✱CURRICULUM VITAE✱

MENELAOS FOLLIDIS
MPharm, PharmD, MICR, ACRP Member

SENIOR CLINICAL RESEARCH ASSOCIATE II

EDUCATION

PhD, Pharmaceutical Technology/Biopharmaceutics-Pharmacokinetics & Pre-clinical Drug Development, 1995

Laboratory of Biopharmaceutics-Pharmacokinetics, Department of Pharmaceutical Technology, Faculty of Pharmacy, "IULIU HATIEGANU" University of Medicine & Pharmacy, Cluj-Napoca, Romania

MSc, Pharmaceutical Sciences (Joint Bachelor and MSc), 1985

Faculty of Pharmacy, Institute of Medicine & Pharmacy, CIuj-Napoca, Romania.

THERAPEUTIC EXPERIENCE

Circulatory System: Heart Failure, Acute Pulmonary Embolism
Digestive System: Peptic Ulcer, GERD
Endocrine/Metabolic Disorders: Diabetes Mellitus Type II, Mixed Dyslipidemia
Infections/Parasitic Diseases: RSV Disease, RSV Prophylaxis, Chronic Hepatitis B
Mental Disorders: Dementia of Alzheimer Type
Musculoskeletal System: Rheumatoid Arthritis, Osteoarthritis
Nervous System/Sense Organs: Open Angle Glaucoma, Posterior & Anterior Chamber Uveitis,
Refractory Partial Seizures
Oncology/Hematology: NSCLC, Hormone-refractory Prostate Cancer, Bone Metastases, Melanoma, Glioblastoma, Multiple Myeloma (MM), Relapsed Chronic Lymphocytic Leukemia (CLL), Von Willebrand Disease (VWD)
Respiratory System: Allergic Bronchial Asthma, Allergic Rhinitis, Nosocomial Pneumonia, Bronchopulmonary Dysplasia, Severe Persistent Asthma, Asthma Control
Transplantation: Kidney Transplantation/Clinical Immunology-Rejection in End-Stage Renal Failure
Dermatology: Prevention of UV-induced Infections & Carcinogenic Skin Alterations

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PROFESSIONAL EXPERIENCE

PharmaSense®, Aghia Paraskevi, Greece ***SCRA II*** ***08/2009-up to date***

COM (Clinical Oversight Manager): Clinical Oversight Manager in an International Open-Label, PMS Phase IV Study in Subjects with Von Willebrand Disease. Feasibility, study start up activities, local & central submissions, site management activities performed.

SCRAII: Senior Clinical Research Associate in an International Comparative Study briefly entitled "A European, observational, three-year cohort comparative study on the safety of the fixed-dose combination pravastatin 40 mg/fenofibrate 160 mg (XXX®) versus statin alone in real clinical practice" (The "POSE" Study) (**Non-interventional Observational Study**). Feasibility, study start up activities, local and central institutional submissions, site management and monitoring activities performed.

SCRAII: Senior Clinical Research Associate in an International EU-funded Investigator-initiated phase III trial in Very Preterm Infants at Risk for Bronchopulmonary Dysplasia. Feasibility, study start up activities, local & central submissions, site management activities performed.

SCRAII: Senior Clinical Research Associate in a prospective, multicenter, randomized, double-blind, placebo-controlled, 2-parallel group, relapsing multiple myeloma Phase III study. Feasibility, study start up activities, and site management activities performed.

SCRAII: Senior Clinical Research Associate in a prospective, multi-centre randomised, double-blind, placebo-controlled, 2-parallel groups, Severe Persistent Asthma Phase III study. Feasibility, study start up activities, and site management activities performed.

SCRAII: Senior Clinical Research Associate in a prospective, multi-center randomized, open-label, active-controlled, two-parallel groups, unresectable or metastatic stage 3 or stage 4 melanoma phase III study. Feasibility, study start up activities, local submissions, and site management activities performed.

SCRAII: Senior Clinical Research Associate in a prospective, randomized, double-blind, placebo-controlled, international, multi-center, parallel-group comparison trial in acute pulmonary embolism with echographic (or spiral CT) and laboratory evidence of right ventricular dysfunction. Site management and monitoring activities performed.

