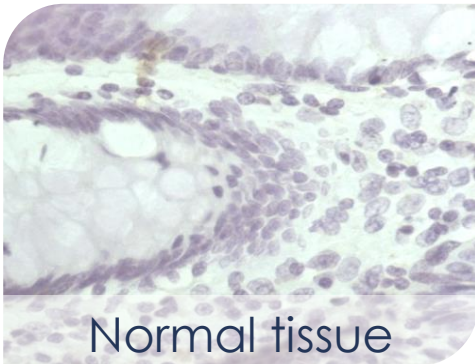
Benign lesion



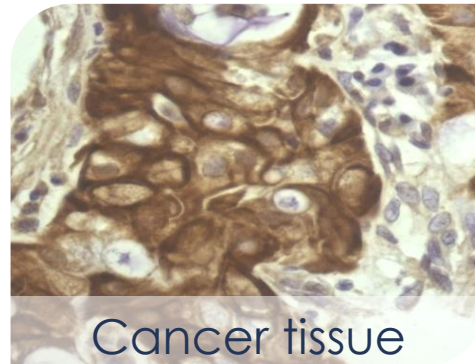
Poorly differentiated



Locally advanced



Normal tissue



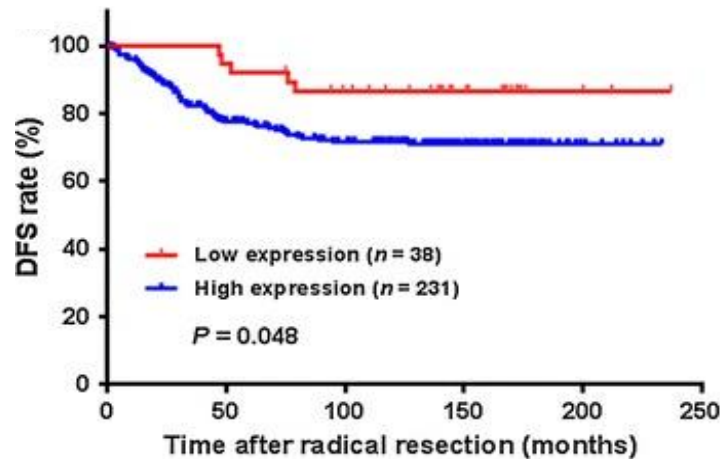
Cancer tissue

Immunostaining (brown) shows the presence of neonatal channel proteins in human colon cancer tissue.

Several cancers express only the neonatal form of the VGSC, something that is not observed in normal adult human tissue.

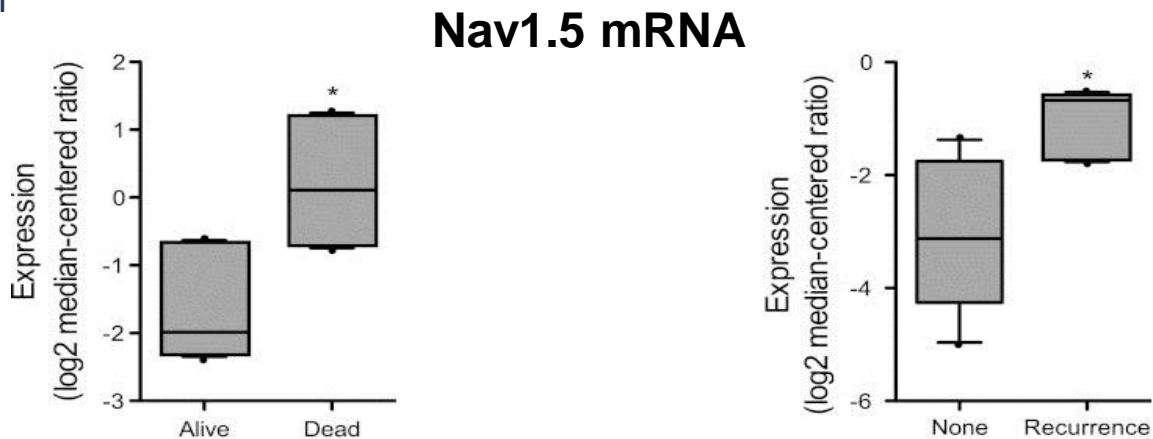
Correlation of VGSC (nNav1.5) expression with disease progression, recurrence and survival in human cancer patients

