Summary

DanDrit Biotech is a Medicon Valley company developing cancer vaccines based on dendritic cell technologies.

Founded in 2001, DanDrit has two lead products (Phase I/II clinical trials completed) for colorectal cancer and non-small cell lung cancer. Phase IIb/III studies are beginning.

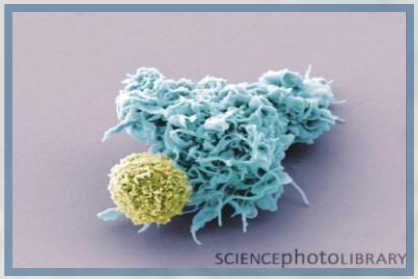
DanDrit will seek compassionate use authorisations for lead products. DanDrit was the first European company to become GMP qualified for cellular therapies.

DanDrit will out-license non-core technologies and applications of the platform technology in non-competitive areas. A key out-licensing opportunity is for tolerance-inducing dendritic cells. This has application in auto-immune diseases such as early stage Type 1 diabetes.

Later in 2008 or early in 2009 DanDrit hopes to close a private investment round, raising Euro 30 million (based on a company valuation of about Euro 100 million).

DanDrit Biotech – a cancer vaccine company

- Cancer is responsible for almost 25% of deaths in the developed world, and may soon overtake heart disease as the major cause of death
- DanDrit's MelCancerVac® (MCV) dendritic cell cancer vaccines help the cancer patient to mount an immune response against tumours. Dendritic cells direct the cell killing response against tumours through direct communication with T cells.

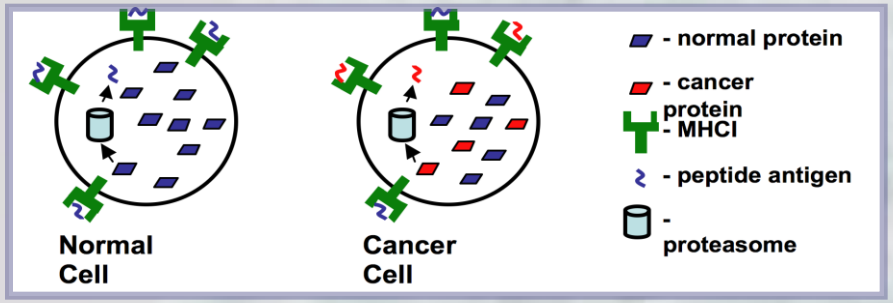


The photograph (left, courtesy Science Photo Library) shows a dendritic cell (in blue) communicating with a T-lymphocyte (gold). You might imagine that the dendritic cell is instructing the T-cell to multiply and kill cancer cells carrying a specific set of antigens.

- DanDrit's two lead applications for MCV are colorectal cancer (CRC) and non-small cell lung cancer (NSCLC). Together, CRC and NSCLC account for 40% of all cancer deaths
- Some terminal CRC and NSCLC patients who participated in Phase I/II clinical trials of DanDrit's MCV therapies are alive two years after beginning therapy