SCRAII: Senior Clinical Research Associate in an InternationaL cross-sectIonAl and longItudinal assessment on aSthma cONtrol (The "LIAISON" Study) (**Non-interventional Observational Study**). Feasibility, study start up activities, local and central institutional submissions, site management and monitoring activities performed.

SCRAII: Senior Clinical Research Associate in an open, multi-center, randomized, inter-individual comparative, prospective clinical trial in immunosuppressed outpatients after solid organ transplantations for the prevention of UV-induced infections and carcinogenic skin alterations. Site management and monitoring activities performed.

Blinded SCRAII & Unblinded Pharmacist SCRAII: Blinded & subsequently Unblinded Senior Clinical Research Associate in an International, Randomized, Double-Blind, Newly Diagnosed, Surgically Resected, EGFRvIII-positive Glioblastoma Controlled Study (The "ACT IV" Study). Feasibility, study start up activities, local & central submissions, site management activities performed.

SCRAII: Senior Clinical Research Associate in a Multicentre, Open-label, Recently Diagnosed Multiple Myeloma Phase Ib/II Clinical Trial. Feasibility, study start up activities, local & central submissions, site management activities performed.

LES (SCRAII): Local Enrollment Specialist in a Randomized, Double-Blind, Multicenter, Previously Untreated Advanced or Metastatic Squamous Non-Small Cell Lung Cancer (NSCLC) Phase III Study. Study start up activities, site management activities performed.

Coordinating Network (CN) SCRAII: Senior Clinical Research Associate in a Long-Term experience study with XXX Study Drug SC in routine clinical practice (The "ASCORE" Study). (**Non-interventional Observational Study**). Feasibility, study start up activities, and site management activities performed.

PPD Global Ltd, Athens Branch, Greece *SCRA I* *03/2007-08/2009*

SCRAI: Senior Clinical Research Associate in a global phase Ill Refractory Partial Seizures trial. Feasibility and study start up activities performed.

SCRAI: Senior Clinical Research Associate in a global phase II/Ill Relapsed Chronic Lymphocytic Leukaemia trial. Feasibility and study start up activities performed.

SCRAI: Senior Clinical Research Associate in a global phase IIIb 12 active Rheumatoid Arthritis trial. Feasibility and study start up activities performed.

SCRAI: Senior Clinical Research Associate in a global phase Ill prophylaxis on reduction of the incidence of serious early childhood wheezing in preterm Infants trial. Feasibility and study start up activities performed.

SCRAI: Senior Clinical Research Associate in a global phase Ill Chronic Hepatitis B in Adolescents trial. Feasibility and study start up activities performed.

SCRAI: Senior Clinical Research Associate in a global phase Ill Hormone-refractory Prostate Cancer trial. Monitoring and study start up activities performed.

Antaea Medical Services Ltd, Athens, Greece *Senior CRA* *2004-2007*

Participated in the conduction of clinical trials; review of project-related materials and critical documents for submission to regulatory departments; participation in investigator meetings; investigator recruitment; development and maintenance of Study Master Files; site visits for selection$_1$ monitoring, and close-out in accordance to international and local regulations; CRE review and source documentation to ensure adherence to protocol and regulations; resolution of CRF discrepancies and/or clarifications; drug accountability and assurance of prompt AE/SAE reporting

Interamerican Group, Athens, Greece *Insurance & Financial Advisor* *2003-2004*

Main activities included performing feasibility surveys in focused target groups; Specialized in Health Insurance Programs, including MEDISYSTEM, Life & Pension Insurance Programs, Investments-Savings, Home, Motor & Property Insurance Programs, Income Protection Programs, Legal Protection, Third-Party Liability, including Pharmaceutical, Medical & Health Care Professional Liability & Indemnity Programs. All activities were performed as a Trainee Insurance Associate & following a successful State examinations pass, as an Insurance & Financial Advisor at Interamerican's "Heliopolis" Branch (A Member of EURECO B.V. Group).