Colon Cancer



Kaplan–Meier curves comparing 5-year disease-free survival (DFS) of colon cancer patients with high and low Nav1.5 protein expression. This is shorter in patients with high Nav1.5 expression than in those with low expression [Peng et al. - Chin J Cancer (2017) 9;36(1):89]

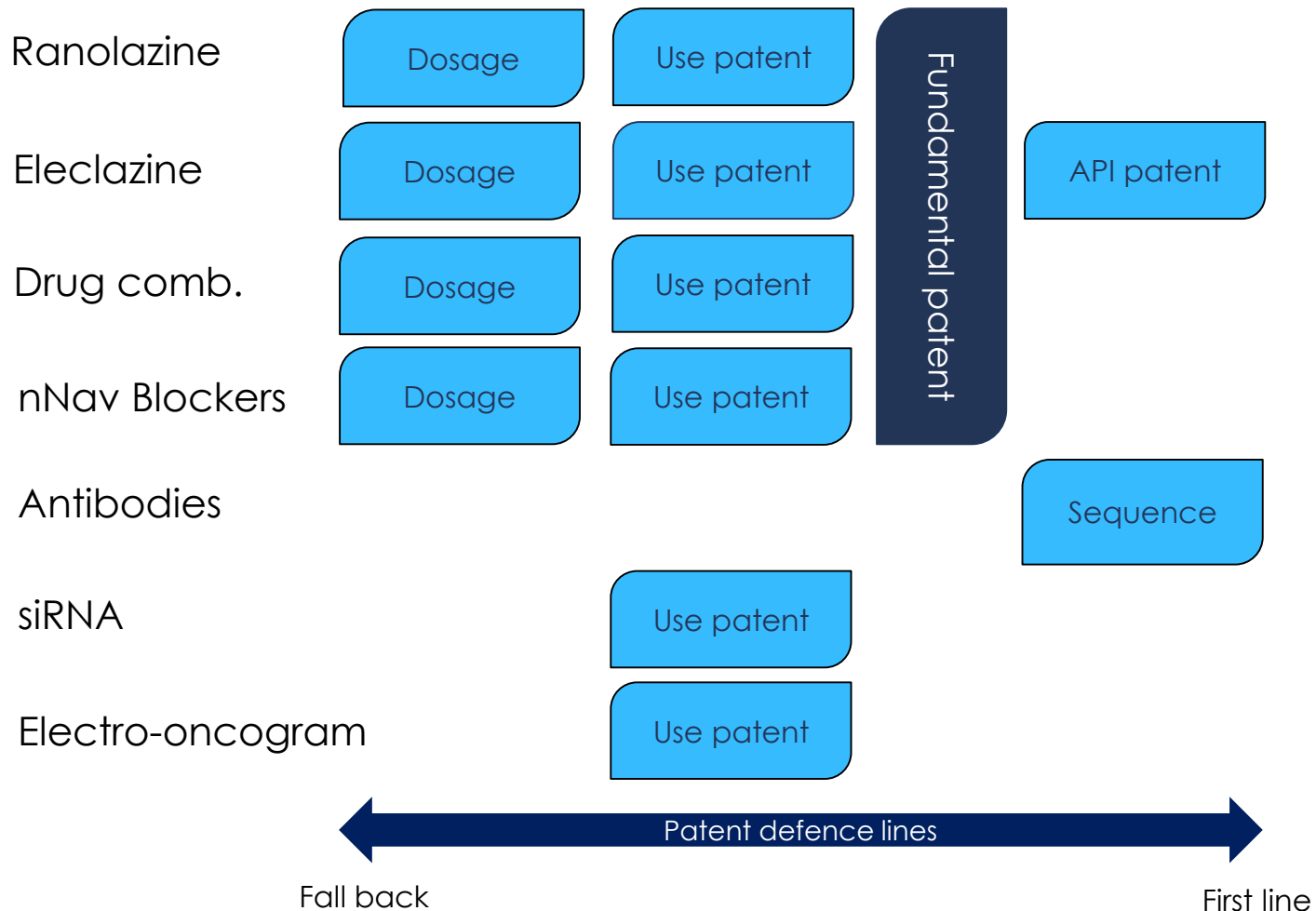
Breast Cancer



Yang et al. Breast Cancer Res Treat (2012) DOI 10.1007/s10549-012-2102-9