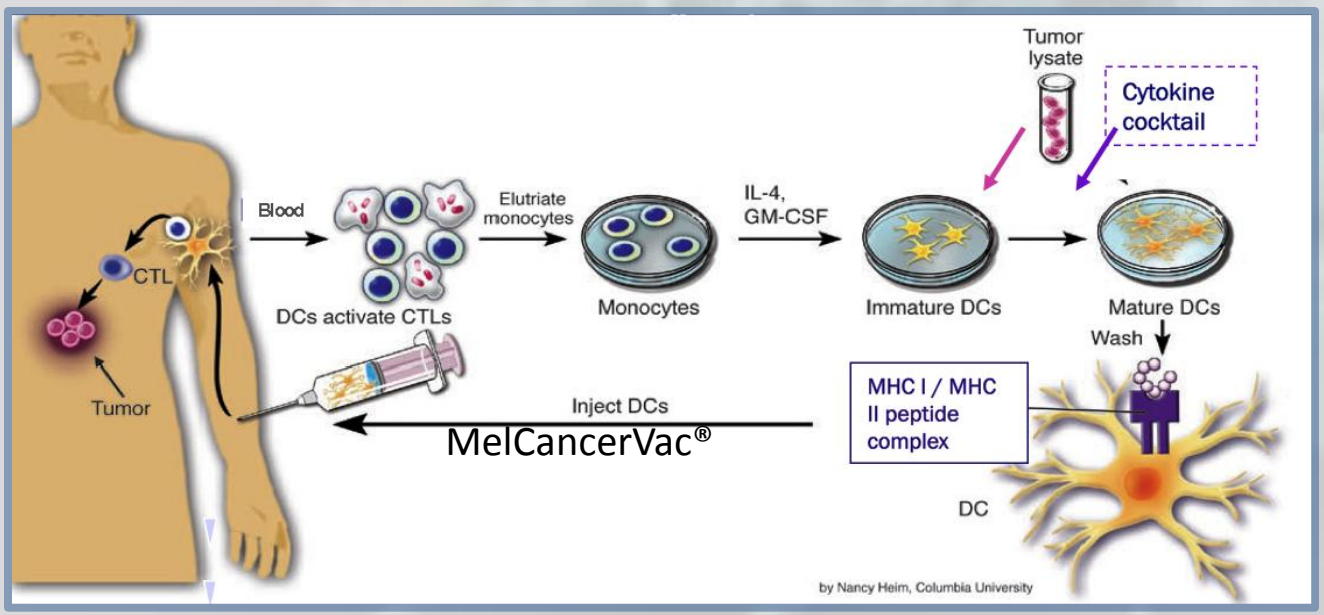
DanDrit® Biotech

MelCancerVac® – how it works



Most cells of the body – and most cancer cells – can be recognised by markers on the cell surface. These markers (or antigens) are small fragments of cellular proteins that have been processed in the cell (by the proteasome) and exported to the Class 1 Major Histocompatability complex (MHC-1).

The immune system may not recognise the cancer antigens (in red above) as foreign. DanDrit's MCV programs T-cells (CTL) to recognise cancer cells as foreign - to be attacked. This is mediated by dendritic cells, sensitised to cancer antigens "*in vitro*".



The diagram (left) shows how DanDrit transforms blood monocytes into dendritic cells (with cytokines IL-4 and GM-CSF) and sensitises them to tumour antigens "*in vitro*". The cells are then matured with a cytokine cocktail, washed and re-injected. Dendritic cell quality control confirms that tumour antigens are presented to T-cells "*in vivo*".

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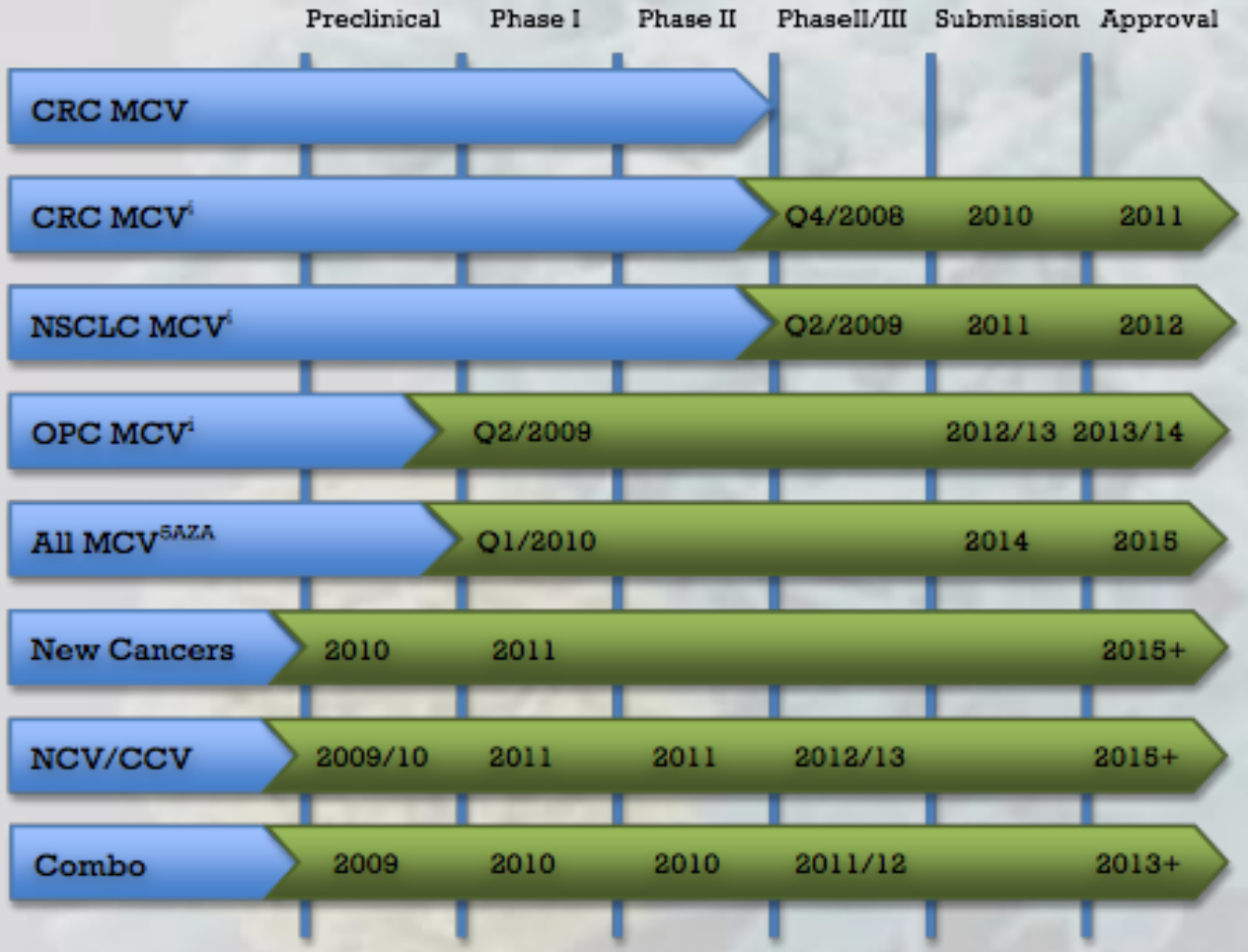
DanDrit's therapeutic pipeline



