Recce
Targeting Superbugs
recce.com.au
ACN 124 849 065

ASX ANNOUNCEMENT

11 April 2016

Progress Update

Recce -

- **Confirms the appointment of an FDA consultant**
- **Plans to submit application for IND status by 30 June 2017**
- **Acts to determine the range of its technology's potential capabilities**
- **Moves to Boston USA to complete its pilot plant**
- **Plans manufacture over licensing**
- **Transfers its Head Office to Sydney and appoints international lawyers**
- **Unanimously approves restructuring plans**

This announces further important progress of Recce Ltd, and summarises substantial achievements since its ASX listing on 15 January 2016.

Recce has acted aggressively and successfully to gain unchallenged protection of its intellectual properties, and its trade marks (See Appendix 1). Granted patent status gives Recce manufacturing and marketing monopoly over some 80% of the global pharmaceutical markets, and may be expanded with future approvals.

1. Recce is positioned that its predominant FDA oriented activities will be centred in USA. Accordingly, three executive directors of Recce have recently returned from a foundation-building visit to the United States.

We do not report details of contacts, which Recce has worked hard to research and develop; however we do report that as a result of this visit:

2. Recce has confirmed the appointment of its FDA consultant – to advise upon and facilitate communications between Recce and the FDA, with a view to Recce obtaining IND (Investigational New Drug) status with the latter.

Below: Executive Directors, Michele Dilizia, James Graham & Graham Melrose with our FDA Consultant



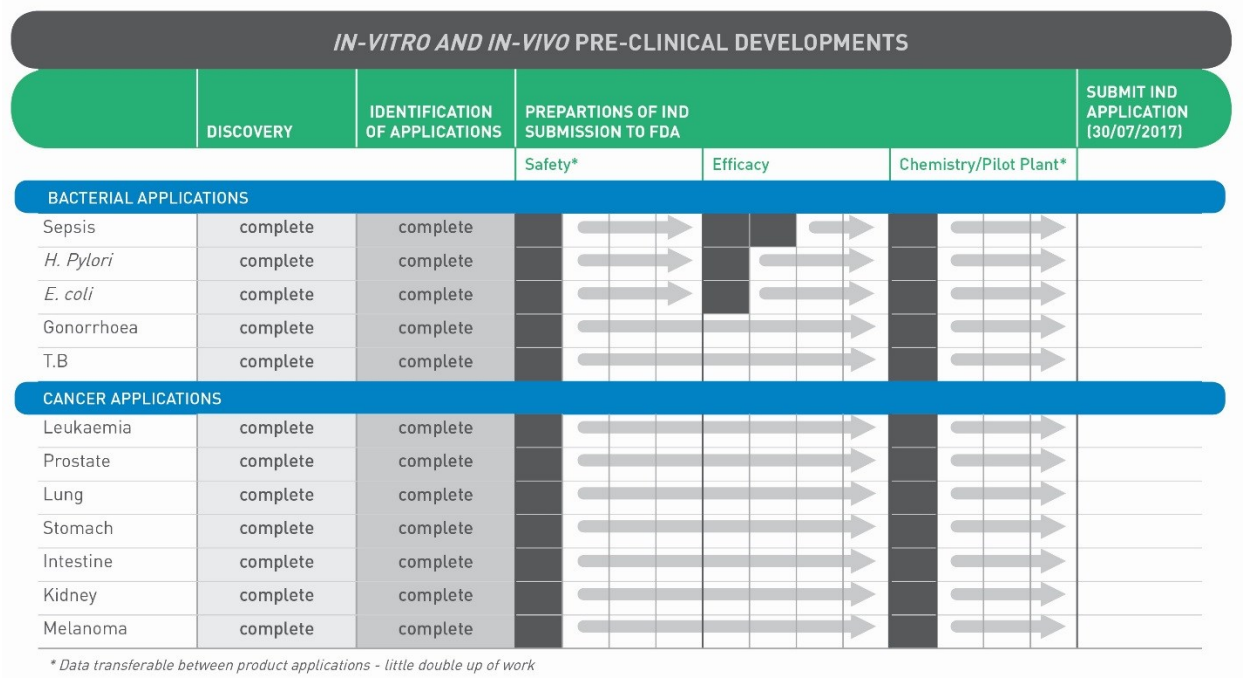
3. Recce is planning to submit its formal application for IND status by 30 June 2017.

