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CLINICAL DEVELOPMENT PROGRAM

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LILLY IS COMMITTED TO REDUCING BARRIERS AND MAKING LIFE BETTER FOR PEOPLE LIVING WITH CANCER.

Lilly is committed to the development of patient-tailored therapeutics that integrate disease and target biology with drug characteristics in order to optimize treatments for patients. Our multidisciplinary approach allows for the translation of molecular and cellular discoveries into clinically meaningful outcomes. Key to this approach is Lilly's extensive and growing catalog of biomarkers.

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CLINICAL DEVELOPMENT PIPELINE

PHASE 3

BTK INHIBITOR

PIRTOBRUTINIB

- BRUIN CLL-321, NCT04666038
  CLL/SLL
- BRUIN MCL-321, NCT04662255
  MCL
- BRUIN CLL-322, NCT04965493
  CLL/SLL
- BRUIN CLL-313, NCT05023980
  CLL/SLL
- BRUIN CLL-314, NCT05254743
  CLL/SLL

CDK4/6 INHIBITOR

ABEMACICLIB

- MONARCH 2, NCT02107703
  Breast Cancer
- MONARCH 3, NCT02246621
  Breast Cancer
- monarchE, NCT03155997
  Breast Cancer
- postMONARCH, NCT05169567
  Breast Cancer

KRAS G12C INHIBITOR

OLOMORASIB

- SUNRAY-01, NCT06119581
  NSCLC

RET INHIBITOR

SELPERCATINIB

- LIBRETTO-531, NCT04211337
  MTC
- LIBRETTO-431, NCT04194944
  NSCLC
- LIBRETTO-432, NCT04819100
  NSCLC

SELECTIVE ESTROGEN RECEPTOR DEGRADER

IMLUNESTRANT

- EMBER-3, NCT04975308
  Breast Cancer
- EMBER-4, NCT05514054
  Breast Cancer

VEGF RECEPTOR-2 ANTAGONIST

RAMUCIRUMAB

- RELAY, NCT02411448
  NSCLC

CANCER TYPE KEY

- Breast
- Gastrointestinal
- Genitourinary
- Gynecologic
- Hematologic
- Lung
- Other Solid Tumors
- Sarcoma
- Thyroid

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CLINICAL DEVELOPMENT PIPELINE (cont.)

PHASE 2

BTK INHIBITOR
PIRTOBRUTINIB

BRUIN, NCT03740529

- CLL/SLL or NHL

CDK4/6 INHIBITOR
ABEMACICLIB

NCT04238819

- Pediatric Cancer or Other Solid Tumors

CAMPFIRE, NCT05440786

- Sarcoma

KRAS G12C INHIBITOR
OLOMORASIB

NCT04956640*

- NSCLC
- CRC
- Other Solid Tumors

RET INHIBITOR
SELPERCATINIB

LIBRETTO-001, NCT03157128

- NSCLC
- MTC, PTC
- Other Solid Tumors

LIBRETTO-121, NCT03899792

- Pediatric Cancer or Other Solid Tumors

VEGF RECEPTOR-2 ANTAGONIST
RAMUCIRUMAB

CAMPFIRE, NCT04145349

- Pediatric Cancer or Sarcoma

CANCER TYPE KEY

- Breast
- Gastrointestinal
- Genitourinary
- Gynecologic
- Hematologic
- Lung
- Other Solid Tumors
- Sarcoma
- Thyroid

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CLINICAL DEVELOPMENT PIPELINE (cont.)

PHASE 1

FGFR3 INHIBITOR
LOXO-435

NCT05614739

- Urothelial Cancer
- Other Solid Tumors

FRα ANTIBODY-DRUG CONJUGATE
LY4170156

NCT06400472

- Breast Cancer
- Gastrointestinal Cancer
- Gynecologic Cancer
- Lung Cancer

NECTIN-4 ANTIBODY-DRUG CONJUGATE 1
LY4101174

EXCEED, NCT06238479

- Breast Cancer
- Gastrointestinal Cancer
- Genitourinary Cancer
- Gynecologic Cancer
- Lung Cancer
- Other Solid Tumors