Multiple lines of Patent Protection and unrivalled Competitive Position



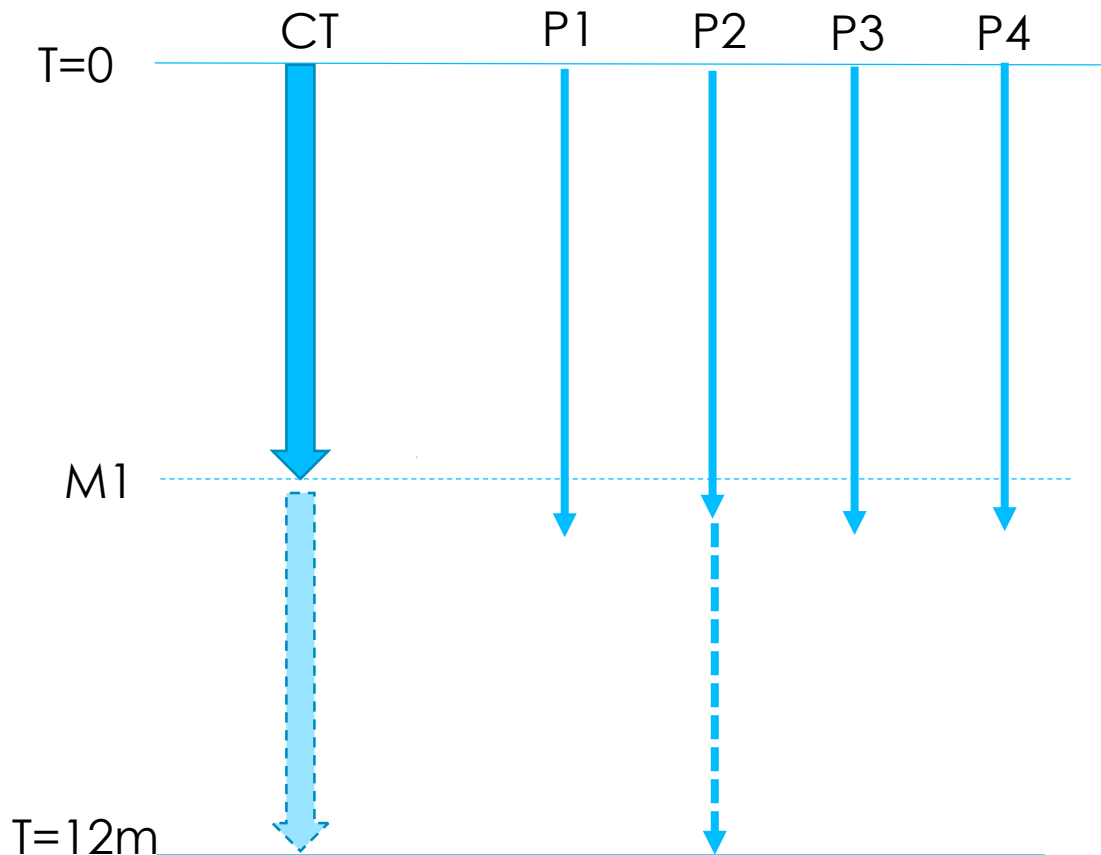
- Celex holds a broad portfolio of patents to protect the possible business opportunities that it has identified.
- The patent portfolio is constantly being expanded and maintained.
- The Ranolazine patent has been granted.
- The others are patent applications.
- The fundamental patent application covers all uses of VSGC blockers to inhibit metastasis.



