Information for the Patient

We kindly ask you to consent to the use of your blood for the study entitled:
“Comparative efficacy of once-daily LAMA/LABA combinations versus tiotropium on constant-work-rate cycle endurance in COPD: a randomized crossover study”

Study purpose. The aim of the study is to compare the effects of commonly available combined bronchodilator preparations (LABA/uLAMA) with tiotropium (LAMA) on physical exercise capacity in patients with COPD.

Study design. The planned study will be conducted in a group of approximately 100 COPD patients treated at the 2nd Department of Pulmonology, Medical University of Białystok (UMB), and at the Pulmonary Outpatient Clinic of the University Clinical Hospital (USK), as a prospective, open-label, observational study with random allocation of patients to treatment groups in a crossover scheme (alternating assignment of participants to subsequent groups with the study drugs), in a head-to-head formula (direct comparison of drugs against each other on the assessed endpoints and against a common comparator).
The study group will consist of patients qualified for COPD treatment with uLAMA + LABA. The control group will consist of patients treated for COPD with tiotropium.

Treatment will be carried out with four COPD medications available on the market (Anoro Ellipta, Spiriva, Spiolto Respimat, Ultibro). The treatment duration with each drug will be 28 days, followed by a 7-day wash-out period; after that you will be randomly assigned to a new group with the next drug. The procedure will be repeated so that you have a chance to be treated with each of the drugs.

Assessments. During screening/qualification and after each 28-day treatment period, the following tests will be performed:

1. General assessments o Blood pressure measurement o Anthropometric measurements:	2. Exercise capacity assessments o Spirometry with bronchodilator reversibility testing

height, body weight, BMI o St. George's Respiratory Questionnaire (SGRQ) o COPD Assessment Test (CAT) o mMRC dyspnoea scale o BODE index o Body composition analysis o DASI, VSAQ questionnaires	o Cardiopulmonary exercise testing (CPET) on a cycle ergometer 3. Laboratory tests o Venous blood sampling to determine myostatin concentration in plasma

The tests will be carried out at the 2nd Department of Pulmonology, Medical University of Białystok and are part of the routine evaluation of every patient with COPD. In addition, an exercise test on a cycle ergometer will be performed. This test allows assessment of exercise capacity and the potential for improvement of respiratory function as a result of the applied treatment. When performed correctly, the exercise test involves placing a mask connected to a measurement set and performing the assigned physical effort (cycling on a stationary bicycle). Before the test, an appropriately fitting mask must be selected to ensure a good seal during the procedure. The test is conducted until you decide to stop. When you show the agreed stop signal or discontinue the effort, the load is reduced to the baseline level and the device records 3 minutes of recovery.

The medications used during the study will be provided to you free of charge as part of the study.

Białystok, on: ……

Signature of the investigator: …….

Annex No. 1 to the Personal Data Protection Rules for Research at the Medical University of Białystok

Information clause for participants in studies conducted at the Medical University of Białystok

Pursuant to Article 13 of the General Data Protection Regulation of 27 April 2016 (OJ L 119 of 04.05.2016), I inform you that:

1. The Data Controller is the Medical University of Białystok, ul. Kilińskiego 1, 15-089 Białystok, represented by the Rector.
2. Contact for the Data Protection Officer at the Medical University of Białystok: iod@umb.edu.pl.
3. Your personal data will be processed for the purpose of conducting the study measuring the myostatin level.
4. Your personal data may be disclosed only to persons authorized by the Controller to process personal data, to processors under a data processing agreement, and to other entities authorized under the law.
5. Your personal data will be stored only for the period necessary to conduct the research.
6. You have the right to access your data, the right to rectification, erasure, restriction of processing, data portability, and the right to object.
7. You have the right to withdraw consent to the processing of personal data at any time.
8. You have the right to lodge a complaint with the President of the Personal Data Protection Office if you believe that your personal data are processed by the Controller in a manner inconsistent with the GDPR.
9. Providing personal data is voluntary, but necessary to participate in the study.

Date and legible signature of the study participant: ……

Informed Consent Form

Project title:
Comparative efficacy of once-daily LAMA/LABA combinations versus tiotropium on constant-work-rate cycle endurance in COPD: a randomized crossover study

Patient’s first and last name: .....

I declare that, after becoming acquainted with the information on the purpose and nature of the study and after receiving answers to all my questions, I give my full, informed and voluntary consent to participate in the proposed study.

I also consent to the publication of the results obtained in scientific journal(s), subject to the anonymization of my personal data, in accordance with the Personal Data Protection Act of 10.05.2018.

I am aware of my right to withdraw from the study at any stage, without giving a reason. I also understand that exercising this right will not affect my further treatment. I have received the Patient Information Sheet and the Informed Consent Form for participation in the study.

Date: ..... Patient’s signature: ….....

Name, surname and signature of the person obtaining consent: .....
Date: .....

Note on consistency

In the GDPR information clause, point 3 names a different project (on iPSCs in COPD). If that is a placeholder, you may want to replace it with the actual COPD pharmacotherapy study title for consistency across documents.