Réseau de Rossy cancérologie Cancer Rossy Network

				BREA	ST			
3		clinicaltrials.gov Identifier (NCTxxx)	Study Title	Phase	Name of PI (Hospital)	Manager (Hospital)	Study Coordinator (Hospital)/Extension MUHC: 514-934-1934 JGH: 514-340-8222 SMHC: 514-345-3511	Comments
				Surgio	al			
			A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy		Basik (JGH)		Gabi Alexandru-Rolea 25526 (JGH)	T1-3 N1 M0 Complete all chemotherapy prior to surgery A min 1 sentinel node, max total nodes (sentinel + nonsentinel) are identified and
	MAC 19	NCT01901094		3	Lambert (MUHC)	Penny Chipman (MUHC)	Dianna Leroux Pager: 514-406-7410	excised by the surgeon At least 1 lymph node (sentinel or non-sentinel) wit a metastasis greater than 0.2 mm
				Neoadju				
3C	KEYNOTE 522 Merck	NCT03036488	A Randomized, Double-blind Phase III Study to Evaluate Pembrolizumab (MK-3475) plus Chemotherapy vs Placebo plus Chemotherapy as Neoadjuvant Therapy and Pembrolizumab vs Placebo as Adjuvant Therapy for Triple Negative Breast Cancer (TNBC)	3	Boileau (JGH)	Linda Robitaille (JGH)	Gladys El Helou (JGH) 25526	Tumour > 2 cm or > 1 cm & pN+ No prior chemotherapy, targeted or radiation therapy within past 12 months
	NSABP B-59	NCT03281954	A Randomized, Double-Blind, Phase III Clinical Trial of Neoadjuvant Chemotherapy with Atezolizumab or Placebo in Patients with Triple-Negative Breast Cancer Followed by Adjuvant Continuation of Atezolizumab or Placebo	3	Boileau (JGH)		Gabi Alexandru-Rolea 25526 (JGH)	Opening soon. Primary tumor T2 or T3 if N0 Primary tumor T1c, T2, or T3 if N+ No previous anthracycline of taxane treatment
				Adjuva	nt	<u> </u>		
+	PALLAS	NCT02513394	A Randomized Phase III Trial of Palbociclib With Standard Adjuvant Endocrine Therapy Versus Standard Adjuvant Endocrine Therapy Alone for Hormone Receptor Positive (HR+) / Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Early Breast Cancer (PALLAS)		Boileau (JGH)	(JGH)	Gabi Alexandru-Rolea 25526 (JGH)	Prior (neo)adjuvant therapy and/or radiotherapy OK < 1 year since initial biopsy Stage 1 or 4 not eligible > ARM II CLOSED > 2.0cm node negative
				3	Asselah (MUHC)	Penny Chipman (MUHC)	Rosie Santos Pager: 514-406-6566	



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6		NSABP B-58	NCT03155997	A Randomized, Open-Label, Phase 3 Study of Abemaciclib Combined with Standard Adjuvant Endocrine Therapy vs Standard Adjuvant Endocrine Therapy Alone in Patients with High Risk, Node Positive, Early Stage, Hormone Receptor Positive, Human Epidermal Receptor 2 Negative, Breast Cancer	3	Boileau (JGH)	Linda Robitaille (JGH)	Gabi Alexandru-Rolea 25526 (JGH)	Negative margins following lump/masectomy (neo)adj and pN+ no prev endocrine therapy
7	TNBC	NRG	NCT02488967	A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-	3	Thirlwell (MUHC)	Stelliana Moreno (MUHC)	Stelliana Moreno 43131 (MUHC)	pN+ eligible If pN0, tumor must be > 3.0 cm.
		BR003	110102400301	Negative Triple-Negative Invasive Breast Cancer	J	Boileau (JGH)	Linda Robitaille 27562 (JGH)	Gabi Alexandru-Rolea 25526 (JGH)	
8	BRCA	MA36 OlympiA	NCT02032823	A randomized, double blind, parallel group, placebo-controlled multi-centre phase III study to assess the efficacy and safety of olaparib versus placebo as adjuvant treatment in patients with germline BRCA1/2 mutations and high risk HER2 negative primary breast cancer who have completed definitive local treatment and neoadjuvant or adjuvant chemotherapy	3	Ferrario (JGH)		Kriti Arora 23766 (JGH)	BRCA2+ Must be HER2- TNBC: pN0 > 2cm or pN+ ER + and/or PgR +: pN2; if Neoadjuvant non pCR
9	Her2+	PUMA-NER-6201	NCT02400476	An Open-Label Study to Characterize the Incidence and Severity of Diarrhea in Patients with Early-Stage HER2+ Breast Cancer Treated with Neratinib and Intensive Loperamide Prophylaxis	2	Thirlwell (MUHC)	Stelliana Moreno (MUHC)	Stelliana Moreno 43131 (MUHC)	Stage 1-3 Prior treatment with adjuvant herceptin
10	All	RTOG 1304/NSABP B- 51	NCT01872975	A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chestwall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy	3	Basik (JGH) Lambert (MUHC)	(JGH) Marianna	Gabi Alexandru-Rolea 25526 (JGH) Tatiana Carvalho (MUHC) ext. 43698 Ginette Ricard (MUHC) ext 43186 Josie Pepe (MUHC) ext 48186	T1-T3 node positive Previous neoadjuvant treatment must be CHEMO not hormonal. Positive lymph nodes
								. , ,	
				I	Metasta		T		
11	ER+	SHERBOC	NCT03241810	A Double-blind, Placebo-controlled, Phase 2 trial of Seribantumab Plus Fulvestrant in Postmenopausal Women with Hormone Receptorpositive, Heregulin Positive (HRG+), HER2 Negative Metastatic Breast Cancer	2	Ferrario (JGH)		Kriti Arora 23766 (JGH)	*Postmenopausal +Pestmenopausal +HER2- •No prev trx with anti-ErbB3 antibody •No CNS disease Coming soon



