PORTFOLIO NEWSLETTER

JANUARY 2022

NIHR University College London Hospital Clinical Research Facility Cancer Trials

INSIDE THIS ISSUE:

COVID-19 and Early Phase Cancer Trials at UCLH

COVID-19 continues to pose challenges in the delivery of clinical research in 2022. Currently we are experiencing reduced staff levels which is impacting upon our timelines to enrol patients.

We continue to keep the Early Phase Cancer Programme open and are setting up new studies; however there is likely to be delays in enrolling patients over the next couple of months.

Please liaise closely with the Principal Investigator for the relevant study to keep updated to the situation. We will be assessing the waiting times of each individual patient on a regular basis during this period.

Dr. Rakesh Popat, Consultant Haematologist

Cancer Lead NIHR UCLH Clinical Research Facility

How to refer a patient

By Post:
NIHR UCLH Clinical Research Facility,
University College London Hospitals NHS Foundation Trust, 4th Floor, 170 Tottenham Court Road,
London, W1T 7HA

By Telephone:
Reception: 020344 72929/72930
Reception Fax: 020344 72994

By Email*:
*When referring patients, ensure you use nhs.net emails. Patient identifiable data *should not* be sent to/ via non-NHS email accounts.

Principal Investigators

Dr. Sarah Benafif

Prof. John Bridgewater

Dr. Martin Forster

Prof. Daniel Hochhauser

Prof. Sam Janes

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Dr. Elisavet Papadimitraki

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Dr. Rebecca Roylance

Dr. Beatrice Seddon

Dr. Heather Shaw

Dr. Sandra Strauss

Dr. William Townsend

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Latest News

New Senior Cancer Staff at the Clinical Research Facility

We are pleased to introduce the appointment of three Consultants in Thoracic Oncology , Gastro-Intestinal Oncology and Uro-Oncology, and the recruitment of a new Band 7 Cancer Research Nurse.

Dr. Khurum Khan is an Honorary Associate Professor and Consultant in Gastrointestinal Oncology at UCLH. His main research interests involve stratification of therapies in patients with gastrointestinal malignancies.

Dr. Sarah Benafif, having previously worked as a Clinical Research Fellows within the CRF, has recently been appointed to a consultant position in Medical Lung Oncology and early phase trials.

Dr. Anuradha Jayaram is a Senior Clinical Research Fellow at the UCL Cancer Institute, and has been appointed Consultant in Uro-Oncology, with a focus on Prostate cancer and translational oncology.

In addition, we are pleased to introduce Jingle Sanchez, who has been appointed as the new Senior Research Nurse, who will be supporting the co-ordination and management of early phase cancer clinical trials within the CRF.

UCLH Find a Study

To find more information on UCLH CRF Early Phase Cancer Clinical Trials visit the UCLH Find a Study database:

https://findastudy.uclh.nhs.uk/#/trial

Using the 'Study Name' and/or 'Local Project Reference' (LRP).

NIHR UCLH Clinical Research Facility
Cancer Trials Open to Recruitment

For more information on a trial, including eligibility criteria click the hyperlinked **Local Project Reference (LRP)** ID.

Gastro-Intestinal

Study Acronym/ Full Title	LPR	PI	Drug Class/ Tumour Target
DESTINY-Gastric 03 A Phase 1/2b Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (DS-8201a) Monotherapy and combinations in Adult Subjects with HER2 Overexpressing Gastric Cancer.	137677	Prof. Daniel Hochhauser	**Topoisomerase I Inhibitor** HER2-Overexpressing Gastric Cancer
FIDES-03 (DZB-CS-202) A Phase 1b/2 study of derazantinib as monotherapy and combination therapy with paclitaxel, ramucirumab or atezolizumab in patients with HER2-negative gastric adenocarcinoma harboring FGFR genetic aberrations (FIDES-03)	133317	Prof. John Bridgewater	**FGFR Inhibitor** Stomach or Gastro-esophageal Adenocarcinoma harbouring FGFR2 genetic aberrations
PORCUPINE2 (RXC004/0003) A Modular, Phase II, Open-Label, Multicentre Study to Assess the Preliminary Efficacy and Safety of RXC004, in Patients with Advanced Solid Tumours that have Progressed following Therapy with Current Standard of Care	138861	Prof. John Bridgewater	**FGFR Inhibitor** Pancreatic Ductual Adenocarcino-ma (PDAC) or Biliary Tract Cancer (BTC)
PORCUPINE1 (RXC004/0002: REACT) A Multi-arm, Phase II, Open-Label, Multicentre Study to Assess the Preliminary Efficacy of RXC004 in Monotherapy and in Combination with Nivolumab, in Patients with Ring Finger Protein 43 (RNF43) or R-spondin (RSPO) Aberrated, Metastatic, Microsatellite Stable, Colorectal Cancer who have Progressed following Therapy with Current Standard of Care	137631	Prof. John Bridgewater	**FGFR Inhibitor +/- PD-1 inhibiting IgG4 Monoclonal** RNF43/RSP Colorectal Cancer