IND status would be the stepping-stone of approval from which Recce, following tests in animals, would receive permission for testing in humans.

We were impressed by the authority and influence of our FDA consultant (A Department Head having access to some 60 co-consultants), to provide expertise appropriate to the stage of Recce's progress.

Our FDA consultant arranged for us:
(a) To have free entry over 3 days to the annual Society of Toxicology conference where we had access (and afterwards) to some 100 animal contract research laboratories (CRO's) of USA;
(b) A day-long discussion and documentation from the ex-Head of the FDA, where he was responsible for the supervision of applicants of pilot plants and approval (or not) of all IND applications to the FDA throughout USA.

The below diagram shows both our progress to date and the potential additional market applications of RECCE® technology; Recce has always emphasised that its broad technology (in contrast to a single product) gives added security and potential substantial up-side to its shareholders.



As it is more economic and protects our Intellectual Properties:

4. Recce will continue to assess the range of its potential disease-applications of which its technology is potentially capable.

Accordingly, as the result of deliberate and confident experimentation, Recce has announced that its technology, as well as anti-bacterial activity, in-vitro, has anti-cancer activity against 7 types of cancers - of an order equal or better than an existing commercial anti-cancer drug (See Appendix 2). Potentially, this is a huge and important opportunity for Recce to pursue global pharmaceutical markets related to ubiquitous cancers.

The USA culture consistently attracted Recce's directors. By culture we mean:

- Staff - with knowledge, experience and interest (a 'can do' attitude)
- Mature business protocols and laws
- Available equipment and its servicing
- Access to the FDA

- Raw materials with exact specifications
- Quality assurance standards
- Finance e.g. capital markets
- Market - buyers
- Competent and industry-orientated education system
- Transport system/distribution
- Knowledgeable and supportive government
- Competitive pricing

Recce further announces that:

5. Following synthesis of RECCE® antibiotic, successfully completed in its Perth laboratory, it will, effective May 2016, establish pilot-plant operations within two-year leased office-laboratory facilities in Boston, Massachusetts USA. Massachusetts is the pharmaceutical R&D center of east coast USA and the facilities are proximate to literally hundreds of pharmaceutical companies and animal research laboratories; additionally with Harvard and MIT, Boston it is a center of world-excellence.



Above: Recce's Office/Laboratory in Boston, MA (USA)

6. Also effective May 2016, Recce will transfer its Head Office from Perth to Sydney CBD (whilst continuing to maintain its original research laboratories in Perth). Within these plans, Executive Chairman, Dr Graham Melrose will actively support activities in Sydney, Boston and Perth; Executive Director and responsible for Marketing and Business Development, Mr James Graham will permanently exercise responsibilities from Sydney.
7. Recce has appointed international lawyers in Sydney; and is acting to establish a 100% owned subsidiary (Recce (USA) LLC) in Boston, supported by a local accountant firm.
8. Within the next months Recce will establish a serviced office in the UK, and appoint a regulatory consultant to supervise counter-part regulatory activities in Europe.
9. As it is potentially some ten-fold more profitable, and better protects intellectual properties – Recce will maintain its objective of manufacture (in contract to licensing).
10. Recce is well on its way, with the progress and achievements since the IPO, to initiating its next stage of development which will include Head Office in Sydney, continuing R&D in Perth, a 100% subsidiary having pilot plant and potential manufacturing facility in the US. Along with these structural changes, our Board's composition will now also evolve as foreshadowed in our prospectus and ASX-announced presentations. Accordingly, directors Mr Ian Brown and Professor Dongke Zhang are stepping-down to make way for new skills and knowledge on the Board which will be announced soon. Dr Graham Melrose, Executive Chairman and his fellow directors wish to express their appreciation of their contributions to the achievements of Recce's goals to this date.