Blue arrow shows current state of clinical development and the green arrow shows future plans with dates. The original MCV has been replaced by improved MCV^{i}.

Abbreviations:

CRC – colorectal cancer

NSCLC – non small cell lung cancer

OPC – oesophopharyngeal cancer

MCV – MelCancerVac®

MCV^{i} – improved MelCancerVac, replaces MCV from 2006/7

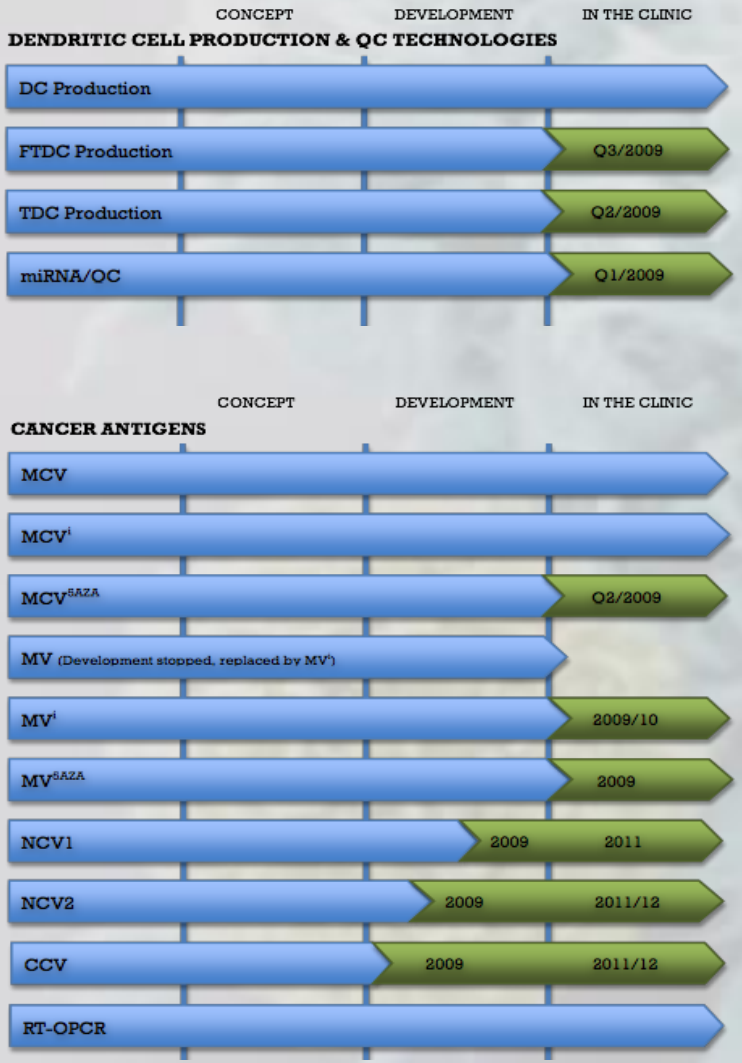
MCV^{5AZA} – Melanoma cell line is stimulated with 5-azacytidine to improve antigen expression

NCV – NewCancerVac to complement MCV with perhaps 2 or 3 new lysates

CCV – Combined Cancer Vac, new vaccine including all lysate strains

Combo – combination of MCV with other cancer therapies

DanDrit's technology platform pipeline



To support the current cancer targets, DanDrit has developed strong intellectual property positions in dendritic cell production technologies and relevant quality control.