				PLEASE REFER TO SOLID TUMO	ORS CLINICAL T	RIAL LIST FOR MO	RE OPTIONS		1 NOSSY (VELVO)
12		CR1718GSK	NCT02964507	A Phase I/II Dose Escalation and Expansion Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of GSK525762 in Combination With Fulvestrant in Subjects With ER+ Breast Cancer	1/2	Bouganim (MUHC)	Penny Chipman (MUHC)	Rosie Santos Pager: 514-406-6566	FIRST LINE •Any menopausal status •Progressing within 12 months of adjuvant ET or previously treated for M1 disease with AI / Tam / CDK4/6i •Max 1 line of prior chemo for M1
		GSK 201973	NO 10230-507		112	Panasci (JGH)	Adele Cascini (JGH)	Sheila Rincon 24624 (JGH)	*MEASURABLE disease only
13		CR1322AZ	NCT01226316	A Phase I, Open- Label, Multicenter, Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumor Activity of Ascending Doses of AZD5363 under Adaptable Dosing Schedules in Patients with Advance Solid malignancies	1	Batist (JGH)	Adele Cascini (JGH)	Sheila Rincon 24624 (JGH)	ALL LINES •ER positive, ANY HER2 status •No limit of previous lines •Any menopausal status •NO Diabetes •no previous Fulvestrant
14		AurKa CR1714AA	NCT03092934	A Phase I/II Open-Label Multicenter Study to Evaluate the Safety and Efficacy of AK-01 as Monotherapy in Patients With Locally Advanced or Metastatic Solid Tumors	1/0	Bouganim (MUHC)	Adele Cascini (JGH) Penny Chipman	Amanda Kanesci (JGH) 26394 Shweta Jasra (MUHC) Pager: 514-406-4655	SECOND LINE *HER2 negative *Must have failed hormone therapy and CDK4/6 inhibitor *CNS mets ok as long as asymptomatic and no corticosteroids
							(MUHC)		
15	TNBC	IMMU-132-05 (ASCENT)	NCT02574455	Phase III Study of Sacituzumab Govitecan (IMMU- 132) in Refractory/Relapsed Triple-Negative Breast Cancer	3	Ferrario (JGH)	Aline Mamo (JGH)	Kriti Arora 23766 (JGH)	THIRD LINE Must have been treated with a taxane MEASURABLE disease Coming soon