All of the announced plans were unanimously approved by Recce Ltd's Board.

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About Recce Ltd

Recce Ltd (ASX: RCE), led by Dr Graham Melrose, is a world-leader in synthetic-polymer antibiotics. RECCE® antibiotics have been synthesised by an extremely simple and economic method.

RECCE® antibiotics have shown in laboratory tests that they have continued activity against bacteria including superbugs, even after repeated use.

Recce is positioned to achieve milestones in both pre-clinical trials for FDA purposes and the development of a pilot plant for flow-system manufacture of RECCE® antibiotics.

Appendix 1

1. **Intellectual Property**

Recce's intellectual property portfolio has continued to expand and is summarised:

Patent Family 1 – Granted – protecting Recce's unique and highly economical manufacturing process

Filed	Status	Expiry
Australia	Granted	2028
USA	Granted	2029
Europe	Granted	2028
Japan	Granted	2028
China	Granted	2028

Patent Family 2 – Provisional – protecting Recce's drug delivery opportunities

Lodged	Filed	Status	Expiry (if granted)
January 2016	All PCT Countries	Pending	2036

Patent Family 3 – Provisional – protecting Recce's anti-cancer applications

Lodged	Filed	Status	Expiry (if granted)
March 2016	All PCT Countries	Pending	2036

Granted patent status gives Recce manufacturing and marketing monopoly over some 80% of the global pharmaceutical market, and may be expanded with future approvals.

Trade Marks – Approved and Registered – protecting RECCE® for use on antibiotic and pharmaceutical products and services

Filed	Status	Renewal
Australia	Registered	2026
USA	Registered	2026
Europe	Registered	2026

Japan	Registered	2026
China	Registered	2026

Appendix 2

2. Anti-cancer Opportunity

On 14 March 2016, Recce announced some early, but encouraging anti-cancer activity of product from RECCE® technology. This discovery was an outcome of forecast R&D to investigate new market opportunities that may be applicable to the up-coming IND application.

The anti-cancer market is worth some $100b/annum, and could reach US$147bn by 2018, according to a new report by the IMS Institute for Healthcare Informatics – and represents a most significant future opportunity.

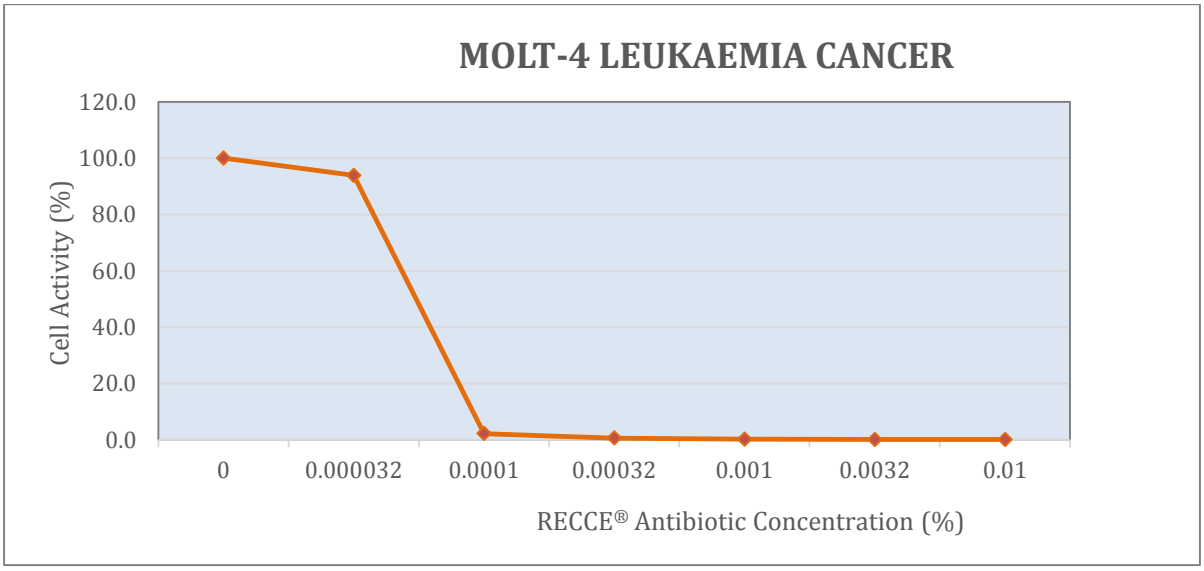
These findings are illustrated in detail in the following table and graphs:

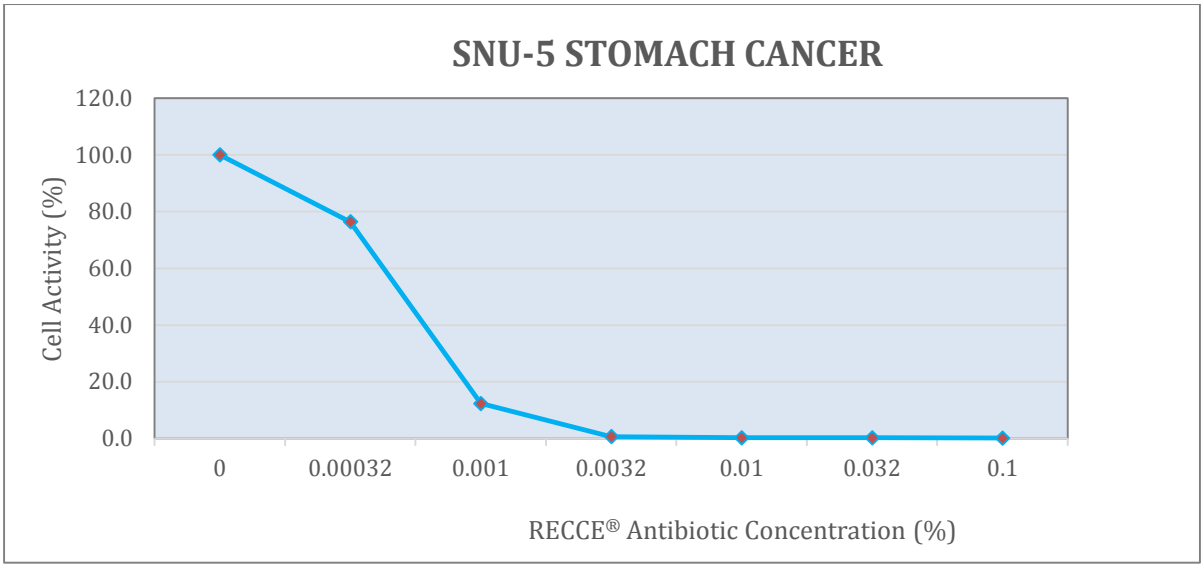
Concentrations of Control and RECCE® antibiotic, respectively, over 3 days, giving 50% loss of cancer-cell activity