DC Production – DanDrit's patented process for dendritic cell production
FTDC Production – DanDrit's patented fast track dendritic cell production technology
TDC Production – DanDrit's patented tolerogenic dendritic cell production technology – to be licensed out or developed with partner
miRNA/QC – DanDrit's patented (with Bioneer A/S) microRNA characterisation technology for dendritic cell quality control.

DanDrit will continue to improve its cancer antigen expression technologies with improved MCV and novel cancer lysates. See also therapeutic platform.

MCV – original Mel Cancer Vac
MCV^{i} – improved Mel Cancer Vac
MCV^{5AZA} – MCV with antigen expression enhanced by exposure of melanoma cell line to 5-azacytidine
MV – MelVaxin, melanoma cell lysate as in MCV, but used as stand-alone vaccine
MV^{i} – MelVaxin, based on improved melanoma lysate
MV^{5AZA} – MelVaxin, melanoma cell line is stimulated with 5-azacytidine to improve antigen expression
NCV1, NCV2 – New Cancer Vac 1/2, cancer cell line lysates to complement MCV
CCV – Combined Cancer Vac, new vaccine including all lysate strains
RT-QPCR – Reverse Transcriptase Quantitative Polymerase Chain Reaction – quality control method to compare patient tumour antigen expression profile with cancer vaccine antigen profile

DanDrit's Alliance Strategy

DanDrit has built a strong pipeline of dendritic cell based cancer therapies, currently addressing 40% of all cancer-related deaths. DanDrit controls key technologies with relevance outside our core business area and these we may out-license or co-develop with suitable partners. Strategic Alliances strengthen DanDrit's pipeline generating new collaborations and revenues.

Licensing-out

•DanDrit can generate tolerance-promoting dendritic cells for use in the treatment of autoimmune disease and is looking for an industrial partner or partners to take over the lead in the commercial development of this technology in specific clinical areas, such as type 1 diabetes or rheumatoid arthritis.

•DanDrit may be able to license-out its platform technologies for non-competitive applications, for example, in infectious disease. DanDrit is working on the accelerated production of dendritic cells – a capability of interest to many workers in the field.

Licensing-in dendritic cell technologies

•DanDrit welcomes contacts from academic or commercial concerns that wish to out-license or partner technologies that may strengthen our core business in cancer therapeutics. These might relate to novel cancer antigens, dendritic cell characterization or related immune technologies. For example DanDrit is involved in the co-development of a dendritic cell miRNA characterization platform with Bioneer, Denmark.

The mortality statistics for the seven leading causes of death in the USA and EU are tabulated below. Cancer is increasingly survivable with 3 survivors per death. In addition to cancer, dendritic cell technologies have relevance to infection and diabetes. Heart, Stroke and Lung disease, also influenced by infectious agents, are targets for immunotherapies. The data show the huge size of the market (USA and EU potentially over 25 million patients - with 3 million new patients diagnosed each year) for dendritic cell therapies.

Region	Citizens 1000,000s	All Deaths 1000s	Heart 1000s	Cancer 1000s	Stroke 1000s	Lung 1000s	Accident 1000s	Infection* 1000s	Diabetes 1000s
USA	300	2250	660	560	145	131	120	100	80
EU	500	3600	1000	900	220	225	200	160	85
Both	800	5850	1660	1460	365	355	320	260	165

DanDrit® Biotech

DanDrit's Business Strategy

By 2012 DanDrit will be a global company serving the needs and hopes of cancer sufferers.

Together the USA and Europe generate a market of over €150 billion for cancer therapies. CRC and NSCLC are markets worth €60 billion. MCV will not replace existing therapies such as surgery, radiotherapy and chemotherapy, but will form part of a box of anti-cancer tools.

The business model

DanDrit targets a weakness in cell therapy business plans – that is: how to address the market? Dendritic cell therapies such as MCV combine patient-specific cells and cancer-specific antigens in a complex therapeutic setting.

•DanDrit will make its dendritic cell cancer therapies available in dedicated clinics, combining GMP facilities with a warm welcome for patients.

•DanDrit will operate such clinics as a mix of wholly owned and franchised operations. This strategy will allow DanDrit to serve a large number of patients in widely scattered geographical settings.

•Careful oversight of staff training, SOP implementation and GMP validation will maintain and augment confidence in the DanDrit brand. Dedicated informatics systems will maintain the highest levels of quality control from early stage R&D of new products through to patient contact.

Milestones

DanDrit has established clear milestones, detailing:

•the advance of products through clinical trials to product approval

•the development of new dendritic cell cancer therapies to include new patient and cancer groups

•the development of new technology platforms to support clinical goals

•timetable for reimbursement implementation ahead of approvals

•out-licensing goals for non-core technologies and non-competitive applications of platform technologies

•corporate expansion, funding and staffing needs to implement clinical goals and to serve cancer sufferers