Cancer Association of South Africa (CANSA)

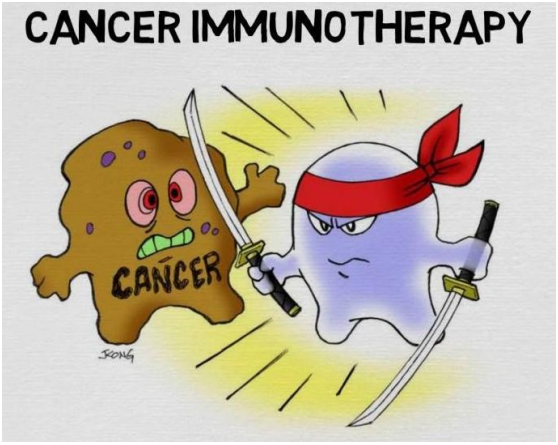
Fact Sheet on Immunotherapy (Nivolumab) now Available in South Africa

Introduction
The Cancer Association of South Africa (CANSA) is not involved in the treatment of Cancer. The Purpose of CANSA is to lead the fight against cancer in South Africa while its Mission is to be the preferred non-profit organisation in South Africa that enables cancer research, educates the public and provides support to all people affected by cancer.

In this vein, CANSA would like to inform the public about the availability of cancer immunotherapy that has now become available in South Africa.

Immunotherapy, also sometimes referred to as biologic therapy, is a type of cancer treatment designed to boost the body's own natural defences to fight the cancer. It uses substances either made by the body or in a laboratory to improve or restore immune system function. Immunotherapy may work in the following ways:

- Stopping or slowing the growth of cancer cells
- Stopping cancer from spreading to other parts of the body
- Helping the immune system work better at destroying cancer cells



[Picture Credit: Cancer Immunotherapy]

There are several types of immunotherapy, including:

- Monoclonal antibodies
- Non-specific immunotherapies
- Oncolytic virus therapy
- T-cell therapy
- Cancer vaccines

Monoclonal antibodies - when the body's immune system detects something harmful, it produces antibodies. Antibodies are proteins that fight infection.

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Monoclonal antibodies are a specific type of therapy made in a laboratory. They may be used in a variety of ways. For example, monoclonal antibodies can be used as a targeted therapy to block an abnormal protein in a cancer cell.

Monoclonal antibodies can also be used as an immunotherapy. For example, some monoclonal antibodies attach to specific proteins on cancer cells. This flags the cells for the body's immune system so it can recognize and destroy those cells.

Other types of antibodies work by releasing the brakes on the immune system so it can destroy the cancer cells. Researchers have identified the PD-1/PD-L1 and CTLA-4 pathways as being critical to the immune system's ability to control cancer growth. These pathways are often called "immune checkpoints." Many cancers use these pathways to evade the body's immune system. Blocking these pathways with specific antibodies called immune checkpoint inhibitors allows the body's immune system to respond to the cancer. Once the immune system is able to recognize and respond to the cancer, it can stop or slow cancer growth.

The following are examples of immune checkpoint inhibitors:

- Ipilimumab (Yervoy)
- Nivolumab (Opdivo) – now available in South Africa
- Pembrolizumab (Keytruda).

Clinical trials of monoclonal antibodies are ongoing for several types of cancers.

The side effects of monoclonal antibody treatment depends on the purpose of the drug. For example, the side effects of monoclonal antibodies used for targeted therapy are different than those used for immunotherapy. The side effects of immune checkpoint inhibitors may include side effects similar to an allergic reaction.
(Cancer.Net).

Nivolumab (Obdivo): Now Available in South Africa
Alternataive names for nivolumab include:

- Anti-PD-1 monoclonal antibody - Medarex/Ono
- BMS-936558
- MDX-1106
- Nivolumab BMS
- ono-0123
- ONO-4538
- Opdivo

Current Highest Development Phases of Nivolumab
Nivolumab is currently marketed for the treatment of:

- Malignant melanoma
- Non-small cell lung cancer
- Renal cell carcinoma

It has been registered for clinical trials for the treatment of:

- Head and neck cancer
- Hodgkin's disease
- Urogenital cancer

It is currently in the preregistration phase for the treatment of:

- Gastric cancer (stomach cancer)

Phase III Clinical Trials are currently ongoing for the treatment of:

- Glioblastoma
- Hepatocellular carcinoma
- Mesothelioma
- Multiple myeloma
- Oesophageal cancer
- Ovarian cancer
- Small cell lung cancer

Phase II Clinical Trials are currently ongoing for the treatment of:

- Acute myeloid leukaemia
- Breast cancer
- Cancer
- Cervical cancer
- Chronic lymphocytic leukaemia
- Diffuse large B cell lymphoma
- Follicular lymphoma
- Lymphoma
- Myelodysplastic syndromes
- Soft tissue sarcoma
- Uterine cancer
- Uveal melanoma

Phase I/II Clinical Trials are currently ongoing for the treatment of:

- Colorectal cancer
- Haematological malignancies
- Non-Hodgkin's lymphoma
- Rectal cancer
- Solid tumours

Phase I Clinical Trials are currently ongoing for:

- Biliary cancer

- Bladder cancer
- Chronic myeloid leukaemia
- Glioma
- Hepatitis C

(Adis Insight).

Side effects of Nivolumab (Opdivo)
The common adverse reactions reported in the clinical trials include:

- skin rash (21%)
- cough (17%)
- upper respiratory tract infection (11%)
- hyperkalaemia (increase in potassium level; 15%)
- hyponatraemia (decrease in sodium level; 25%)
- ALT elevation (liver enzyme; 16%)
- serum creatinine elevation (kidney function; 13%)

More serious adverse reactions include:

- hyperthyroidism
- hypothyroidism (change in thyroid level; 2-8%)
- immune-mediated hepatitis (liver problems; 1.1%)
- immune-mediated gastrointestinal problems (such as pancreatitis or colitis; 1%)
- neuropathy (less than 1%)
- immune-mediated nephritis (renal dysfunction; 0.7%)
- immune-mediated pneumonitis (lung problems; 2.2%)

(Reconsult).

Dosage of Nivolumab (Opdivo)
Opdivo is supplied in either a 40 mg/4 mL single-use vial or a 100 mg/10 mL single-use vial. The recommended dose of Opdivo is 3 mg/kg by intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity.

A single dose of Nivolumab (Opdivo) for a male patient weighing 85kg will be 255mg of Opdivo at a price of ±R372/mg = ±R94 860,00. This dosage is repeated every two weeks.

Opdivo should be stored under refrigeration at 2^{o}C to 8^{o}C and protected from light by storing in the original package until use.
(Reconsult).

The Cost of Nivolumab (Obdivo) Immunotherapy in South Africa
According to the exchange rate of the US$ to the ZAR (South African Rand) on 27 February 2017, the cost of Nivolumab will be approximately 4 000 times the cost of gold. Nivolumab (Obdivo) currently costs about US$28,75/mg (± R372/mg).

According to prices of Nivolumab (Obdivo) currently available on the internet, the cost for the initial 12-week phase of the combination is **about $141,000** (± R1 827 797), and then $12,500 (R162 038) a month for Opdivo alone, totalling **roughly $256,000** (± R3 318 553) if a patient stays on therapy for a year. Subsequent full-year costs of therapy would be **about $150,000** (± R1 944 465) for Opdivo alone.

Medical Disclaimer

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