NECTIN-4 ANTIBODY-DRUG CONJUGATE 2
LY4052031

NEXUS-01, NCT06465069

- Breast Cancer
- Gastrointestinal Cancer
- Genitourinary Cancer
- Gynecologic Cancer
- Lung Cancer
- Other Solid Tumors

SELECTIVE ESTROGEN RECEPTOR DEGRADER
IMLUNESTRANT

EMBER, NCT04188548*

- Breast Cancer
- Endometrial Cancer

CANCER TYPE KEY

- Breast
- Gastrointestinal
- Genitourinary
- Gynecologic
- Hematologic
- Lung
- Other Solid Tumors
- Sarcoma
- Thyroid

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MOLECULES IN CLINICAL DEVELOPMENT

BTK INHIBITOR | PIRTOBRUTINIB

Bruton's tyrosine kinase (BTK) is critical for the propagation of B-cell receptor signaling and is upregulated in many B-cell malignancies as compared with normal B cells. BTK inhibition, both in vitro and in vivo, decreases proliferation and survival signals.[1]

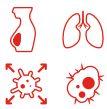
Pirtobrutinib is an investigational, oral, highly selective (in preclinical studies, over 300-fold more selective for BTK vs 98% of 370 non-BTK-kinases), non-covalent (reversible) BTK inhibitor.[2,3] It possesses nanomolar potency independent of BTK C481 status in enzyme and cell-based assays.[2-4] Pirtobrutinib has been shown in preclinical studies to reversibly bind BTK, have high target coverage regardless of BTK turnover rate, preserve activity in the presence of the C481 acquired resistance mutations, and predominantly avoid off-target kinases.[2]

PIRTOBRUTINIB is being investigated in clinical trials in patients with chronic lymphocytic leukemia/small lymphocytic lymphoma, mantle cell lymphoma, and non-Hodgkin's lymphoma.

CDK4/6 INHIBITOR | ABEMACICLIB

Many human tumors acquire alterations which can lead to the activation of cyclin-dependent kinases (CDKs). These alterations include mutations that directly activate CDK4/6; gene amplifications, which increase expression of various protein activators such as D-type cyclins; as well as genetic losses, which reduce expression of protein inhibitors such as p16. These various mechanisms as well as loss of retinoblastoma (Rb) can lead to an enhanced proliferative potential by decreasing dependency on external growth factors and mitogenic signaling pathways, which are required to stimulate growth under normal conditions.[5,6]

Abemaciclib has been shown in vitro to be a selective ATP-competitive inhibitor of CDK4/6 kinase activity that prevents the phosphorylation and subsequent inactivation of the Rb tumor suppressor protein, thereby inducing G1 cell-cycle arrest and inhibition of cell proliferation.[7,8]



ABEMACICLIB is being investigated in clinical trials in patients with breast cancer, non-small cell lung cancer, pediatric cancers, or sarcoma.

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MOLECULES IN CLINICAL DEVELOPMENT (cont.)

FGFR3 INHIBITOR | LOXO-435

Fibroblast growth factor (FGF) receptor 3 (FGFR3) is a member of the highly conserved FGFR family of transmembrane receptors.[9-11] There are four FGF receptors, FGFR1-4, that each consist of an extracellular ligand-binding domain, transmembrane domain, and an intracellular tyrosine kinase domain.[10,11] Receptor dimerization induced upon binding of the extracellular domain with a high-affinity member of the FGF family of ligands leads to phosphorylation of the intracellular domain and phospholipase Cγ, PI3K-AKT, RAS-MAPK-ERK, and STAT pathways activation, playing a critical role in several biological and developmental processes.[9,11,12] FGFR3 aberrations act as oncogenes across tumor types and have been identified in 15% to 20% of advanced urothelial bladder cancers, ~15% of uterine carcinosarcomas, ~5% of endometrial cancers, and less frequently (<5%) in other solid tumor malignancies.[10,11,13,14] Activating FGFR3 alterations are diverse and include point mutations, fusions, amplifications, and overexpression.[9-12] Dysregulation of FGFR3 promotes oncogenesis and tumor cell proliferation, migration, and survival.[9-12,15]

LOXO-435 is a potent and isoform-selective FGFR3 inhibitor that has shown antitumor activity across FGFR3-mutant in vivo preclinical models, with preserved potency against FGFR3 gatekeeper resistance mutants.[14] LOXO-435 spares FGFR1 and FGFR2 in preclinical in vivo models.[14]

LOXO-435 is being investigated in an open-label, multicenter, phase 1a/b study in patients with FGFR3-altered advanced urothelial carcinoma and other solid tumors.