The NEXT STEPS



Proof-of-Concept milestone (Phase II clinical trial on TNBC) while developing long-term value (pre-clinical projects P1-P4)



CT = Clinical Trial (Phase II, TNBC)
Repurpose ranolazine (Ranexa®), which is currently approved for the treatment of angina pectoris

P1 = Autoantibody testing
P2 = (i) mAb validation and (ii) testing (in vitro and in vivo)

P3 = Combination (in vivo testing)

P4 = Eleclazine (in vivo testing)

M1 = Milestone 1



Strong, Staged Development Plan

Activity	Year 1	Year 2	Year 3	Year 4
TNBC monotherapy with Ranolazine	Phase 2a Clinical trial			
Human serum and in vivo animal tests (projects P1-P4)	Pre-clinical			
TNBC combination therapy (Ranolazine+)		Phase 1 ----- 2a ----- 2b		
Prostate cancer monotherapy (Ranolazine)		Phase 2a ----- 2b		
Prostate cancer combination therapy (Ranolazine+)		Phase 1 ----- 2a ----- 2b		
mAb development and applications inc. Partnering	Continuous			
IN RESERVE Mono and combination therapies with Eleclazine on TNBC and/or PCa			Phase 1 ----- 2a ----- 2b	



Post-POC Business Plan

- The first stage with the proposed **Proof-of-Concept** Clinical Trial in man will unlock the door for novel (non-toxic), long-term effective treatments of several major cancers.
- Exit or big pharma collaboration likely after first successful proof-of-concept trial.
- Further development to next stage (Phase 2 of the patented combination drug and partnering mAb development) set out in full business plan (costed at £50m) available under NDA.



Point of Inflection Funding of £5m (ca. 12 months)

Activity	Budget
Working capital Includes amongst other expenses: Salaries Premises inc Labs Patents and Regulatory	£ 1,200,000
Non-clinical and clinical development Includes: TNBC phase 2a Proof-of-Concept Ranolazine trial Further key animal studies (in preparation for years 2-4) mAb validation and pre-clinical studies	£ 3,500,000
IP Legal and Consulting	£ 300,000
Total, to allow us to achieve our key POC Milestone	£ 5,000,000



The
MARKET OPPORTUNITY
and
BENEFIT TO PATIENTS



Exceptional Market Opportunity

The top 5 cancer drugs generate annual revenues in excess of \$30 billion

Breast Cancer (BCa)

Est. 279,100 new cases in USA in 2020¹

Prostate Cancer (PCa)

Est. 191,930 new cases in USA in 2020¹

Colorectal Cancer (CRCa)

