

Trinity St. James's Cancer Institute

ANNUAL REPORT 2021

List of Cancer Clinical Trials

Name	Full Title	Principal Investigator
Tiger	A RANDOMIZED PHASE III TRIAL COMPARING CONVENTIONAL-DOSE CHEMOTHERAPY using paclitaxel,ifosfamide and cisplatin (TIP) with high-dose chemotherapy using mobilizing paclitaxel plus ifosfamide followed by high-dose carboplatin and etoposide (TI-CE) as first salvage treatment in relapsed or refractory germ cell tumours	Dearbhaile O'Donnell
Lymrit	A phase I/II study of lutetium (177Lu) lilotomab satetraxetan (Betalutin®) antibody-radionuclide-conjugate for treatment of relapsed non-Hodgkin lymphoma	E Vandenberghe
MK3475-811	A Phase III, Randomized, Double-blind Trial Comparing Trastuzumab Plus Chemotherapy and Pembrolizumab or Placebo as First-line Treatment in Participants With HER2 Positive Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma (KEYNOTE 811)	Maeve Lowery
MK3475-859	Phase 3, randomized, double-blind clinical study of pembrolizumab (MK-3475) plus chemotherapy versus placebo plus chemotherapy as first-line treatment in participants with previously untreated, HER2 negative, advanced gastric or gastroesophageal junction adenocarcinoma	Maeve Lowery
Astellas Glow	A Phase 3, Global, Multi-Center, Double-Blind, Randomized, Efficacy Study of IMAB362 plus CAPOX Compared with Placebo Plus CAPOX as First-line Treatment of Subjects with Claudin (CLDN) 18.2-Positive, HER2-Negative, Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma.	Maeve Lowery
FEDR-MF-0002	A Phase 3, multicentre, Open- Label, randomised study to evaluate the efficacy and safety of Fedratinib compared to Best Available Therapy In Subjects With DIPSS (dynamic international prognostic scoring system) - intermediate or high-risk primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis (post-PV MF), or post-essential thrombocythemia myelofibrosis (post-ET MF) and previously treated with ruxolitinib	Eibhlin Conneally
Natalee	NATALEE/ TRIO033: A phase III, multicenter, randomized, open-label trial to evaluate efficacy and safety of ribociclib with endocrine therapy as an adjuvant treatment in patients with hormone receptor-positive, HER2-negative, early breast cancer (New Adjuvant TriAl with Ribociclib [LEE011]:NATALEE).	Cathy Kelly

M14-239	Phase 2, Open-Label Safety and Efficacy Study of Telisotuzumab Vedotin (ABBV-399) in Subjects with Previously Treated c-Met+ Non-Small Cell Lung Cancer	Sinead Cuffe
DZB-CS-301	A pivotal study of derazantinib in patients with inoperable or advanced intrahepatic cholangiocarcinoma and FGFR2 gene fusions or FGFR2 gene mutations or amplifications	Maeve Lowery
Polargo MO40598	A phase III, open-label, multicenter, randomized study evaluating the safety and efficacy of polatuzumab vedotin in combination with rituximab plus gemcitabine plus oxaliplatin (R-GEMOX) versus R-GEMOX alone in patients with relapsed/refractory Diffuse large B-cell lymphoma	Elisabeth Vandenberghe
BGB-3111-306	A Phase 3 Randomized, Open-Label, Multicenter Study Comparing Zanubrutinib (BGB-3111) plus Rituximab Versus Bendamustine plus Rituximab in Patients with Previously Untreated Mantle Cell Lymphoma Who Are Ineligible for Stem Cell Transplantation	Elisabeth Vandenberghe
MK3475-689	A Phase III, Randomized, Open-label Study to Evaluate Pembrolizumab as Neoadjuvant Therapy and in Combination With Standard of Care as Adjuvant Therapy for Stage III-IVA Resectable Locoregionally Advanced Head and Neck Squamous Cell Carcinoma (LA HNSCC)	Cliona Grant
MK3475-671	A Phase III, Randomized, Double-blind Trial of Platinum Doublet chemotherapy +/- Pembrolizumab as neo-adjuvant/adjuvant therapy for participants with resectable stage IIb or IIIa non-small cell lung cancer	Sinead Cuffe
MK7902-001	A Phase 3 Randomized, Open-Label, Study of Pembrolizumab (MK-3475) Plus Lenvatinib (E7080/MK-7902) Versus Chemotherapy for First-line Treatment of Advanced or Recurrent Endometrial Carcinoma (LEAP-001)	Dearbhaile O'Donnell
MK3475-630	A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Evaluate pembrolizumab versus placebo as adjuvant therapy following surgery and radiation in participants with high-risk locally advanced cutaneous squamous cell	Cliona Grant
GSK 209227	A Randomized, Open-label, Phase III Study of GSK3359609 in Combination with Pembrolizumab ± Platinum-based Chemotherapy Doublets versus Pembrolizumab plus 5FU/Platinum Chemotherapy for First-Line Treatment of Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma	Cliona Grant

