

# Bruton's Tyrosine Kinase (BTK) Inhibitor - Pipeline Insight, 2022

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## Abstracts

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DelveInsight's, "Bruton's Tyrosine Kinase (BTK) Inhibitor - Pipeline Insight, 2022" report provides comprehensive insights about 30+ companies and 30+ pipeline drugs in Bruton's Tyrosine Kinase (BTK) Inhibitor pipeline landscape. It covers the pipeline drug profiles, including clinical and nonclinical stage products. It also covers the therapeutics assessment by product type, stage, route of administration, and molecule type. It further highlights the inactive pipeline products in this space.

### Geography Covered

Global coverage

### Bruton's Tyrosine Kinase (BTK) Inhibitor Understanding

#### Bruton's Tyrosine Kinase (BTK) Inhibitor: Overview

Bruton's tyrosine kinase (Bruton's agammaglobulinemia tyrosine kinase; BTK) is a nonreceptor, cytoplasmic tyrosine kinase which plays an important role in B-lymphocyte development, differentiation, and signaling. It is a member of the Tec family of kinases which is involved in regulating the B cell proliferation. Btk also has a role in Toll-like receptor and FcR signaling in myeloid cells. Bruton's tyrosine kinase (BTK) inhibitors work by binding to the BTK protein. BTK inhibitors block this protein's activity by the BCR-induced BTK activation and its downstream signalling.

Function - BTK is predominantly expressed in B lymphocytes but not in plasma cells. BTK expression in the B-cell lineage is also developmentally regulated, with marrow-derived hematopoietic stem cells, common lymphoid progenitor cells, developing B and myeloid lineages showing the highest levels, whereas resting mature cells prior to activation have reduced cellular BTK. BTK is expressed in many hematopoietic cell types, where its involvement in various pathways has been defined. Likewise, in B cells, BTK participates in multiple pathways, including chemokine receptor and TLR signaling.

Bruton's Tyrosine Kinase (BTK) Inhibitors - Targeting of BTK, which has a central role in several signaling pathways in B cells, particularly the BCR, has shown impressive efficacy as therapeutic option for various B cell malignancies in clinical trials. Much progress has been made in recent years in defining the complex mechanisms of action of BTK inhibition. These involve intrinsic signaling pathways in leukemic cells that are central to cellular survival, proliferation and - most importantly - retention in supportive microenvironments. Moreover, BTK inhibition shows promise as a therapy that influences crucial immune cells in the tumor microenvironment. Because data from BTK-deficient or inhibitor-treated myeloid cells in the context of cancer are scarce, it is not clear whether BTK inhibition by e.g. ibrutinib is based on its specificity for BTK in particular myeloid cells and/or due to off-target effects in signaling pathways in CD4+ or CD8+ T cells.

## Bruton's Tyrosine Kinase (BTK) Inhibitor Emerging Drugs Chapters

This segment of the Bruton's Tyrosine Kinase (BTK) Inhibitor report encloses its detailed analysis of various drugs in different stages of clinical development, including phase III, II, I, preclinical and Discovery. It also helps to understand clinical trial details, expressive pharmacological action, agreements and collaborations, and the latest news and press releases.

## Bruton's Tyrosine Kinase (BTK) Inhibitor Emerging Drugs

### Tolebrutinib: Sanofi

Tolebrutinib (SAR442168) is a covalent, orally active, irreversible BTK inhibitor that penetrates the central nervous system (CNS). It penetrates the Central Nervous System in order to effectively and safely modulate B-cell function without depleting B-cells. Tolebrutinib is in Phase III clinical studies for the treatment of both relapsing and

progressive forms of multiple sclerosis (MS). During neuro-inflammation, the number of B cells in the brain increases, which is thought to play a central role in the pathology of MS and other CNS diseases. This provides the potential of targeting the adaptive and innate immunity in both the periphery and also within the CNS. The drug was originally developed by Principia and later on the company was acquired by Sanofi.

#### Evobrutinib: Merck

Evobrutinib (M-2951) is an orally administered, irreversible antagonist of BTK which inhibits signal transduction until the protein is naturally degraded. Evobrutinib is designed to inhibit primary B cell responses such as proliferation and antibody and cytokine release, without directly affecting T cells. Evobrutinib is currently undergoing Phase III clinical trials for the treatment of Multiple Sclerosis.

#### ICP-022: Beijing InnoCare Pharma Tech

ICP-022 (Orelabrutinib) is an orally available potent BTK inhibitor that irreversibly binds to BTK to induce downstream kinase inactivation and cell death. Orelabrutinib was designed with a single ring at the scaffold center instead of a fused bi-cycle core. BTK, a key kinase in the B cell receptor signaling pathway, plays important roles in the development and function of B cells, macrophages, and microglia, which are involved in the immunopathological characteristics of MS.