Est. 147,950 new cases in USA in 2020¹

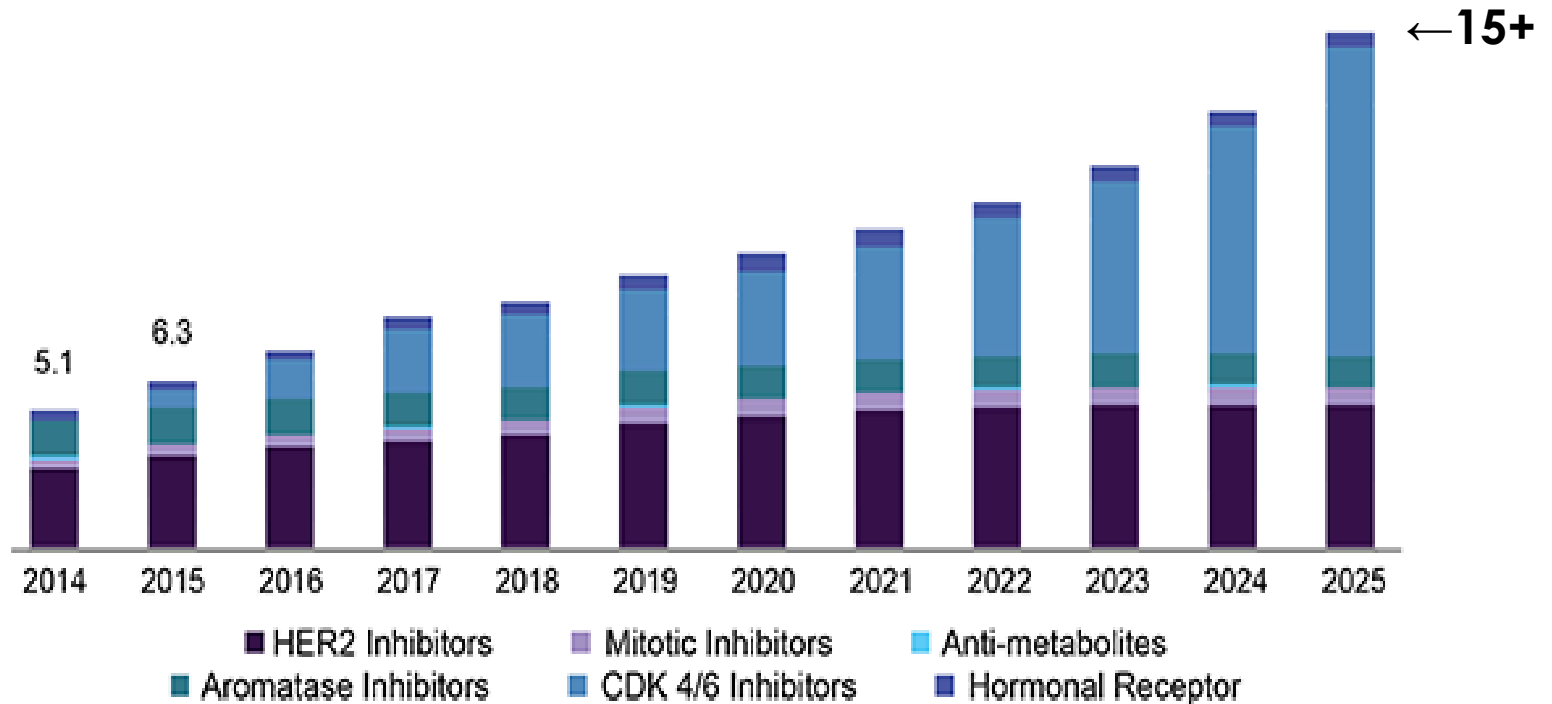
To appreciate the full potential of CELEX – functional voltage-gated sodium channels (VGSCs) have been shown to occur in 14 different cancers, including some major carcinomas. In several of these (starred), the VGSC (Nav1.5 or Nav1.5) has been determined to be 'neonatal'. The rest remain to be confirmed whether the VGSC subtype expressed is of the adult or neonatal type.

Cancer VGSC SUBTYPE(S) (* indicates nNav1.5 expression)	
Breast*	nNav1.5
Colon*	nNav1.5
Astrocytoma*	nNav1.5
Neuroblastoma*	nNav1.5
Ovarian	Nav1.5
Lymphoma	Nav1.5
Leukaemia	Nav1.5
Neuroblastoma	Nav1.5
Astrocytoma	Nav1.5
Melanoma	Nav1.5
Cervical	Nav1.6
Prostate*	nNav1.7
Gastric	Nav1.7
NSCLC	Nav1.7

¹American Cancer Society <https://www.cancer.org/> accessed 8th June 2020

Breast Cancer

US drugs market 2014-2025 (USD Billion)