Technical Translation & Interpretation Associate, Athens Greece *1998-to date*

Supervisor of a group of 7 assistants for translation services in the medical, chemical, pharmaceutical, biological, and biochemical areas; review, approval, proofreading and DIP finalization of translation projects at several Translation, Interpretation, and Consultancy Companies. Technical Patent and Law Literature, Clinical Protocol Literature and Drug Expert Reports translation expert for pharmaceuticals.

Alfamedica, Ltd, Athens Greece *Pharmacist & Product Manager* *2001-2002*

As a Pharmacist-in-charge person and Registered Pharmacist the main responsibilities included officially accounting for, and according to Local Laws, Drug and Medical Devices distribution activities to hospitals and various medical institutions. As Product Manager, responsibilities included marketing and promotional activities for the portfolio of ALFAMEDICA's products, (e.g. Allergen preparations, vaccines for immunization from Hall Allergy NV) and for medical devices (eg. nebulizers from PARI GmbH).

CRA-Freelancer, Athens Greece *2001-2001*

Main activities included performing feasibility surveys; Site and Principal Investigator selection; submissions to EC/IRB and Regulatory Authorities of application files for the conduct of phase IV Clinical Trials; monitoring activities of phase IV Clinical Trials from various Hellenic Pharmaceutical Companies; protocol and protocol amendments, ICF's, SPC's, PIL's translations; IP label preparation and design.

Quintiles GmbH, Athens Greece **CRA** ***2000-2000***

Main activities included EC/IRB and Regulatory Authority submission of an application file for a multinational 1DM II Clinical Trial.

Vianex SA, Athens Greece ***CRA & Pharmacovigilance Officer*** ***1998-2000***

Main activities included CRA monitoring activities for several clinical trials conducted in Greece, sponsored by pharmaceutical companies represented by VIANEX SA (e.g., Searle/Monsanto Group, Fujisawa Japan, Takeda Japan, KnoII/BASF GmbH); participated as back-up Pharmacovigilance Officer for EOF and Complaints Quality Control Assistance responsible for accounting for products marketed by Vianex SA.

Medicus SA, Athens Greece ***Sales & Marketing Manager*** ***1997-1997***

Main activities included sales and marketing management activities for diagnostic (e.g., diagnostic detection kits for *Helicobacter pylori, HIV)* and OTC products.

Help SA, Athens Greece ***Business Unit Manager for Export Operations*** ***1997-1997***

Main activities included sales and marketing activities and collaborating with the Export Sales Department especially for Romanian and Moldavian Market.

UCB Pharma Greece SA, Athens Greece ***Sales Force Associate & Product Specialist 1991-1997***

Main activities included scientific promotion activities for all (JCB Pharma's portfolio products (Nootrop, Atarax, Zyrtek, Tuclase, Pulmoclase, Lyso-6, etc.) for Physicians and Pharmacists; Product Specialist for Somatostatin/Bioproducts SA, for Gastroenterologists.

Elpen SA, Athens Greece ***Sales Force Associate*** ***1991-1991***

Main activities included scientific promotion of Cardiology and Gastroenterology products to Physicians and Pharmacists.

P. & D. Marinopoulos Drugstore, Athens Greece ***Galenic Laboratory Manager 1988-1991***

Main activities included management and supervision of staff preparing drugs and recipes for the public; preparing of compositions for mid-scale production through FAMAR SA Industrial Pharmaceutical Plant.

LICENSES & CERTIFICATIONS

License to practice a Pharmaceutical Profession (Ministry of Health, Central Health Council ["KESY"]) [**No2854/14.10.1988-Validation date: 14.04.1989**].