Haematology

Study Acronym/ Full Title	LRP	PI	Drug Class/ Tumour Target
AML1001 A Phase 1, First in Human (FIH), Dose Escalation Study of JNJ-74856665 (dihydroorotate dehydrogenase [DHODH] Inhibitor) in Participants with Acute Myeloid Leukemia (AML) or Myelodysplastic Syndrome (MDS)	135994	Dr. Jenny O'Nions	**Dihydroorotate Dehydrogenase (DHODH) Inhibitor** Acute Myeloid Leukemia (AML) or Myelodysplastic Syndrome (MDS)

Haematology (II)

Study Acronym/ Full Title	LRP	PI	Drug Class/ Tumour Target
BP41072 An Open-Label, Phase I Study To Evaluate The Safety, Pharmacokinetics And Preliminary Antitumor Activity Of Ro7227166 (A Cd19 Targeted 4-1bb Ligand) In Combination With Obinutuzumab And Incombination With Ro7082859 (Cd20-Tcb) Following A Pre-Treatment Dose Of Obinutuzumab Administered In Participants With Relapsed/ Refractory B-Cell Non-Hodgkin's Lymphoma.	129333	Dr. William Townsend	**Ro7227166 (CD19-directed 41BB ligand) + Obinutuzumab (anti-CD20 Monoclonal Antibody) or Glofitamab (CD3-CD20 T-Cell Bispecific Antibody)** Relapsed/Refractory B-Cell Non-Hodgkin's Lymphoma
CC-220-MM-001 A Phase 1B/2A Multicenter, Open-Label, Dose-Escalation Study to Determine the Maximum Tolerated Dose, Assess the Safety and Tolerability, Pharmacokinetics and Preliminary Efficacy of CC-220 Monotherapy and in Combination with Dexamethasone in Subjects with Relapsed and Refractory Multiple Myeloma.	16/0336	Dr. Rakesh Popat	**Cereblon E3 Ligase Modulator** Relapsed and Refractory Multiple Myeloma
CC-92480-MM-001 A Phase 1 Multicenter, Open-Label Study to Assess The Safety, Pharmacokinetics And Preliminary Efficacy of CC-92480 in Combination With Dexamethasone in Subjects With Relapsed And Refractory Multiple Myeloma.	18/0040	Dr. Rakesh Popat	**Cereblon E3 Ligase Modulator** Relapsed and Refractory Multiple Myeloma
CCS1477-02 An open-label Phase I/IIa study to evaluate the safety and efficacy of CCS1477 as monotherapy in patients with advanced haematological malignancies	121140	Dr. Jenny O'Nions	**P300/CBP Inhibitor** Advanced Haematological Malignancies
CO41942 Ph1b study of bispecifics with lenalidomide in relapsed/ refractory FL.	130416	Dr. William Townsend	**CD3-CD20 Bispecific Antibody** Relapsed or Refractory Follicular Lymphoma
DREAMM-6 A Phase I/II, Open-label, Dose Escalation and Expansion Study to Evaluate Safety, Tolerability, and Clinical Activity of the Antibody-Drug Conjugate GSK2857916 Administered in Combination with Lenalidomide Plus Dexamethasone (Treatment Arm A), or Bortezomib Plus Dexamethasone (Treatment Arm B) in Participants with Relapsed or Refractory Multiple Myeloma.	18/0571	Dr. Rakesh Popat	**Humanised Monoclonal Antibody (anti-BCMA)** Relapsed or Refractory Multiple Myeloma
EP0042-101 A Modular, Multipart, Multi-arm, Open-label, Phase I/IIa Study to Evaluate theSafety and Tolerability of EP0042 Alone and in Combination with Anti-cancer Treatments in Patients with Advanced Malignancies.	134892	Dr. Jenny O'Nions	**FLT3 inhibitor & Aurora Kinase Inhibitor** Acute Myeloid Leukaemia (AML) or Myelodysplastic Syndromes (MDS)
GRACE (BP42233) An Open-Label, Multicenter, Phase I Study Evaluating The Safety And Pharmacokinetics Of Escalating Doses Of RO7425781 In Participants With Relapsed Or Refractory Multiple Myeloma	137532	Dr. Rakesh Popat	**T-Cell Engager against GPR5CD** Relapsed or Refractory Multiple Myeloma

Haematology (III)