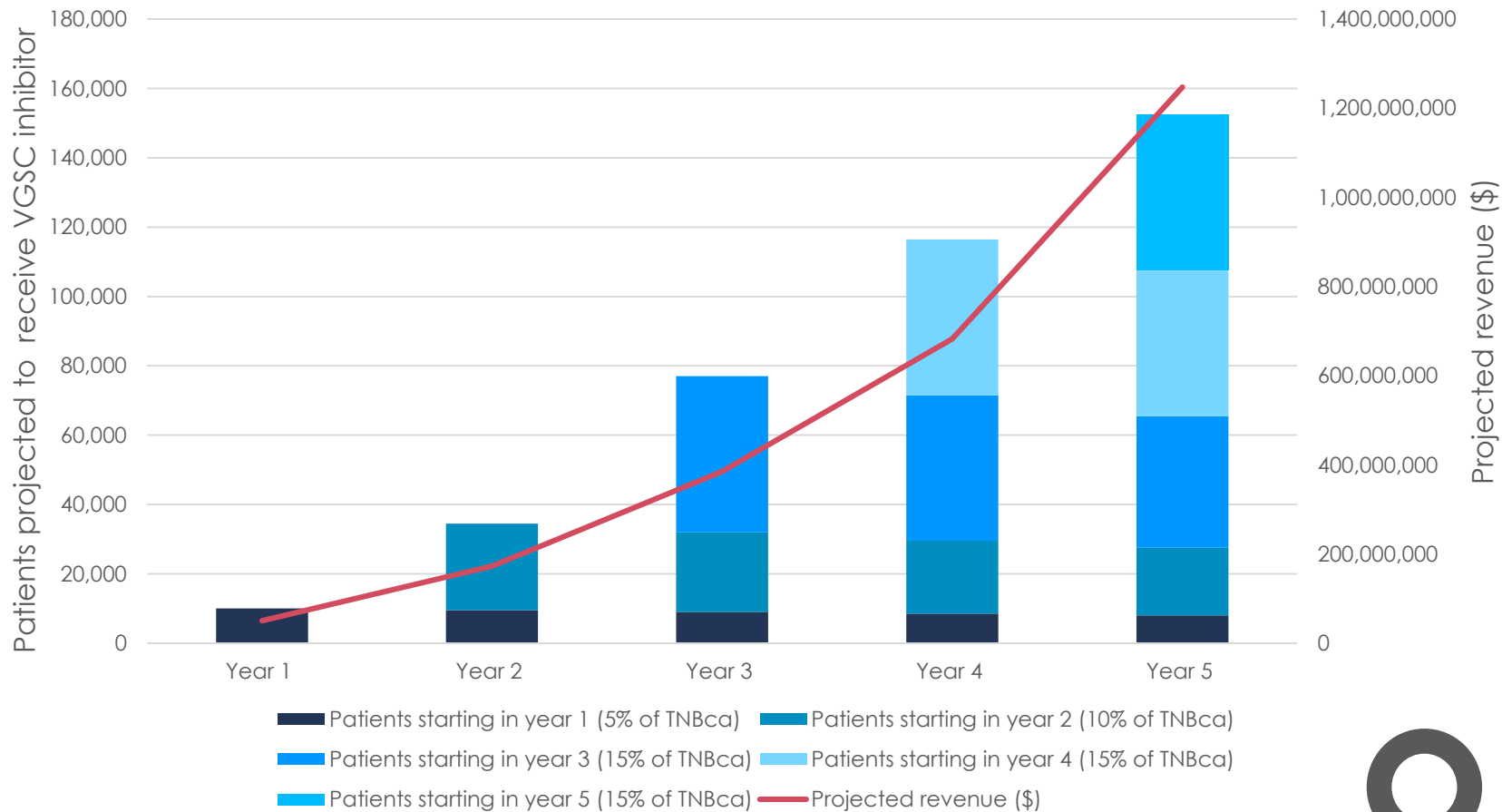


Source: www.grandviewresearch.com



Strong Revenue Potential for just 'triple negative' breast cancer (TNBC) – the initial target of Celex

5 year projected global patient uptake of small molecule VGSC inhibitor and revenue in triple negative breast cancer



Market potential for Celex patent protected drugs

For just new cases of breast, prostate, lung and colon cancer (3.4 Million) detected yearly in the industrialized world

Market penetration	10\$ per day	20\$ per day
10%	12.4B \$	24.8 B \$
25%	31 B \$	62 B \$
50%	62 B \$	124 B \$
75%	93 B \$	186 B \$



Multiple Inflection Points for Exit

Post Phase 2a study results

Due to the size of the opportunity, interest is likely to be generated from potential partners or acquirers once in-man proof-of-concept has been produced.

Post Phase 2b study results

At the end of phase two, the probability of success will be considerably enhanced and therefore the company will be well positioned for an IPO or acquisition.

Post sequencing of anti-nNav1.5 monoclonal antibody

The monoclonal antibody has been sequenced and patented. This will be a very attractive proposition for out-licensing.



