

North American Pharmaceutical Pipeline

Our development work in North America is coordinated with global colleagues to bring new medicines to patients around the world in 4 therapeutic areas: neurology, immunology & allergy, oncology, and nephrology. Many of our programs target rare diseases for which patients lack sufficient treatment options.

Clinical testing of novel compound drugs is a complex process with no guaranteed results. Our hope in pursuing these indications is to deliver to patients the advances that may have a profound impact on their disease. However, the safety and efficacy of these agents remain under investigation and have not been established or reviewed by regulatory agencies or health authorities.

Our North American teams are currently working on these assets. To view the most current global Kyowa Kirin pipeline, click [here](#).

Proposed indication

Mycosis fungoides and Sézary syndrome

■ **Oncology**

Mogamulizumab (KW-0761) is a CCR4-targeted monoclonal antibody that leverages POTELLIGENT® technology.

Market

Canada

Candidate

Mogamulizumab

KW-0761 | Injection

Collaborators

In-house with Stanford University

Filed (CA)

Proposed indication

Follicular lymphoma (FL), marginal zone lymphoma (MZL)

■ **Oncology**

Zandelisib (ME-401) is an inhibitor of phosphatidylinositol 3-kinase delta (PI3Kδ).

Study name

COASTAL

Clinical trial information

[NCT04745832](#)

Candidate

Zandelisib combined with Rituximab

ME-401 | Oral

Sponsor

[MEI Pharma](#)

Phase 3 (US)

▲ Immunology/allergy

● Central Nervous System

■ Oncology

Key

Proposed indication

Atopic dermatitis

▲ Immunology/allergy

KHK4083 is an anti-OX40 fully human monoclonal antibody that leverages POTELLIGENT® technology.

Clinical trial information

[NCT03703102](#)

Candidate

KHK4083

Injection

Phase 2 (US)

Collaborators

[Amgen](#) (US, International Markets)

Proposed indication

**Follicular lymphoma (FL),
marginal zone lymphoma (MZL)**

■ Oncology

Zandelisib (ME-401) is an inhibitor of phosphatidylinositol 3-kinase delta (PI3Kδ).

Study name

TIDAL

Clinical trial information

[NCT03768505](#)

Candidate

Zandelisib

ME-401 | Oral

Phase 2 (US)

Sponsor

[MEI Pharma](#)

Proposed indication

Parkinson's Disease

● Central Nervous System

KW-6356 is an adenosine A_{2A} receptor antagonist/inverse agonist.

Clinical trial information

[NCT02939391](#), [NCT03703570](#)

Candidate

KW-6356

Oral

Phase 2 (US)

Collaborators

In-house

Proposed indication

Urothelial carcinoma

■ Oncology

KHK2455 is an IDO1 inhibitor.

Clinical trial information

[NCT03915405](#)

Candidate

KHK2455

Oral

Phase 1 (US)

Collaborators

In-house

▲ Immunology/allergy

● Central Nervous System

■ Oncology

Key

Proposed indication

Solid Tumor

■ *Oncology*

Candidate

KHK2455

Oral

Phase 1 (US)

KHK2455 is an IDO1 inhibitor in clinical development for use in combination with KW-0761.

Clinical trial information

[NCT02867007](#), [NCT04321694](#)

Collaborators

In-house

Proposed indication

B-cell malignancies

■ *Oncology*

Candidate

Zandelisib

ME-401 | Oral

Phase 1 (US)

Zandelisib (ME-401) is an inhibitor of phosphatidylinositol 3-kinase delta (PI3Kδ).

Study name

B-cell malignancies

Sponsor

[MEI Pharma](#)

Clinical trial information

[NCT02914938](#)

Information accurate as of September 2021.