License to practice an Insurance Advisor Profession (Ministry of Development, Technical Education & Examination Committee for Intermediaries in Insurance Certificate) [**Examination Date: 28.06.2003, Certification Date: 08.09.2003].**

PROFESSIONAL DEVELOPMENT

Completed PPD CRA Foundation Course, Morrisville, USA 18th – 27th April, 2007
Further training while employed with PPD is available on request

Prior to PPD:

Training received for a XXX-contracted YYY-sponsored Clinical Trial on Haemodynamics and Interventional Cardiology Cardiac Insufficiency Therapeutic Field, (as an employee of Antaea Medical Services Ltd)

Training received for a XXX-contracted YYY-sponsored Clinical Trial on InForm Platform EDC & UMT build on a ZZZ-contracted Vendor (e-CRF), (as an employee of Antaea Medical Services Ltd)

Training received for a XXX-contracted YVY-sponsored Clinical Trial on an EDO Datalabs Platform build for a ZZZ-contracted Vendor (e-CRF), (as an employee of Antaea Medical Services Ltd)

Training received for a XXX-contracted YYY-sponsored Clinical Trial on Ophthalmology Posterior & Anterior Uveitis and Implantable Devices Treatment Therapeutic Field, (as an employee of Antaea Medical Services Ltd)

Training received for a XXX-contracted YVY-sponsored Clinical Trial on Multiple Myeloma Therapeutic Field, (as an employee of Antaea Medical Services Ltd)

Training received for a XXX-contracted YVY-sponsored Clinical Trial on the Management of NSCLC into

Clinical Oncology/Pulmonology Therapeutic Field, (as an employee of Antaea Medical Services Ltd)

Training received for a XXX-contracted YYY-sponsored Clinical Trial on the Management of Hospitalized Pneumonia caused by MRSA pathogens Therapeutic Field, (as an employee of Antaea Medical Services Ltd)

Training received on the use and functions of state-of-the-art Nebulizers, made by the XXX Company, (as an employee of Alfamedica SA)

Training received on the management of allergenic products and immuno-sensitization techniques, made by the XXX Company, for the management of Allergic Rhinitis & Bronchial Asthma Patients (as an employee of Alfamedica SA)

Training received for an YYY-sponsored Clinical Trial on basic Clinical Immunology/Rheumatology Therapeutic Field dealing with the management of RA and OA, (as an employee of Vlanex Pharmaceuticals Manufacturers SA)

Training received for an YYY-sponsored Clinical Trial on basic Clinical Immunology/Transplantation Therapeutic Field dealing with the rejection of the transplants, (as an employee of Vlanex Pharmaceuticals Manufacturers SA)

"Time & Stress Management", Exact Consulting & Training Center, Athens, Greece, 18-19 July, 2005

"The Pharmaceutical Clinical Research in Greece", Hellenic Society of Pharmaceutical Medicine and the Pan-Hellenic Pharmacist Association, Athens, Greece, May 2004.

"Clinical Pharmacy into Hellenic Actuality", Pan-Hellenic Pharmacist Association, Athens, Greece, February 2004.

"Biodisponibility of Pharmaceutical Products", Society of Pharmaceutical Technology of Greece and 441 Military Pharmaceutical Laboratories, Athens, Greece, May 1995.

"Drug: Pharmacokinetics, Laboratory Exploration and Clinical Practice" Hellenic Society of Medicinal Chemistry - Clinical Biochemistry, Athens, Greece, May 1995.

PROFESSIONAL AFFILIATIONS

International Correspondent of the Clinical Research Focus *(CRfocus) (Edited by the Institute of Clinical Research)* magazine for Greece (22 Aug 2005 and up to date)

Hellenic Society for Terminology **(ELETO)**
Scientific Society of Health Services Management (**EEMYY**)
Pan-Hellenic Association of Pharmacists (**PEP**)
Hellenic Pharmaceutical Society (**EFE**)
Hellenic Scientific Society of Pharmacoeconomics (**EEEF**)
Greek Pharmaceutical Technology Association (**EFTE**) (inactive)
Pan-Hellenic Association of Hospital Pharmacists (**PEFNI**) (inactive)
Hellenic Scientific Society of Phytotherapy and Aromatotherapy (**EEEFA**) (inactive)
Hellenic Society of Pharmaceutical Medicine, [former Member of the 2008-2011 Management Board] (**ELEFI**)
Greek Pharmaceutical Marketing Association (**GPMA**)
Pan-Hellenic Association of High Level Educational Institution Graduates of Romania (**PA.S.A.RO**)
The Institute of Clinical Research (**formerly AcRPI**): (England, UK). (Professional Member-Abroad, MICR, since 19 Oct 2005, initial member since 1998))
Drug Information Association (**DIA**) (USA) (member since 1998)
Center Watch Inc. (USA)
Association of Clinical Research Professionals (**ACRP**), (Belgium, Europe) (member since 1998)
Society of Clinical Research Associates (**SoCRA**) (USA) (member since Nov 2005)
European Forum on Good Clinical Practice (**EFGCP**) (EU) (member since 2006)