Study Acronym/ Full Title	LRP	PI	Drug Class/ Tumour Target
MajesTEC-2 (64007957MMY1004) A Multi-arm Phase 1b Study of Teclistamab With Other Anti-cancer Therapies in Participants with Multiple Myeloma	137973	Dr. Rakesh Popat	**T-Cell Engager targeting BCMA** Multiple Myeloma
NP40126 A Phase 1b Study Evaluating Ro7082859 In Combination With Rituximab (R) Or Obinutuzumab (G) Plus Cyclophosphamide, Doxorubicin, Vincristine, And Prednisone (CHOP) In Participants With Relapsed Refractory Follicular Lymphoma (R/R Fl) Or In Participants With Untreated Diffuse Large B-Cell Lymphoma	17/0859	Dr. William Townsend	**Glofitamab (CD3-CD20 T-Cell Bispecific Antibody)** Relapsed Refractory Follicular Lymphoma Or Untreated Diffuse Large B-Cell Lymphoma
NVG111-101 NVG111-101: An open-label, phase 1/2, first in human study investigating the safety, tolerability, pharmacokinetics and efficacy of NVG-111 in subjects with relapsed/refractory chronic lymphocytic leukaemia and mantle cell lymphoma.	135715	Dr. William Townsend	**Receptor Tyrosine Kinase Like Orphan Like Receptor 1 (ROR1) Bispecific antibody** Relapsed or Refractory Chronic Lymphocytic Leukaemia & Mantle Cell Lymphoma

Hepatobiliary

Study Acronym/ Full Title	LPR	PI	Drug Class/ Target
TAS-120 A Dose Finding Phase I Study of TAS-120 in Patients with Advanced Solid Tumors With or Without Fibroblast Growth Factor/Receptor (FGF/FGFR)-Related Abnormalities Followed by a Phase 2 Study in Patients With Advanced Solid Tumors FGF/FGFR-Related Abnormalities	17/0474	Prof. John Bridgewater	**FGFR2 Inhibitor** Cholangiocarcinoma harbouring FGFR2 Gene Fusion

Sarcoma

Study Acronym/ Full Title	LPR	PI	Drug Class/ Target
Afatinib in Chordoma A phase 2, single arm, European multi-center trial evaluating the efficacy of afatinib as first-line or later-line treatment in advanced Chordoma.	17/0146	Dr. Sandra Strauss	**EGFR Small Molecule Inhibitor** Advanced Chordoma
ImmunoSARC2(GEIS-52) Phase I - II trial of sunitinib plus nivolumab after standard treatment in advanced soft tissue and bone sarcomas	119516	Dr. Sandra Strauss	**PD-1 inhibiting IgG4 Monoclonal Antibody and RTK Inhibitor** Advanced Soft Tissue & Bone Sarcomas

Solid Tumours

Study Acronym/ Full Title	LPR	PI	Drug Class/ Target
ADCT-301-103 Phase 1b, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Antitumor Activity of Camidanlumab Tesirine (ADCT-301) as Monotherapy or in Combination in Patients With Selected Advanced Solid Tumors	138826	Prof. Daniel Hochhauser	**CD25 Monoclonal Antibody** *Part 1 Dose-escalation:* Selected Advanced Solid Tumours
AGI-134 A phase I/IIa, multicentre, open label study designed to evaluate the safety and tolerability of AGI-134 as monotherapy and in combination with pembrolizumab, in unresectable metastatic solid tumours.	104916	Dr. Martin Forster	**Anti-αGal** Unresectable Superficial Metastatic Melanoma or Squamous Cell Cancers
20190136: AMG994 & AMG404 A Phase 1, Multicenter, Open-label, Dose Exploration and Dose Expansion Study Evaluating the Safety, Tolerability, Pharmacokinetics and Efficacy of AMG 994 Monotherapy and Combination of AMG 994 and AMG 404 in Subjects with Advanced Solid Tumors.	134740	Dr. Rowan Miller	**Bivalent Bispecific IgG1 Monoclonal IgG1 against PD-1** Advanced Solid Tumours
BLU-667 A Phase 1 Study of the Highly-selective RET Inhibitor, BLU-667, in Patients with Thyroid Cancer, Non-Small Cell Lung Cancer (NSCLC) and Other Advanced Solid Tumors.	17/0783	Dr. Martin Forster	**RET Inhibitor** Thyroid Cancer, NSCLC, Other RET-driven Advanced Solid Tumours
BICYCLE Study: BT171/8 A Cancer Research UK Phase I/IIa trial of BT1718, (A Bicycle drug conjugate), given intravenously in patients with advanced solid tumours.	100211	Dr Dionysios Papadatos-Pastos	**Bicycle Drug Conjugate** Advanced Solid Tumours
D9170C00001 A Phase I/IIa, Open-Label Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of Ascending Doses of AZD7648 Monotherapy or in Combination with either Cytotoxic Chemotherapies or Novel Anti-Cancer Agents in Patients with Advanced Malignancies	18/0580	Dr. Rowan Miller	**DNA-PK Inhibitor** Advanced Malignancies
GO42144 A Phase Ia/Ib Dose-Escalation And Dose-Expansion Study Evaluating The Safety, Pharmacokinetics, And Activity Of GDC-6036 As A Single Agent And In Combination With Other Anti-Cancer Therapies In Patients With Advanced Or Metastatic Solid Tumors With A KRAS G12c Mutation.	140092	Dr. Martin Forster	**KRAS G12c Inhibitor** Advanced or Metastatic Solid Tumours with KRAS G12c Mutation
IMC-F106C-101 A Phase 1/2 First-in-Human Study of the Safety and Efficacy of IMC-F106C as a Single Agent and in Combination with Checkpoint Inhibitors in HLA-A*02:01-Positive Participants with Advanced PRAME-Positive Cancers	130728	Dr. Heather Shaw	**PRAME Immune-Mobilizing T-Cell Receptor against Cancer** HLA-A*02:01-Positive Participants with Advanced PRAME-Positive Cancers
POTENTIA (CBT307-1) A Phase 1 Open-Label, Dose Escalation and Expansion Trial to Investigate the Safety, Pharmacokinetics and Pharmacodynamics of CB307, a Trispecific Humabody T-cell Enhancer, in Patients with PSMA+ Advanced and/or Metastatic Solid Tumours (POTENTIA)	129679	Dr. Mark Linch	**Trispecific Humabody T-Cell Enhancer** PSMA+ (IHC) Advanced or Metastatic Solid Tumours