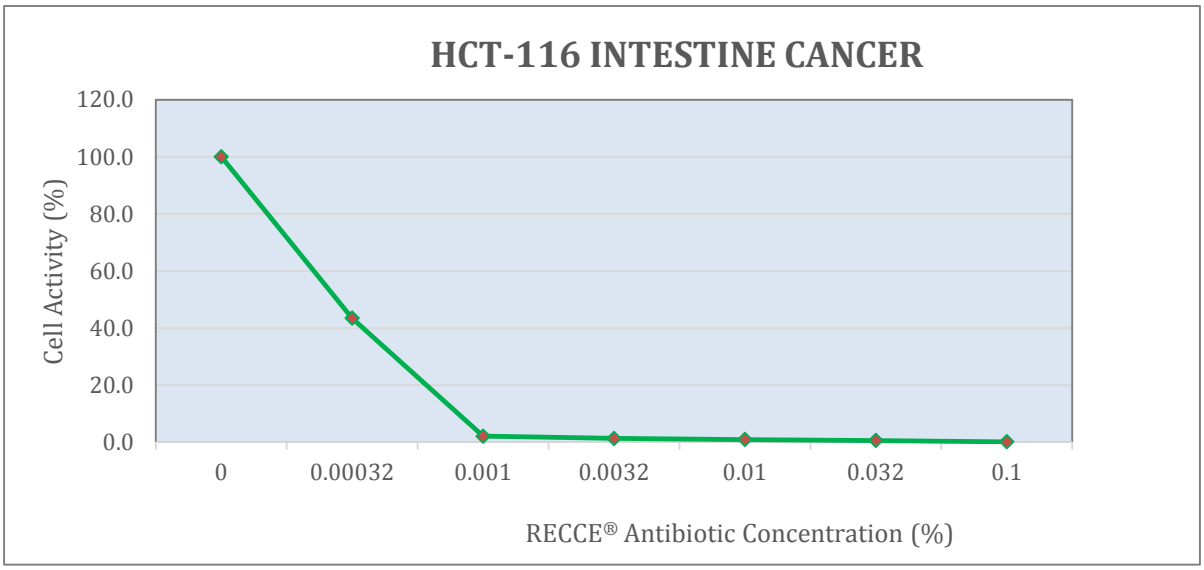
Cancer Type	Cell Line	Tamoxifen Citrate [1] (%)	RECCE® antibiotic (%)
Leukaemia	MOLT-4	0.0001	0.0001
Stomach	SNU-5	0.0005	0.0006
Intestine	HCT116	0.0008	0.0003
Breast	MCF-7	0.0007	0.0005
Prostate	DU-145	0.0008	0.001
Skin Melanoma	SK-MEL-2	0.0006	0.0007
Kidney	TK-10	0.0006	0.0006

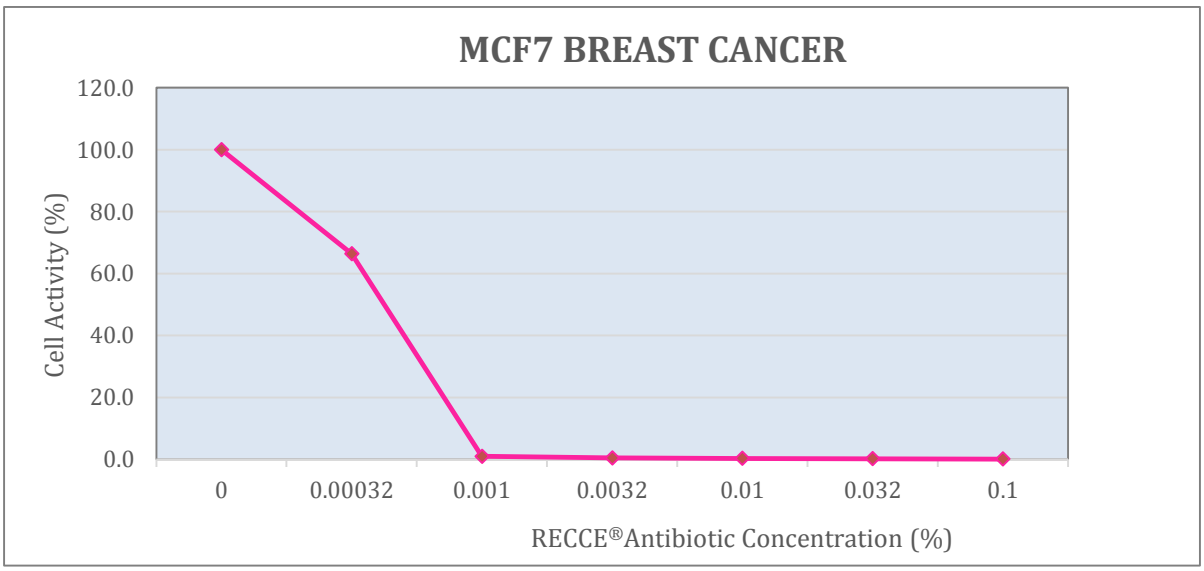
[1] Tamoxifen Citrate is a commercial human anti-cancer drug, used for Control and comparative purposes.

