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PATIENT INFORMATION AND CONSENT FORM FOR IMMUNO-ONCOLOGICAL THERAPY

English Translation

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PATIENT INFORMATION AND CONSENT FORM FOR IMMUNO-ONCOLOGICAL THERAPY

Patient's name: .....
TAJ Number (Social Security Number):……..
Place of birth: ..... Date of birth: .....
Current address: .....
Phone: .....
Diagnosis: .....
Name of performing physician: .....

Dear Patient!

For your recovery, your physicians recommend immuno-oncological therapy. This treatment method aims to restore the body's anti-tumor defence capacity against your disease, the lung cancer.

The aim of immuno-oncological therapy:
The goal of immuno-oncological treatment is to restore the body's own anti-tumor immune defence from the state rendered ineffective by tumor cells (lung cancer). The common goal is to stop tumor growth using immuno-oncological agents, e.g. reduce tumor size, or stop tumor growth or achieve an undetectable tumor-free state, or alleviate your symptoms (e.g. pain). The goal is always to provide you with the best possible quality of life as well.

How does immuno-oncological therapy work?
Immuno-oncological therapy does not directly destroy the dividing tumor cells but it mobilizes and activates the body's own immune-active cells involved in immune defence (lymphocytes). The effect of immuno-oncological therapy develops slowly (on average within 2-3 months). Due to the nature of the treatment, it may happen that the tumor size increases in the initial period even when the therapy is successful.

The treatment can be considered effective in any of the following cases: tumor growth stops; the tumor begins to decrease in size; or the tumor disappears entirely. When the treatment is effective, this therapy is generally applied for a longer period. The effect of immuno-oncological treatment can last for a long time. This also applies to the period beyond the administration of the drug.

Possible side effects:
Immuno-oncological therapy modifies the body's immune system, so side effects arise mainly from this. During treatment, severe, very rarely even fatal side effects may occur. Multiple side effects can occur simultaneously. Please contact your treating physician if you experience any side effect. Your treating physician may prescribe additional medications to prevent more severe complications and reduce your symptoms.

- Non-infectious pulmonary inflammation may develop in the lungs, which initial symptoms may include dry cough, shortness of breath, or chest pain.
- Inflammatory disease of the intestinal mucosa may occur, which may present as diarrhoea, abdominal pain, constipation, nausea, and vomiting.
- Inflammatory diseases of the endocrine glands (especially of the thyroid gland) may develop. Symptoms may include rapid heartbeat, weight change, increased sweating or hair loss, chills, constipation, deepening of the voice, muscle pain, dizziness, fainting, persistent or unusual headache.
- Liver inflammation may occur, accompanied by nausea, decreased appetite, abdominal pain, yellowish discoloration of the skin and whites of the eyes, dark-coloured urine, and increased sensitivity.
- Kidney inflammation may occur, which may present with changed colour or amount of urine.
- Type 1 diabetes may develop, which may be accompanied by increased thirst or hunger compared to usual, increased urge to urinate, or weight loss.
- Skin inflammation may occur, which may present as a rash, itching, blistering of the skin, peeling or pitting, and ulceration of the mucous membranes.
- Rarely, other serious side effects may occur, such as eye inflammation, muscle inflammation, myocarditis, or pancreatic inflammation.
- Previously known autoimmune diseases may flare up.
- Reactions related to the infusion may occur, the most common symptoms of which are shortness of breath, itching or rash, dizziness, or fever.

Side effects can develop depending on the medication used and your body's individual reaction. Our physicians do their best to minimize the risk of side effects. Certain medications, e.g. corticosteroids, can be used to prevent and alleviate more severe side effects. If the side effects are too severe, your treating physician may postpone or permanently discontinue the treatment.

Course of treatment:

Your illness can be cured, suppressed, or kept in balance in a significant proportion of cases with appropriate treatment, but the outcome depends on the severity, progression, and numerous unforeseeable complications, which may be due to the underlying disease, but also a consequence of the treatment.

Immuno-oncological therapy drugs are administered intravenously or through a cannula placed in the vein. During treatment, various tests may be ordered to monitor your condition, of which your physicians will inform you in time.

Take care of yourself!

Make it part of your treatment plan to maintain your vitality and general health to the best of your ability. Pay attention to your diet, appropriate exercise, and get enough sleep and rest.

If you have any questions about your condition or treatment, please consult your physician!

Alternative treatments: currently no other equally effective treatment is available.

Possible consequence of not receiving the intervention: progression or worsening of the disease, onset of symptoms.

Consent declaration for immuno-oncological therapy application

In the case of a patient not eligible to make independent decisions, the name of the legal representative making the declaration: .....
Legal capacity qualification: .....
Treating department: .....

I have completely understood the information described and communicated. I have no further questions in connection with the written and verbal information. I have also received information that I can withdraw the present consent at any time during the treatment.

After reading the patient information and the verbal information, I consent to the application of the proposed therapy:

Budapest, 20…….

....
Patient/legal representative Name, signature and stamp of informing physician

I have understood the information described, I refuse the therapy treatment, I do NOT consent to its performance:

…… …….
Patient/legal representative Name, signature and stamp of informing physician

In our presence, as witnesses:

…… ……
Witness 1. Witness 2.

Budapest, 20…….

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