Solid Tumours (II)

Study Acronym/ Full Title	LPR	PI	Drug Class/ Target
LOXO-TRK-15002 LOXO-TRK-15002: A Phase II Basket Study of the Oral TRK Inhibitor LOXO-101 in Subjects with NTRK Fusion-Positive Tumors.	16/0077	Dr. Martin Forster	**TRK Inhibitor** NTRK Fusion-Positive Tumours
Starpharma CTX A phase 1/2 dose-escalation study to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of CTX-SPL9111 (a cabazitaxel (CTX)-dendrimer conjugate) in patients with advanced solid tumours.	18/0016	Dr. Martin Forster	**Drug-Dendrimer Conjugate** Advanced Solid Tumours
Starpharma DTX A phase 1/2 dose-escalation study to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of DTX-SPL8783 (a docetaxel (DTX)-dendrimer conjugate) as monotherapy in patients with advanced solid tumours or in combination with nintedanib in patients with non-small cell lung cancer (NSCLC).	17/0585	Dr. Martin Forster	**Drug-Dendrimer Conjugate (Tubulin Polymerase Inhibitor)** Advanced solid tumours Or non-small cell lung cancer (NSCLC)

Urology

Study Acronym/ Full Title	LRP	PI	Drug Class/ Target
BXCL701 A Phase 1b/2 Study of BXCL701, a Small Molecule Inhibitor of Dipeptidyl Peptidases (DPP), Administered in Combination with the Anti-Programmed Cell Death 1(PD-1) Monoclonal Antibody Pembrolizumab (PEMBRO; Keytruda®) in Patients with Small Cell Neuroendocrine Prostate Cancer (SCNC; NEPC).	113103	Dr. Mark Linch	**Dipeptidyl Peptidases (DPP) Inhibit & Anti-PD-1 Monoclonal Antibody** Small Cell Neuroendocrine Prostate Cancer (SCNC; NEPC)
CORT125281 Phase 1/2 Dose-Escalation and Expansion Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of CORT125281 with Enzalutamide in Patients with Metastatic Castration-Resistant Prostate Cancer.	18/0135	Dr. Mark Linch	**Glucocorticoid Receptor (GR) Antagonist** Metastatic Castration-Resistant Prostate Cancer (mCRPC)
FIDES-02 (DZB-CS-201) An open-label multi-cohort Phase 1/2 study of derazantinib and atezolizumab in patients with urothelial cancer expressing activating molecular FGFR aberrations (FIDES-02)	124615	Dr. Mark Linch	**FGFR Inhibitor & Anti PD-L1 Monoclonal Anti-body** Advanced Urothelial Cancer expressing FGFR Genetic aberrations. *Substudy 4:* Urothelial progression - FGFR-inhibitor resistant (>12 weeks) & previous chemo and CPI
PRO-MERIT (Prostate Cancer Messenger RNA Immunotherapy): A first-in-human, dose titration and expansion trial to evaluate safety, immunogenicity and preliminary efficacy of W_pro1 in patients with metastatic castration resistant prostate cancer and W_pro1 in combination with cemiplimab and/or goserelin acetate in patients with high-risk, localized prostate cancer.	122815	Dr. Mark Linch	**W_pro1 mRNA Cancer Vaccine** *Group 1:* mCRPC that have exhausted conventional treatment *Group 2:* High-risk, Localized Prostate Cancer prior to Prostatectomy