#### LOU064: Novartis

LOU064 (Remibrutinib) is an oral Bruton's tyrosine kinase (BTK) inhibitor developed by Novartis. In studies, LOU064 inhibits BTK activity with an IC<sub>50</sub> value of 0.023  $\mu$ M in blood. The drug is currently in phase II stage of development for the treatment of chronic spontaneous urticarial and Sjögren's syndrome and in Phase I clinical studies for the treatment of Atopic diathesis/Atopic dermatitis.

#### TG 1701: TG therapeutics

TG-1701 is an investigational oral, once-daily BTK inhibitor that irreversibly binds to and inhibits Bruton's tyrosine kinase (BTK), a crucial driver of B-cell proliferation. B-cell

receptor (BCR) signaling drives normal B-cell development and supports the growth and survival of malignant B-cells. Targeting BTK has been validated as an important therapeutic strategy for select B-cell malignancies including CLL and NHL. Phase II clinical trials are being carried by Reistone Biopharma for SHR-1459 in the treatment of Neuromyelitis optica. A phase 1 study evaluating TG-1701 as a single agent alone and in combination with ublituximab and umbralisib in patients with CLL and NHL is ongoing by TG therapeutics.

Further product details are provided in the report.....

### Bruton's Tyrosine Kinase (BTK) Inhibitor: Therapeutic Assessment

This segment of the report provides insights about the different Bruton's Tyrosine Kinase (BTK) Inhibitor drugs segregated based on following parameters that define the scope of the report, such as:

#### Major Players working on Bruton's Tyrosine Kinase (BTK) Inhibitor

There are approx. 30+ key companies which are developing the Bruton's Tyrosine Kinase (BTK) Inhibitor. The companies which have their Bruton's Tyrosine Kinase (BTK) Inhibitor drug candidates in the most advanced stage, i.e. phase III include, Sanofi.

#### Phases

DelveInsight's report covers around 30+ products under different phases of clinical development like

Late-stage products (Phase III and

Mid-stage products (Phase II and

Early-stage products (Phase I/II and Phase I) along with the details of

Pre-clinical and Discovery stage candidates

Discontinued & Inactive candidates

## Route of Administration

Bruton's Tyrosine Kinase (BTK) Inhibitor pipeline report provides the therapeutic assessment of the pipeline drugs by the Route of Administration. Products have been categorized under various ROAs such as

Oral

Topical.

## Molecule Type

Products have been categorized under various Molecule types such as

Small molecule

Skin disorder therapy

Anti-inflammatory

Antineoplastic

Antirheumatics

## Product Type

Drugs have been categorized under various product types like Mono, Combination and Mono/Combination.

## Bruton's Tyrosine Kinase (BTK) Inhibitor: Pipeline Development Activities

The report provides insights into different therapeutic candidates in phase II, I, preclinical and discovery stage. It also analyses Bruton's Tyrosine Kinase (BTK) Inhibitor therapeutic drugs key players involved in developing key drugs.

## Pipeline Development Activities

The report covers the detailed information of collaborations, acquisition and merger, licensing along with a thorough therapeutic assessment of emerging Bruton's Tyrosine Kinase (BTK) Inhibitor drugs.

## Report Highlights

The companies and academics are working to assess challenges and seek opportunities that could influence Bruton's Tyrosine Kinase (BTK) Inhibitor R&D. The therapies under development are focused on novel approaches for Bruton's Tyrosine Kinase (BTK) Inhibitor.

## Bruton's Tyrosine Kinase (BTK) Inhibitor Report Insights

Bruton's Tyrosine Kinase (BTK) Inhibitor Pipeline Analysis

Therapeutic Assessment

Unmet Needs

Impact of Drugs

## Bruton's Tyrosine Kinase (BTK) Inhibitor Report Assessment

Pipeline Product Profiles

Therapeutic Assessment

Pipeline Assessment

Inactive drugs assessment

Unmet Needs

## Key Questions

## Current Scenario and Emerging Therapies:

How many companies are developing Bruton's Tyrosine Kinase (BTK) Inhibitor drugs?

How many Bruton's Tyrosine Kinase (BTK) Inhibitor drugs are developed by each company?

How many emerging drugs are in mid-stage, and late-stage of development for Bruton's Tyrosine Kinase (BTK) Inhibitor?

What are the key collaborations (Industry–Industry, Industry–Academia), Mergers and acquisitions, licensing activities related to the Bruton's Tyrosine Kinase (BTK) Inhibitor therapeutics?

What are the recent trends, drug types and novel technologies developed to overcome the limitation of existing therapies?