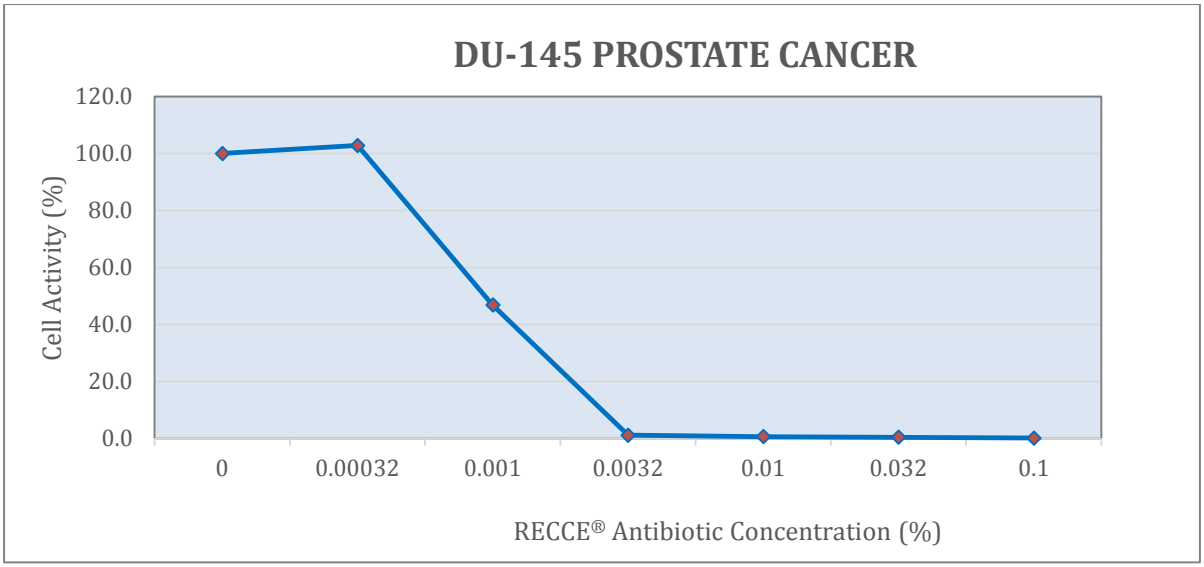
In the following graphs, each illustrates the concentration of RECCE® antibiotic at which the respective cancers are rendered inactive (usually quite suddenly) by gradually increasing, but nevertheless, low concentrations of the antibiotic:

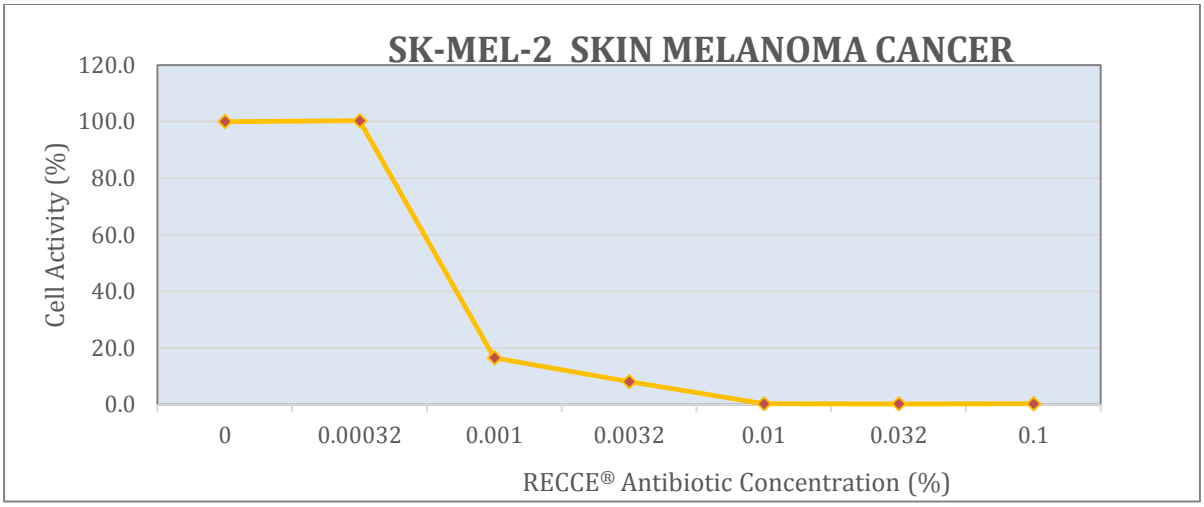


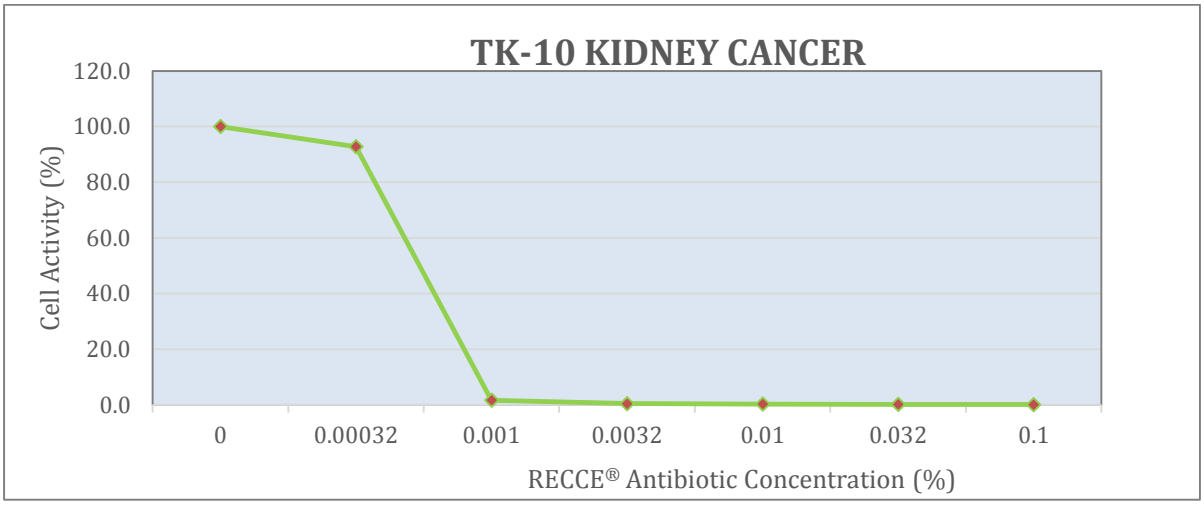

SNU-5 STOMACH CANCER
120.0
100.0
80.0
60.0
40.0
20.0
0.0
Cell Activity (%)
0
0.00032
0.001
0.0032
0.01
0.032
0.1
RECCE® Antibiotic Concentration (%)


HCT-116 INTESTINE CANCER
120.0
100.0
80.0
60.0
40.0
20.0
0.0
Cell Activity (%)
0
0.00032
0.001
0.0032
0.01
0.032
0.1
RECCE® Antibiotic Concentration (%)


MCF7 BREAST CANCER
120.0
100.0
80.0
60.0
40.0
20.0
0.0
Cell Activity (%)
0
0.00032
0.001
0.0032
0.01
0.032
0.1
RECCE®Antibiotic Concentration (%)







Concentrations of RECCE® antibiotic described as successful above were additionally tested, and did not cause toxicity in normal human epithelial cells or Vero (monkey) cells.

At any time, this finding would be considered to be of great potential medical importance – and even more so in this case, because antibiotic activity and anti-cancer activity are found in the same product. This emphasis is made since inflammation from prolonged bacterial activity is increasingly

being associated with the propensity for cancer; the classic example is infection by *Helicobacter pylori* bacteria being strongly associated with inflammation and the subsequent development of cancer in the stomach and duodenum of the upper intestines of humans.

Also, cancers promote a propensity for patients to develop bacterial diseases, potentially treated by RECCE® antibiotics.