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16		IMpassion130 MO39169 Roche	NCT02425891	A Phase III, Multicenter, Randomized, Placebo- Controlled Study of Atezolizumab (Anti-PD-L1 Antibody) in Combination With Nab-Paclitaxel Compared With Placebo With Nab-Paclitaxel for Patients With Previously Untreated Metastatic Triple-Negative Breast Cancer	3	Bouganim (MUHC)	Penny Chipman (MUHC)	Dianna Leroux Pager: 514-406-7410	•No prior chemotherapy or targeted systemic therapy (including endocrine therapy) for inoperable locally advanced or metastatic TNBC •MEASURABLE disease •No CNS mets
17		Novartis CR1615NS	NCT02900664	Phase Ib, open-label, multi-center study to characterize the safety, tolerability and pharmacodynamics (PD) of PDR001 in combination with CJM112, EGF816, Ilaris® (canakinumab) or Mekinist® (trametinib)	1	Miller (JGH)	Adele Cascini (JGH)	Mahsid Mortazavi (JGH) 25981	• MEASURABLE disease • Prior PD-1/PDL-1 inhibitors is allowed • No CNS mets
18		CR1618MK KEYNOTE 355	NCT02819518	A Randomized, Double-Blind, Phase III Study of Pembrolizumab (MK-3475) Plus Chemotherapy vs Placebo Plus Chemotherapy for Previously Untreated Locally Recurrent Inoperable or Metastatic Triple Negative Breast Cancer	3	Ferrario (JGH)	Adele Cascini (JGH)	Sheila Rincon 24624 (JGH)	FIRST LINE •TNBC (<1% ER/PR) Male/Female •MEASURABLE disease •No previous chemo for M1 •if patient received (neo)adjuvant chemo, they should NOT have progressed within 6 months from end of treatment •No brain metastases •No steroids
19		CR1717BR	NCT03102320	Phase 1b multi-indication study of Anetumab Ravastine (BAY 94-9343) in Patients with Mesothelin Expressing Advanced or Recurrent Malignancies	1	Batist (JGH)	Adele Cascini (JGH)	(JGH) 24301	•NO more than one prior anti tubulin/microtubule agent •Max 1 prior trx
20	Her2+	CR1623ONT Cascadian HER2CLIMB	NCT02614794	Phase 2 Randomized, Double-Blinded, Controlled Study of Tucatinib vs Placebo in Combination With Capecitabine and Trastuzumab in Patients With Pretreated Unresectable Locally Advanced or Metastatic HER2+ Breast Carcinoma (HER2CLIMB)	2	Ferrario (JGH)	Adele Cascini (JGH)	Sheila Rincon 24624 (JGH)	•Allows brain metastases •Requires previous treatment with taxane, Herceptin, pertuzumab and T-DM1 •Measurable or non measurable disease RECIST 1.1 •No lapatinib within 12 months



21	All	CO40016	NCT03337724	A Double-Blind, Placebo-Controlled, Randomized Phase III Study of Ipatasertib in Combination With Paclitaxel as a Treatment for Patients With PIK3CA/AKT1/PTEN-Altered, Locally Advanced or Metastatic, Triple-Negative Breast Cancer or Hormone Receptor-Positive, HER2-Negative Breast Cancer	3	Ferrario (JGH)	Aline Mamo (JGH)	Kriti Arora 23766 (JGH)	FIRST LINE •MEASURABLE disease •BRCA-associated tumors ok •HER2- •Confirmation of PIK3CA/AKT1/PTEN-altered status in tumor tissue •no brain mets
22		ATTAIN - NKTR-102	NCT02915744	A Study of Etirinotecan Pegol (NKTR-102) Versus Treatment of Physician's Choice (TPC) in Patients With Metastatic Breast Cancer Who Have Stable Brain Metastases and Have Been Previously Treated With an Anthracycline, a Taxane, and Capecitabine (ATTAIN)	3	Thirlwell (MUHC)	Stelliana Moreno (MUHC)	Stelliana Moreno 43131 (MUHC)	non-progressing brain mets MUST have had WBRT/SRS or surgical resection measurable or non-measurable disease according to RECIST version 1.1. Second line and more
					Radiothe				
23		Targit		Targeted Intra-Operative radiotherapy (Targit) during breast conserving surgery for patients with early stage breast cancer	2	Abdulkarim (MUHC)	Marianna Perna (MUHC)	Josie Pepe (MUHC) ext 48186	
24		SPORT CK	NCT01717261	Single Pre-Operative Radiation Therapy (SPORT) for Low Risk Breast Cancer	1	Hijal (MUHC)	Marianna Perna (MUHC)	Tatiana Carvalho (MUHC) ext. 43698 Ginette Ricard (MUHC) ext 43186 Josie Pepe (MUHC) ext 48186	
25		BR-002	NCT02364557	A phase IIR/III trial of standard of care therapy with or without stereotactic body radiotherapy (SBRT) and/or surgical ablation for newly oligometastatic breast cancer	2/3	Hijal (MUHC) Muanza (JGH)	,	Tatiana Carvalho (MUHC) ext. 43698 Ginette Ricard (MUHC) ext 43186 Josie Pepe (MUHC) ext 48186 Carolane Blais ext.25098 Fax: 514-340-	The sites of allowed metastases are: peripheral lung, central lung, medistinal/cervical lymph node, liver, spinal/paraspinal,
							27562 (JGH)	8106	pelvic NO brain mets
26		BR-001	NCT02206334	A Phase 1 Study of Stereotactic Body Radiotherapy (SBRT) for the Treatment of Multiple Metastases	1	Muanza (JGH)	Linda Robitaille 27562 (JGH)	Carolane Blais ext.25098 Fax: 514-340-8106	The sites of allowed metastases are: peripheral lung, central lung, medistinal/cervical lymph node, liver, spinal/paraspinal, osseous, and abdominal-pelvic NO brain mets