CA209-7FL	A randomized, multicenter, double-blind, placebo-controlled phase 3 Study of Nivolumab Versus Placebo in Combination With neoadjuvant chemotherapy and adjuvant endocrine therapy in the treatment of high-risk, Stage II-III estrogen receptor-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer	Cathy Kelly
Ca209-73L	A Phase 3, Randomized, Open Label Study to Compare Nivolumab plus Concurrent Chemoradiotherapy (CCRT) followed by Nivolumab plus Ipilimumab or Nivolumab plus CCRT Followed by Nivolumab vs CCRT followed by Durvalumab in Previously Untreated, Locally Advanced Non-small Cell Lung Cancer	Sinead Cuffe
SORAYA	A phase III single arm trial to evaluate mirvetuximab monotherapy in women with folate receptor alpha (FR α) high platinum resistant ovarian cancer who have been previously treated with Avastin $\text{\textcircled{R}}$ (bevacizumab).	Karen Cadoo
AcceleRET B042864	A Randomized, Open-Label, Phase 3 Study of Pralsetinib (formerly known as BLU-667) versus Standard of Care for First Line RET-fusion, Metastatic Non-Small Cell Lung Cancer.	Sinead Cuffe
Hovon 150	A phase 3, multicenter, double-blind, randomized, placebo-controlled study of AG-120 or AG- 221 in combination with induction therapy and consolidation therapy followed by maintenance therapy in patients with newly diagnosed acute myeloid leukemia or myelodysplastic syndrome with excess blasts-2 with an IDH-1 or IDH-2 mutation eligible for intensive chemotherapy	Catherine Flynn
Hovon 156	A Phase 3, Multicenter, open-label, Randomized, Study of Gilteritinib versus Midostaurin in Combination with Induction and Consolidation Therapy followed by one-year maintenance in Patients with Newly Diagnosed Acute Myeloid Leukemia (AML) or myelodysplastic syndromes with excess blasts-2 (MDS-EB2) with FLT3 Mutations Eligible for Intensive Chemotherapy	Eibhlin Conneally
Ca209-8HW	A Phase 3b Randomized Clinical Trial of Nivolumab alone, Nivolumab in Combination with Ipilimumab, or an Investigator $\text{\textcircled{R}}$'s Choice Chemotherapy in Participants with Microsatellite Instability High (MSI-H) or Mismatch Repair Deficient (dMMR) Metastatic Colorectal Cancer	David Gallagher
CLL17	A phase 3 multicenter, randomized, prospective, open-label trial of ibrutinib monotherapy versus fixed-duration venetoclax plus obinutuzumab versus fixed-duration ibrutinib plus venetoclax in patients with previously untreated chronic lymphocytic leukemia CLL	Elisabeth Vandenberghe

ACE-536-MF-002	ACE-536-MF-002: A Phase 3, Double-blind, Randomized Study to Compare the Efficacy and Safety of Luspatercept (ACE-536) Versus Placebo in Subjects with Myeloproliferative Neoplasm-Associated Myelofibrosis on Concomitant JAK2 Inhibitor Therapy and Who Require Red Blood Cell Transfusions	Eibhlin Conneally
MOR208C310	A Phase 3, multicenter, randomized, double-blind, placebocontrolled trial comparing the efficacy and safety of Tafasitamab plus Lenalidomide in addition to R-CHOP versus R-CHOP in previously untreated, high-intermediate and highrisk patients with newly diagnosed Diffuse Large B-Cell Lymphoma (DLBCL)	Elisabeth Vandenberghe
GSK ZEST	A Randomized Phase 3 Double-Blinded Study Comparing Efficacy of Niraparib to Placebo in Participants with Either HER2-Negative BRCA-Mutated or Triple-Negative Breast Cancer with Molecular Disease Based on Presence of Circulating Tumor DNA after Definitive Therapy	Cathy Kelly
DESTINY05 DS8201-A-U305	A phase 3, multicenter, randomized, open-label, active-controlled study of trastuzumab deruxtecan (T-DXd) versus trastuzumab emtansine (T-DM1) in subjects with high-risk HER2-positive primary breast cancer who have residual invasive disease in breast or axillary lymph nodes following neoadjuvant therapy (DESTINY-Breast05)	Cathy Kelly
EFC15992 ITHACA	A phase 3 randomised, open label, multicentre study of Isatuximab (SAR650984) in combination with lenalidomide and dexamethasone versus lenalidomide and dexamethasone in patients with highrisk smouldering multiple myeloma	Patrick Hayden
Destiny04 DS8201-A-U306	A Phase 3, multicenter, 2-arm randomized, open-label study of trastuzumab deruxtecan in subjects with HER2-positive metastatic and/or unresectable gastric or gastro-esophageal junction (GEJ) adenocarcinoma subjects who have progressed on or after a trastuzumab-containing regimen	Maeve Lowery
GSK ZEAL	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study Comparing Niraparib Plus Pembrolizumab Versus Placebo Plus Pembrolizumab as maintenance Therapy in Participants Whose Disease has Remained Stable or Responded to First-Line Platinum-Based Chemotherapy with Pembrolizumab for Stage IIIB/IIIC or IV Non-Small Cell Lung Cancer	Sinead Cuffe