PUBLICATIONS AND PRESENTATIONS

Publications:

1. Prodruguri de Metronidazol (Metronidazole Prodrugs), Menelaos Follidis, Graduate Diploma Dissertation for a MSc Thesis, Catedra de Chimie Farmaceutica, Facultatea de Farmacie, Institutul de Medicina si Farmacie (Department of Pharmaceutical Chemistry, Faculty of Pharmacy, Institute of Medicine & Pharmacy), Cluj-Napoca, Romania, Oct 1985 *[Book)*

2. Sisteme farmaceutice de uz oral cu oxprenolol cu cedare controlata (Controlled release oral oxprenolol pharmaceutical systems), Menelaos Follidis, PhD Thesis, Laboratorul de Biofarmacie si Farmacocinetica, Catedra de Tehnologie Farmaceutica, Facultatea de Farmacie, Universitatea de Medicina si Farmacie "Iuliu Hatieganu" (Biopharmaceutics & Pharmacokinetics Laboratory, Department of Pharmaceutical Technology, Faculty of Pharmacy, Iuliu Hatieganu University of Medicine & Pharmacy) Cluj-Napoca, Romania, Oct 1994 *[Book]*

3. Oral Controlled-Release dosage forms with oxprenolol: Hydrophilic matrix and floating tablets. M Follidis, SE Leucuta, Department of Biopharmaceutics and Pharmacokinetics, Faculty of Pharmacy, Institute of Medicine & Pharmacy, 41 Victor Babes street, 3400 Cluj-Napoca, Romania. Proceedings of the 10th

International Conference on Pharmaceutical Technology, Bologna, Italy 16-18 April 1991 (Sponsored by Colorcon Ltd, UK and Solid Dosage Research Unit) Vol 1, Part I, pp 52-65 1991(Full *Paper]*

4. Oral megaloporous system containing oxprenolol microspheres, in vitro release kinetics and pharmacokinetics in man, M Follidis, SE Leucuta, Department of Pharmaceutical Technology and Biopharmaceutics, Faculty of Pharmacy, Institute of Medicine & Pharmacy, 41 Victor Babes street, 3400 Cluj-Napoca, Romania. Proceedings of the 6th International Conference on Pharmaceutical Technology Paris, France (Association de Pharmacie Galenique Industrielle, apGI) 2-4 June 1992 (Paper presented on 2 June 1992 afternoon pp 73-80) *[Full Paper]*

5. Studii biofarmaceutice asupra unor sistem experimentale de uz oral cu cedare controlata a oxprenololului: comprimate cu matrita hidrofila, flotabila sau macroporoasa si capsule cu microsfere bioadezive. SE Leucuta, R Capalneanu, M Follidis, A Mocan, Laboratorul de Biofarmacie: si Farmacocinetica, Catedra de Tehnologie Farmaceutica, Facultatea de Farmacie,(IMF Cluj-Napoca l.ISP). Al 3-lea Simpozion de Biofarmacie si Farmacocinetica Cluj-Napoca 1990 (Rezumatele Lucrarilor) pp 1, Litografia IMF Cluj-Napoca, Romania *[Abstract]*

6. Relative bioavailability of different oral sustained release oxprenolol tablets. Leucuta SE, Follidis M, Capalneanu R, Mocan A. Biopharmaceutics & Pharmacokinetics Laboratory, Department of Pharmaceutical Technology, Faculty of Pharmacy, luliu Hatieganu University of Medicine & Pharmacy, Eur J Drug Metab Pharmacokinet 1998 Apr-Jun 23 (2) PP 178-84 *[Full Paper]*