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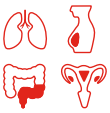
MOLECULES IN CLINICAL DEVELOPMENT (cont.)

FRα ANTIBODY-DRUG CONJUGATE | LY4170156

Folate receptor alpha (FRα) is a cell-surface glycoprotein encoded by the gene *FOLR1*. It binds to folic acid and reduced folates with high affinity.[16,17] Upon binding, the receptor-ligand complex is internalized via potocytosis and fused with a lysosome, releasing the folate for use in reactions.[17] The expression of FRα in non-malignant tissues is limited, whereas it is overexpressed in many solid tumors such as ovarian, non-small cell lung, and colorectal cancers, making the receptor an attractive therapeutic target for these indications.[16,18]

LY4170156 is an FRα-targeting antibody-drug conjugate (ADC) composed of an Fc-silenced, humanized IgG1 monoclonal antibody, a proprietary polysarcosine hydrophobicity masking agent with a dipeptide cleavable linker, and the topoisomerase I inhibitor payload exatecan. It has a drug-antibody ratio (DAR) of 8:1. In preclinical models, LY4170156 has shown activity against a range of FRα-expressing tumors, including low and moderate FRα-expressing ovarian tumors as well as other solid tumors.[18]



LY4170156 is being studied in ovarian and endometrial cancers, as well as other FRα-expressing solid tumors, in a phase 1 study.

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MOLECULES IN CLINICAL DEVELOPMENT (cont.)

KRAS G12C INHIBITOR | OLOMORASIB

KRAS is the most common oncogene across all tumor types. *KRAS* G12C represents a *KRAS* mutation in patients with non-small cell lung cancer (14%), colorectal cancer (3%), and other solid tumors (1%-3%).[19]

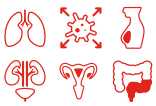
Olomorasib is a selective covalent inhibitor of KRAS G12C; in preclinical models, it shows activity as monotherapy and in combination with other anticancer therapies. It has pharmacokinetic properties supporting its advancement into clinical testing. Olomorasib has been shown in vitro to target a *KRAS* G12C mutation, thereby inhibiting mutant KRAS-dependent signaling.[20]

OLOMORASIB is being studied in patients with non-small cell lung cancer, colorectal cancer, or other solid tumors.

NECTIN-4 ANTIBODY-DRUG CONJUGATE 1 | LY4101174

Nectin-4 is a type I transmembrane protein and a member of the nectin glycoprotein family.[21] Nectin-4 is primarily expressed in the placenta during fetal development and is weakly expressed in some adult human tissues, such as skin.[21,22] Overexpression of Nectin-4 has been observed in several solid tumor types including urothelial, breast, cervix, lung, and ovarian cancers,[22,23] and is associated with promoting tumor proliferation and metastasis.[21] The higher expression of Nectin-4 in tumor cells compared to normal cells makes the protein an ideal target for tumor-specific delivery of cytotoxic agents via an antibody-drug conjugate (ADC).[21]

LY4101174 is a next-generation anti-Nectin-4 targeting ADC. It is comprised of a humanized IgG1 Fc-silent monoclonal Nectin-4 antibody linked to the topoisomerase I inhibitor, exatecan, via a maleimide-B-glucuronide poly-sarcosine linker with a homogeneous drug-antibody ratio (DAR) of 8:1. In preclinical in vivo models, LY4101174 has shown antitumor activity across a range of Nectin-4 expression levels including a Nectin-4 MMAE ADC resistant model.



LY4101174 is being investigated in a global open-label, multicenter, phase 1a/1b study in patients with advanced or metastatic urothelial carcinoma and select solid tumors.

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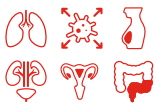
MOLECULES IN CLINICAL DEVELOPMENT (cont.)

