

## **S.O.T. (Supportive Oligonucleotide Therapy) Overview for Patient**

### **WHAT IS SOT AND HOW DOES IT WORK?**

The RGCC laboratory is located in Greece and has developed a process that enables them to identify the specific gene sequences of different targets such as cancer, Lyme and various viruses.

A patient's blood is sent to RGCC and they identify the main genetic sequence (gene epitope) of the target replication genes. Once they identify the main genetic epitope of the target, they cross reference the gene sequences to an international database of genetics to ensure they have the proper sequences. The SOT only interferes with the target (i.e. cancer cells, Lyme spirochete, EBV virus, etc.) and does not interfere with any other human cells. Once the replication genes (sense strand) are identified, the laboratory creates an anti-copy of these replication genes. This in turn creates an anti-sense therapy, which prevents replication of cancer cells, Lyme spirochetes, EBV virus, etc. After creating the complimentary copy of the replication sequences, they surround this copy with a synthetic messenger RNA so that it can penetrate within the cell wall of the target. Once this mRNA sequence is created, they replicate 500 million up to 1 billion copies of your unique SOT molecules. These molecules are delivered to our clinic where you receive your SOT IV treatment.

Once you receive your SOT molecules, they are at work 24 hours a day, seven days a week for up to six months inhibiting the replication cycle of the target (i.e. cancer, bacteria, virus).

In summary, when the genetic sequence of a particular gene is known to be a causative gene of a particular disease, it is possible to synthesize a strand of nucleic acid (DNA, RNA or a chemical analogue) that will bind to the messenger RNA (MRNA) produced by that gene and effectively turn that gene "off". This is called gene silencing therapy or apoptosis inducing therapy.

### **Are there any contraindications to the SOT THERAPY?**

- Pregnancy or breast feeding
- Radioactive Seeds – not eligible for therapy
- Recent blood transfusion – Please allow a safety period of 120 days
- Recent cytotoxic chemotherapy or radiotherapy - Please allow 2-3 weeks from last dose
- Children under the age of 10 for cancer
- Children under the age of 4 for viral or Lyme

**\*See pre therapy guidelines on page 4 for full list of avoidances pre blood draw and pre administration.**

## **Are there any possible adverse reactions with the SOT THERAPY?**

While SOT is well tolerated, when dealing with living pathogens in a human body there are potential side effects even with a gene silencing therapy like SOT. Some of the common side effects we've seen have been:

- Headaches
- Increased fatigue
- Pain at surgical site (with cancer)
- Flu like symptoms
- TLS syndrome mainly with large volume of the disease.

## **Are there any risks with the SOT THERAPY?**

TLS or Tumor Lysis Syndrome (fever, local edema, accumulation of fluid in the area of the tumor etc.) is a potential risk with SOT. This occurs mainly with large or numerous tumors. If we have a clinical suspicion that a patient may experience TLS, then we intentionally do not offer this therapy. Thus, we do Not anticipate you would have any symptoms associated with TLS (Tumor Lysis Syndrome).

## **What kind of pre-tests are required for the SOT THERAPY for cancer?**

- Cancer: Positive test result confirming presence of CTCs by RGCC. You are able to use any of the RGCC tests that contain a CTC (Example: Oncotrace, Oncotrail, Onconomics Plus)
- Test results must be within six months.

## **What kind of pre-tests are required for the SOT THERAPY for Viral or Lyme?**

- Positive test result confirming presence of targeted pathogen (can be PCR or antibody result)
- Must be within six months
- Must be from a reputable lab

**How many of the SOT THERAPIES can be given in a year?** NOTE: SOTs work for a long time and can accumulate in the body and build up.

- Cancer - Maximum of three (3) to four (4) total in a 12-month period
- Viral or Lyme - Maximum of nine (9) total in a 12-month period
- Viral or Lyme - Maximum of three (3) to four (4) total for the same target in a 12-month period

## **How close together can the SOT THERAPIES be given for multiple targets?**

- For virus or Lyme – there needs to be a minimum of seven (7) days between two different SOTs. It is never recommended to give more than one SOT on the same day.
- For cancer – three to four months apart with a maximum of three (3) or four (4) in a 12-month period.

## Can the SOT be split up?

Yes, the SOT can be given in half doses spaced at least 21 days apart. We have a special freezer just for splitting SOT doses so that more patients can receive this treatment. The practice of splitting SOT doses allows us to optimize the safety profile for patients with more advanced disease states.

## What pre-medications are required for the SOT THERAPY?

**Mandatory:** 4 mg dexamethasone I.V. in a 20-50 ml rapid drip saline solution or slow bolus push in order to counteract the possibility of extravasation of the IV application by **stabilizing the veins** lumen and allowing more normal distribution of the therapy.

## What needs to be avoided before the SOT THERAPY?

- See the full Therapies – Pre and Post Administration Guidelines below

## What needs to be avoided after the SOT THERAPY?

- See the full Therapies – Pre and Post Administration Guidelines below

## What follow up tests are required for the SOT THERAPY?

- For **Cancer:** Oncotrace or Oncotrail are recommended every 3-4 months after the administration of the SOT to evaluate the status of the CTC and the immunophenotype.
- For **Viral or Lyme:** The same test that originally diagnosed the pathogen after 3 to 4 months of the SOT administration to evaluate the status of the pathogen.

## THERAPIES - PRE & POST SOT ADMINISTRATION GUIDELINES

The purpose of these guidelines is to ensure the highest level of effectiveness for each therapy. Adherence to these guidelines will improve therapy effectiveness and patient outcomes.

### 1) For Virus/Lyme (V. Antagonist) SOT:

**Pre-Administration:** The patient must be off ALL antiviral/antibacterial/antiparasitic medications and therapies **14 days** prior to the administration of the therapy.

**Day of Administration:** Absolutely No other therapies are recommended on the day of the SOT injection.

**Post Administration:** All therapies can be resumed **7 days** after the administration to allow the SOT time to locate its target without interference.

### 2) For ALL Cancer Therapies

**Pre-Therapy Administration:** The patient must be off ALL cytotoxic therapies as outlined below.

Reminder: Patient's that have radioactive seeds are not eligible for RGCC therapies.

- **Natural Substances (IV):** cytotoxic substances like Vitamin C or Ozone at least **14 days**.
- **Natural Substances (oral supplements):** cytotoxic substances (per patient's Onconomics Plus results) at least **14 days**.
- **Chemotherapy (non-platinum derivative):** at least **14 days**.
- **Chemotherapy (platinum derivative):** at least **21 days**.
- **Blood Transfusions:** at least **120 days**
- **Radiation:** at least **14 days**.
- **Contrast:** at least **14 days**.
- **Surgery (simple/routine):** at least **7-10 days**.
- **Surgery (brain or extensive):** minimum of **30 days** based on time of recovery. Could be longer if slow recovery or if the person had some type of adverse reaction. Must be evaluated on a case by case basis.
- **Fever:** at least **14 days**.
- **Hyperthermia (local/concentrated/microwave ablation):** at least **30 days** due to increase in cellular debris released into blood stream.
- **Hyperthermia (generalized/systemic):** no waiting.
- **Cryoablation:** no waiting.

**Day of Administration:** Absolutely NO other therapies are recommended on the day of the therapy administration.

**Post Administration:** For **Cancer** all therapies can be resumed **14 days** after the administration