7. Προφάρμακα: Μια πρώτη προσέγγιση (Prodrugs: A first approach). Μενέλαος Φωλλίδης, Φαρμακοποιός. ΤΟ ΠΕΡΙΣΚΟΠΙΟ ΤΗΣ ΕΠΙΣΤΗΜΗΣ Μάιος 1990, 129 pp 51-59 *[Full Paper]*

Presentations:

1. Oral Controlled-Release dosage forms with oxprenolol: Hydrophilic matrix and floating tablets. M Follidis, SE Leucuta, Department of Biopharmaceutics and Pharmacokinetics, Faculty of Pharmacy, Institute of Medicine & Pharmacy, 41 Victor Babes street, 3400 CIuj-Napoca, Romania. Oral presentation on 10th International Conference on Pharmaceutical Technology, Bologna, Italy 16-18 April 1991 (Sponsored by Colorcon Ltd, UK and Solid Dosage Research Unit)

2. Oral megaloporous system containing oxprenolol microspheres, in vitro release kinetics and pharmacokinetics in man. M Follidis, SE Leucuta, Department of Pharmaceutical Technology and Biopharmaceutics, Faculty of Pharmacy, Institute of Medicine & Pharmacy, 41 Victor Babes street, 3400 Cluj-Napoca, Romania. Oral presentation on 6th International Conference on Pharmaceutical Technology Paris, France (Association de Pharmacie Galenique lndustrielle, apGl) 2-4 June 1992 (presented on 2 June 1992 afternoon)

3.Noi sisteme farmaceutice cu cedare modificata a oxprenololului. SE Leucuta, M Folidis. Laboratorul de Biofarmacie si Farmacocinetica, Catedra de Tehnologie Farmaceutica, Facultatea de Farmacie, IMF, Simpozion: Stiinta Medicala Clujeana in Contextul Universal, Comisia de Stiinte Medicale 27 Oct 1993. Zilele Academice Clujene, Academia Romana, Filiala Cluj-Napoca, Romania, 25-30 Oct 1993, Program pp 23

4. Relative bioavailability of different oral sustained release oxprenolol tablets. Leucuta SE, Follidis M, Capalneanu R, Mocan A. University of Medicine and Pharmacy, Faculty of Pharmacy, 3400 Cluj-Napoca, Romania. 6th European Congress of Biopharmaceutics and Pharmacokinetics, Athens, Greece, 22-24 April 1996

COMPUTER EXPERIENCE

Microsoft Word, Excel, Power Point, Access, Microsoft Office 2003/2010, and Windows XP Professional SP3/Windows 7, Advanced Computer Training [ACT] Ltd.)

Experienced in LANs (Windows XP Professional-Windows 98 SE Plus 2-PC LAN, ISDN2, ADSL II 24 Mbps, Home/Office-Based, and Internet Provider: Hellas on Line)

LANGUAGES

Mother tongue: **Greek**, Proficient in English & Romanian languages.

CLINICAL TRIAL EXPERIENCE

Circulatory System: A phase II study to assess the hemodynamic effects of XXX in patients hospitalized with worsening **heart failure** and a reduced left ventricular systolic function.

Circulatory System: A prospective, randomized, double-blind, placebo-controlled, international, multicenter, parallel-group comparison trial evaluating the efficacy and safety of single i.v. bolus XXX as compared with standard treatment in normotensive patients with **acute pulmonary embolism** and with echographic (or spiral CT) and laboratory evidence of right ventricular dysfunction"

Digestive System: 1 local/National (GR) Gastroenterology (**peptic ulcer**)/**GERD** study: Local, Post-Marketing Surveillance (PMS), national, open-label study with XXX (XXXX Brand Name, XXXXX Company)

Endocrine/Metabolic Disorders: Multinational Diabetology/DM II study: MRCT with XXX to patients with **Diabetes Mellitus II** (IRB/IEC Regulatory Approval, and National Authority Regulatory Approval aspects & issues)

✱CURRICULUM VITAE✱

Endocrine/Metabolic Disorders: A European, observational, three-year cohort comparative study on the safety of the fixed-dose combination pravastatin 40 mg/fenofibrate 160 mg (XXX Brand Name, XXXX Company) versus statin alone in real clinical practice. (**The "POSE" Study: XXX® Observational Study in Europe**) (**Non-interventional Observational Study**). An Obeservational Study in **Mixed Dyslipidemia** with a fixed combination of a Statin and a Fibrate.