What are the clinical studies going on for Bruton's Tyrosine Kinase (BTK) Inhibitor and their status?

What are the key designations that have been granted to the emerging drugs?

## Key Players

Sanofi

Merck

Beijing InnoCare Pharma Tech

Hoffman-La-Roche

BeiGene

Principia Biopharma

Janssen

AstraZeneca

Sorrento Therapeutics

Novartis

Zhejiang DTRM Biopharma

Merck Sharp & Dohme

TG therapeutics

AbbVie

Telios Pharma

Taiho Pharmaceutical

Gilead Sciences

Aptose Biosciences

Sinomab

Nurix

Biogen

Carna Biosciences

Eli Lilly and Company

## Key Products

Tolebrutinib



Evobrutinib

ICP-022

RG7845

Zanubrutinib

PRN-1008

Imbruvica

Acalabrutinib

Abivertinib

LOU064

DTRM-555

MK-1026

TG-1701

ABBV-599

TL 895

TAS 5315

Tirabrutinib

Luxepatinib

SN1011

NX-2127

BIIB091

AS-0871

## Contents

Introduction

Executive Summary

Bruton's Tyrosine Kinase (BTK) Inhibitor: Overview

Structure

Mechanism of Action

Pipeline Therapeutics

Comparative Analysis

Therapeutic Assessment

Assessment by Product Type

Assessment by Stage and Product Type

Assessment by Route of Administration

Assessment by Stage and Route of Administration

Assessment by Molecule Type

Assessment by Stage and Molecule Type

Bruton's Tyrosine Kinase (BTK) Inhibitor – DelveInsight's Analytical Perspective

In-depth Commercial Assessment

Bruton's Tyrosine Kinase (BTK) Inhibitor companies' collaborations, Licensing,  
Acquisition -Deal Value Trends

Bruton's Tyrosine Kinase (BTK) Inhibitor Collaboration Deals

Company-Company Collaborations (Licensing / Partnering) Analysis

Company-University Collaborations (Licensing / Partnering) Analysis

Late Stage Products (Phase III)

Comparative Analysis

Tolebrutinib: Sanofi

Product Description

Research and Development

Product Development Activities

Drug profiles in the detailed report.....

Mid Stage Products (Phase II)

Comparative Analysis

LOU064: Novartis

Product Description

Research and Development

Product Development Activities

Drug profiles in the detailed report.....

Early Stage Products (Phase I)

Comparative Analysis

**SN1011: Sinomab**

Product Description

Research and Development

Product Development Activities

Drug profiles in the detailed report.....

Pre-clinical and Discovery Stage Products

Comparative Analysis

**KBP-7536: KBP Biosciences**

Product Description

Research and Development

Product Development Activities

Drug profiles in the detailed report.....

Inactive Products

Comparative Analysis

Bruton's Tyrosine Kinase (BTK) Inhibitor Key Companies

Bruton's Tyrosine Kinase (BTK) Inhibitor Key Products

Bruton's Tyrosine Kinase (BTK) Inhibitor- Unmet Needs

Bruton's Tyrosine Kinase (BTK) Inhibitor- Market Drivers and Barriers

Bruton's Tyrosine Kinase (BTK) Inhibitor- Future Perspectives and Conclusion

Bruton's Tyrosine Kinase (BTK) Inhibitor Analyst Views

Bruton's Tyrosine Kinase (BTK) Inhibitor Key Companies

Appendix

## List Of Tables

### LIST OF TABLES

Table 1 Total Products for Bruton's Tyrosine Kinase (BTK) Inhibitor

Table 2 Late Stage Products

Table 3 Mid Stage Products

Table 4 Early Stage Products

Table 5 Pre-clinical & Discovery Stage Products

Table 6 Assessment by Product Type

Table 7 Assessment by Stage and Product Type

Table 8 Assessment by Route of Administration

Table 9 Assessment by Stage and Route of Administration

Table 10 Assessment by Molecule Type

Table 11 Assessment by Stage and Molecule Type

Table 12 Inactive Products

## List Of Figures

### LIST OF FIGURES

Figure 1 Total Products for Bruton's Tyrosine Kinase (BTK) Inhibitor

Figure 2 Late Stage Products

Figure 3 Mid Stage Products

Figure 4 Early Stage Products

Figure 5 Preclinical and Discovery Stage Products

Figure 6 Assessment by Product Type

Figure 7 Assessment by Stage and Product Type

Figure 8 Assessment by Route of Administration

Figure 9 Assessment by Stage and Route of Administration

Figure 10 Assessment by Molecule Type

Figure 11 Assessment by Stage and Molecule Type

Figure 12 Inactive Products

## I would like to order

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