NECTIN-4 ANTIBODY-DRUG CONJUGATE 2 | LY4052031

Nectin-4 is a type I transmembrane protein and a member of the nectin glycoprotein family.[21] Nectin-4 is primarily expressed in the placenta during fetal development and is weakly expressed in some adult human tissues, such as skin.[21,22] Overexpression of Nectin-4 has been observed in several solid tumor types including urothelial, breast, cervix, lung, and ovarian cancers,[22,23] and is associated with promoting tumor proliferation and metastasis.[21] The higher expression of Nectin-4 in tumor cells compared to normal cells makes the protein an ideal target for tumor specific delivery of cytotoxic agents via an antibody-drug conjugate (ADC).[21]

LY4052031 is a next-generation anti-Nectin-4 targeting ADC. It is comprised of a human IgG1 Fc-silent monoclonal Nectin-4 antibody linked to a novel camptothecin (topoisomerase I inhibitor) payload, via a cleavable linker with a homogeneous drug-antibody ratio (DAR) of 8:1. In preclinical in vivo models, LY4052031 has shown antitumor activity across a range of Nectin-4 expression levels, including a Nectin-4 MMAE ADC-resistant model.[24]



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MOLECULES IN CLINICAL DEVELOPMENT (cont.)

RET INHIBITOR | SELPERCATINIB

Rearranged during transfection (*RET*) fusions have been identified in approximately 2% of non-small cell lung cancer,[25, 26] approximately 10% of papillary thyroid cancer,[27,28] and less than 1% in other solid tumors including pancreatic and colorectal cancer.[29-31] *RET* point mutations account for approximately 60% of medullary thyroid cancer.[32-34] Cancers that harbor activating *RET* fusions or *RET* mutations depend primarily on this single constitutively activated kinase for their proliferation and survival. This dependency renders such tumors highly susceptible to small-molecule inhibitors targeting RET.

Selpercatinib is a selective, potent, CNS-active small-molecule inhibitor of RET. Selpercatinib possesses nanomolar potency against diverse *RET* alterations, including *RET* fusions, activating *RET* point mutations, and acquired resistance mutations. Selpercatinib has been shown in vitro and in vivo to exhibit specificity for RET, with limited activity against other tyrosine kinases.[35,36]

SELPERCATINIB is being investigated in clinical trials in patients with RET-associated medullary thyroid cancer, non-small cell lung cancer, papillary thyroid carcinoma, pediatric cancers, and other solid tumors.

SELECTIVE ESTROGEN RECEPTOR DEGRADER | IMLUNESTRANT

Estrogen signaling plays an important role in organ development and growth. In certain cancers, abnormal estrogen signaling via the estrogen receptor is a component of tumor growth.[37] Disruption of estrogen signaling by selective estrogen receptor degraders (SERDs) is being investigated in patients with estrogen-receptor-positive (ER+) cancers.

Imlunestrant is an orally available SERD that suppresses estrogen signaling and subsequently inhibits cell proliferation in ER-expressing tumor models.[38,39]

IMLUNESTRANT is being investigated in clinical trials in patients with ER+ breast cancer or endometrial cancer.

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MOLECULES IN CLINICAL DEVELOPMENT (cont.)

VEGF RECEPTOR-2 ANTAGONIST | RAMUCIRUMAB

Angiogenesis is a tightly regulated, multiple-step process, which results in the formation of new blood vessels from preexisting vasculature and is an important component in the development and progression of malignant disease. Signaling by vascular endothelial growth factor (VEGF) receptor-2 in endothelial cells plays a role in inducing normal and pathologic angiogenesis and is activated by binding of ligands VEGF-A, VEGF-C, and VEGF-D.[40-42]

Ramucirumab is a human IgG1 monoclonal antibody receptor antagonist that has been shown in preclinical studies to bind to and block the activation of VEGF receptor-2 by preventing the binding of VEGF receptor ligands VEGF-A, VEGF-C, and VEGF-D.[43,44]

RAMUCIRUMAB is being investigated in clinical trials in patients with metastatic non-small cell lung cancer, biliary tract cancer, or pediatric sarcoma.

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