Infections/Parasitic Diseases: A pivotal phase III study of XXX, an enhanced potency humanized Respiratory Syncytial Virus (RSV) monoclonal antibody, for the prophylaxis of serious **RSV disease** in high-risk children.

Infections/Parasitic Diseases: A phase III, randomized, double blind, placebo-controlled trial of the effect of XXX prophylaxis on reduction of the incidence of serious **early childhood wheezing** in preterm infants

Infections/Parasitic Diseases: A randomized, open-label study evaluating the antiviral efficacy, safety, and tolerability of XXX versus YYY in **Chronic Hepatitis B**-infected adolescents

Mental Disorders: A phase lll multi-centre, double-blind, double-dummy, randomized, placebo-controlled (without basic anti-dementia treatment), parallel group comparison, investigating two doses of XXX in patients with mild to moderate **DAT** during a 6 month treatment period. Possibly, a well-introduced AchE-Inhibitor will be used in a fourth treatment arm.

Musculoskeletal System: Multinational Rheumatology/OA study: New Cox-2, specific NSAID compound (XXX, XXXXX Company) in patients with **OA**, phase lllb, MRCT study

Musculoskeletal System: 3 Multinational Rheumatology/RA studies: Multinational, multi-centre double-blind studies in **RA** with a novel monoclonal antibody compound, (XXX, XXXXX Company).

Musculoskeletal System: A phase IIIb, multi-centre study with a 12-week double-blind placebo-controlled randomized period, followed by an open-label extension phase to evaluate the safety and efficacy of XXX administered to patients with active **rheumatoid arthritis**.

Musculoskeletal System: Long-Term experience with XXX SC in routine clinical practice (**The "ASCORE" Study**) (**Non-interventional Observational Study**).

Nervous System/Sense Organs: A double-blind, placebo-controlled, dose-escalation, parallel-group study to evaluate the efficacy and safety of XXX given as adjunctive therapy in subjects with **Refractory Partial Seizures**.

Nervous System/Sense Organs: An 8-week multi-centre, masked, randomized trial (with an 18-week masked extension) to assess the safety and efficacy of XXX posterior segment drug delivery system applicator system compared with sham DEX PS DDS applicator system in the treatment of non-infectious ocular inflammation of the posterior segment in patients with **intermediate Uveitis**.

Nervous System/Sense Organs: An 6-week multi-centre, masked, randomized trial (with an 20-week masked extension) to assess the safety and efficacy of XXX posterior segment drug delivery system applicator system compared with sham DEX PS DDS applicator system in the treatment of non-infectious ocular inflammation of the anterior segment in patients with **anterior Uveitis**.

Nervous System/Sense Organs: The efficacy and safety of XXX 0.5% compared to YYY 1% each given twice daily when added to ZZZ 0.004% given each evening in primary **Open-Angle Glaucoma** or Ocular Hypertensive patients.

Oncology: A phase Ill trial of XXX in patients with locally advanced or metastatic (Stage Ill or IV) **non-small cell lung cancer** who have been previously treated with chemotherapy

Oncology: A randomized double-blind, multi-centre study of XXX compared with YYY in the treatment of bone metastases in men with **hormone-refractory prostate cancer**

Oncology: Randomized, two-arm study to compare the efficacy of IV loading doses followed by maintenance treatment with XXX acid versus YYY in patients with **skeletal metastases** experiencing moderate to severe pain.