			PLEASE REFER TO SOLID TUM	ONS CLINICAL II	MAL LIST FOR WO	NE OF HONS		
27	Bayer 17096		A Phase II Randomized, Double-blind, Placebo- controlled Trial of Radium-223 in Combination With Exemestane and Everolimus Versus Placebo in Combination With Exemestane and Everolimus in Metastatic HER2 Negative Hormone Receptor Positive Breast Cancer Subjects With Bone Metastases	2	Niazi (JGH)	Tarika Liyage (JGH)	Sarah Riggio 26771 (JGH)	•ER+ and HER2- •postmenopausal or pre- menopausal on LHRHa subjects with bone-dominant disease with at least 2 skeletal metastases •No more than 2 Skeletal Related Events •Measurable or non- measurable disease •Must be on bisphosphonate or denosumab •Prev trx with: anastrozole, letrozole, fulvestrant, tamoxifen, toremifene
28	RTOG1119	NCT01622868	Phase II randomized study of whole brain radiotherapy in combination with concurrent lapatinib in patients with brain metastasis from HER2-Positive breast cancer: A collaborative study of RTOG and KROG	2	Muanza (JGH)	Linda Robitaille 27562 (JGH)	Sarah Riggio 26771 (JGH)	HER2+ Must have brain mets Prior lapatinib is allowed as long as the last dose received was > 21 days No previous WBRT No leptomeningeal mets
				Other				
29	Novartis	NCT02753686	Treatment of Canadian Postmenopausal Women with ER+ Advanced Breast Cancer in the Real-World Setting with Hormone Therapy ± Targeted Therapy	observa-tional	Bouganim (MUHC)	Penny Chipman (MUHC)	Rosie Santos (MUHC) 514-406-6566 (MUHC pager)	
	CRAD001YCA09	<u>NOTO2700000</u>		observa tional	Ferrario (JGH)	Adele Cascini (JGH)	Sabrina Cesare (JGH) 24301 (JGH)	
30	JGH		Feasibility Study of the Xoft Axxent eBx System for Intra-operative Radiotherapy (IORT) Following Wide Local Excision (WLE) for Low-Risk Breast Cancer Patients	4	Vuong (JGH)		Harielle Lamarre (JGH) 26199 (JGH)	
31	TRIO-30		A Presurgical Tissue-Acquisition Study to Evalyuate Molecular Alterations in uman Breast Cancer Tissue Following Short-Term Exposure to the Androgen receptor Antagonist ODM-201		Boileau (JGH)	(JGH)	Gabi Alexandru-Rolea 25526 (JGH)	
	McPeak Sirois				Bouganim (MUHC)	Chipman (MUHC)	Rosie Santos Pager: 514-406-6566	
32	NeaONQ		A Prospective Clinical utility and Economic impact Study of the Oncotype Dx Recurrence Score in Node-Positive Patients in Candidates for Neo- Adjuvant Therapy in Quebec		Mihalciou (MUHC)	Penny Chipman (MUHC)	Dianna Leroux Pager: 514-406-7410	

https://www.mcgill.ca/rcr-rcn/clinical-trials

last updated: May 22 2018 by Natasha Ibrahim any comments or changes: natasha.ibrahim@mcgill.ca



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33	RUBY	Observational Women's College	Reducing the bUrden of reast cancer in Young women (RUBY)	Observational	Boileau (JGH)	Linda Robitaille (JGH)	Sarah Murray 24830 (JGH)			
		<u>Research</u>			(MŬHC)	Stelliana Moreno (MUHC)	Stelliana Moreno 43131 (MUHC)			
34	A5481082 (POLARIS) Pfizer/McPeak Sirois		Palbociclib in Hormone Receptor Positive Advanced Breast Cancer: A Prospective Multicenter Non-Interventional Study			Penny Chipman (MUHC)	Rosie Santos Pager: 514-406-6566			