Benefit to Patients

1. Celex drugs are 'non-toxic' and with minimal side effects - if any. This is unlike current treatments like chemotherapy, radiotherapy, even biological therapies.
2. The Celex approach 'freezes' the cancer and inhibits it from spreading. This is unlike chemotherapy which aims to kill tumour cells and, in the long run, can make cancer worse.
3. The Celex drugs are simple to use and cheap to manufacture; the price can be affordable allowing for life-long treatment.
4. Celex medication will enable patients to live with cancer as a chronic condition, rather like diabetes.



Strategic Summary

- Hierarchical plan (Stage 1) to employ Ranolazine as the best understood drug in a 'proof-of-concept' phase 2 clinical trial;
- The ultimate market entry likely to be with a ranolazine + drug combination with significant added advantages;
- Overcoming the traditional difficulties in trialling metastatic disease by introduction of a platform of evidence-based novel clinical end-points;
- The supplementary projects (including autoantibody and mAb) to lay solid foundations for building the company up to Stage 2 and beyond.

The TEAM



Experienced Executive Team

Mustafa Djamgoz



Acting Chief Executive Officer

- Professor Djamgoz is specialised in neuroscience and became Professor of Neurobiology in 1995.
- Through biophysics and biomedicine he initiated a new field of cancer research which he calls "neuroscience solutions to cancer" and identified novel voltage-gated sodium channels as anti-metastatic targets.
- He was given a second professorship (of Cancer Biology) in 2005.
- Professor Djamgoz has published more than 200 primary research papers and has edited 6 books / special journal issues. His book "Beat Cancer" was published in 2014

Ajmal Rahman



Executive Chairman

- Ajmal Rahman is a former Co-Head of Investment Banking for the Asia Pacific Region for Merrill Lynch
- He has raised over \$65B of equity and equity-linked financing in the Global Equity Capital Markets Arena
- He was formally CEO of a private specialty pharmaceutical company with a focus on the treatment of advanced prostate cancer
- He is currently on the board of a number of technology companies
- He has an MA in Law from the University of Cambridge

Laurence Cohen



Corporate Lawyer

- Laurence Cohen is an English Solicitor. He spent 40 years in private practice, finishing his career as a partner of Latham & Watkins LLP, where he was a global co-chair of the IP group.
- He has been involved in licensing agreements for pharmaceutical companies as well as due diligence and other support activities for M&A, licensing agreements and joint ventures.
- He was listed as a leading expert in the legal directories.
- He has an MA with joint honours in Natural Sciences (advanced chemistry) and law from University of Cambridge

Carsten Faltum



Chief Operating Officer

- Carsten Faltum has a strong background within R&D and Business Development in the Life Science area.
- The last four years as Vice President in Biolin Scientific a leading company within the ion channel research.
- He also spend 7 years in senior positions in Corporate Venturing and Ventures funds, responsible for investments in the Life Science area.
- Carsten Faltum has experience from a number of board positions typically within the Life Science and Intellectual Property industry
- He holds a M.Sc. in Biochemistry and B.Sc. in Manufacturing



Expert Board of Advisors

Professor R. Charles Coombes, MD, PhD, FMedSci

Professor of Medical Oncology (breast cancer specialist). Director of The Imperial CRUK Centre, Chair of The ICR (UK) Centre.

Professor Hani Gabra, MD, PhD

Professor of Medical Oncology (ovarian cancer specialist, Imperial College London) and Chief Medical Officer, BerGenBio ASA. Previously: Director, Ovarian Cancer Action Research Centre, Head of Medical Oncology (Imperial College Healthcare NHS Trust); Chief Investigator in the Imperial Clinical Trials Unit; Head of the Clinical Discovery Unit in Early Clinical Development, IMED Biotech Unit (AstraZeneca).

Dr William J Brackenbury, PhD

Senior Lecturer in Biology, University of York. Expert on ion channels and cancer.

Professor Michael Seckl MD, PhD, FMedSci

Professor of Medical Oncology. Lung cancer expert.

Prof Annarosa Arcangeli, MD, PhD

Professor of General Pathology at University of Florence; an expert on ion channels, their role on neoplastic transformation in vivo and monoclonal antibodies.





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