Oncology: A prospective, multicenter, randomized, open-label, active-controlled, two-parallel groups, phase III study to compare the efficacy and safety of XXX at 7.5 mg/kg/day to YYY in the treatment of patients with unresectable or metastatic stage 3 or stage 4 **melanoma** carrying a mutation in the juxta membrane domain of c-kit

Oncology: An International, Randomized, Double-Blind, Controlled Study of XXX/YYY with Adjuvant ZZZ in Patients with Newly Diagnosed, Surgically Resected, EGFRvIII-positive **Glioblastoma** (**The "ACT IV" Study**)

Oncology: Randomized, Double-Blind, Multicenter, Phase III Study Comparing XXX Plus YYY and ZZZ versus Placebo Plus YYY and ZZZ in Previously Untreated Advanced or **Metastatic Squamous Non-Small Cell Lung Cancer** (NSCLC)

Oncology/Hematology: A phase III, multi-center, randomized, double-blind, double-dummy, placebo-controlled study to determine the efficacy and safety of XXX in newly diagnosed **Multiple Myeloma** subjects

treated with YYY and ZZZ and who are 65 years old or older

Oncology/Hematology: A prospective, multicenter, randomized, double-blind, placebo-controlled, 2-parallel group, phase III study to compare efficacy and safety of XXX 6 mg/kg/day in combination with YYY and ZZZ to placebo in combination with YYY and ZZZ in the treatment of patients with **relapsing multiple myeloma** who received one previous therapy

Oncology/Hematology: A randomized, open-label, multi-center, phase II/III study to evaluate the safety and efficacy of study drug in combination with drug regimen, and drug regimen alone in subjects with **Relapsed Chronic Lymphocytic Leukemia**

Oncology/Hematology: Multicentre, Open-label, Phase Ib/II Clinical Trial of XXX, YYY, and ZZZ, in Patients Not Suitable for Transplant, Recently Diagnosed with **Multiple Myeloma**

Hematology: An Open-Label, Multi-Center Post-Marketing Study to Assess the Efficacy and Safety of XXX (brand name) in Subjects with **Von Willebrand Disease**.

Respiratory System: Post Marketing Surveillance (PMS), open-label, observational study with allergenic *per os* (oral drops), XXX preparations (XXXXX Company) to patients with **Allergic Bronchial Asthma**

Respiratory System: Clinical Immunology/Allergology study: Post Marketing Surveillance (PMS), open-label, observational study with allergenic *per os* (oral drops), XXX preparations (XXXXX Company) to patients with **allergic rhinitis**

Respiratory System: Study drug in the treatment of subjects with **Nosocomial Pneumonia** proven to be due to Methicillin-Resistant Staphylococcus Aureus.

Respiratory System: International EU-funded Investigator-initiated phase III trial for the Efficacy and Safety of Inhaled Study Drug XXXX in Very Preterm Infants at Risk for **Bronchopulmonary Dysplasia**

Respiratory System: A prospective, multi-centre, randomised, double-blind, placebo-controlled, 2-parallel groups, Phase III study to compare the efficacy and the safety of XXX at 6 mg/kg/day *versus* placebo in the treatment of patients with **Severe Persistent Asthma** treated with oral corticosteroids

Respiratory System: InternationaL cross-sectIonAl and longItudinal assessment on **aSthma cONtrol** (**The "LIAISON" Study**) (**Non-interventional Observational Study**).

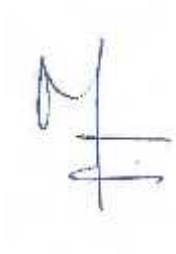
Transplantation: Multinational **Clinical Immunology/Kidney transplantation** study: New immunosuppressive compound in patients with **End-Stage Renal Failure**. Pan-European Multinational,

multi-centre, study

Dermatology: Open, multi-center, randomized, inter-individual comparative, prospective clinical trial with XXX versus commercially available sunscreen products in immunosuppressed outpatients after solid organ transplantations for the **prevention of UV-induced infections and carcinogenic skin alterations**.

I have reviewed this document and confirm that the information is accurate and complete

Signed: 

Initialled: 

Date: **07 October 2020**