Meds Pipeline Monitor 2026

NPDUIS – National Prescription Drug Utilisation Information System

Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Canada

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About the PMPRB

The Patented Medicine Prices Review Board (PMPRB) is a quasi-judicial body responsible for protecting Canadians from patent abuse related to patented medicine prices. To do so, the PMPRB reviews the prices of these medicines and intervenes as necessary in the form of a hearing, during which a panel might determine that the prices are excessive.

The PMPRB also contributes to a greater understanding of the biopharmaceutical ecosystem by publishing annual reports on trends in sales, pricing, and research and development spending.

Additionally, the PMPRB provides neutral, relevant, and timely ad hoc analysis on pharmaceutical trends, at the Minister's request.

The NPDUIS Research Initiative

The National Prescription Drug Utilization Information System (NPDUIS) research initiative was established by federal, provincial, and territorial Ministers of Health in September 2001. It is a partnership between the PMPRB and the Canadian Institute for Health Information (CIHI).

Pursuant to section 90 of the Patent Act and at the request of the Minister of Health, the PMPRB has the mandate to provide the Minister with analysis that provides decision makers with critical information and intelligence on price, utilization, and cost trends so that Canada's healthcare system has more comprehensive and accurate information on how medicines are being used and on sources of cost pressures.

The Minister of Health establishes the general content of the reports to be provided, and the specific research priorities for the NPDUIS research initiative are established with the guidance of the NPDUIS Advisory Committee and reflect the information needs of the participating jurisdictions. The Advisory Committee is composed of representatives from public drug plans in British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, Yukon, the Non-Insured Health Benefits Program (NIHB), and Health Canada. It also includes observers from CIHI, Canada's Drug Agency (CDA), the *Ministère de la Santé et des Services sociaux du Québec* (MSSS), and the pan-Canadian Pharmaceutical Alliance (pCPA) Office.

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Appreciation goes to Brian O'Shea for leading this project with editorial contributions from Shirin Paynter, and to Étienne Gaudette and Kevin Pothier for their oversight in the development of the report.

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In addition, the PMPRB has not independently verified nor endorses the accuracy of any third-party information or third-party opinions or designations in this report including information about pricing, therapeutic effectiveness, sales volume, cost effects, market characteristics, competitor products, regulatory status and other similar information.

Executive Summary

The *Meds Pipeline Monitor* (MPM) is a horizon scanning report that features a selection of new medicines undergoing clinical evaluation or in pre-registration that may gain market authorization in Canada in the future.

This edition features a reorganization of the report sections to emphasize medicines expected to make Canadian market entry in the near future.

The report collects data from two main sources: Health Canada's Drug and Health Product Submissions Under Review (SUR) Lists, which provide information on medicines currently under review in Canada, and GlobalData's Drugs database, which identifies medicines currently undergoing clinical evaluation.

Highlights of the Meds Pipeline Monitor 2026

- Oncology medicines continued to dominate the therapeutic mix in 2025, as was the case in previous editions. Cancer treatments represented 40% of medicines across all stages of development. Medicines for metabolic disorders made up 5% of the overall pipeline but 13% of the drugs in pre-registration.
- As of August 2025, the pipeline contained 10,501 new medicines across all stages of clinical development. The later stages of the pipeline had 200 medicines in pre-registration.
- Orphan medicines continued to be well-represented in the later stages of the pipeline, making up 23% of medicines in Phase III clinical trials and 24% in pre-registration.
- Five new medicines under priority review by Health Canada are featured in the Spotlight on Canada section of this report (Table 4).
- Twenty-four new medicines were selected for the 2026 new medicines list (Table 7) from the pipeline of new medicines in Phase III or pre-registration.
- Of 43 medicines which had been featured in the previous edition (MPM 2023), 11 have since received market authorization (Table 5), 26 were retained on this year's list as they continued to satisfy the selection criteria (Table 6), and six were removed as their clinical trials were discontinued or they no longer meet the selection criteria.

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List of Terms

For the purposes of this report, the following terms and associated definitions apply.

CELL THERAPY: The transplantation of human cells to replace or repair damaged tissue and/or cells.

CLINICAL EFFICACY: The maximum response achievable from a medicine in research settings and the capacity for sufficient therapeutic effect in clinical settings.[i]

GENE THERAPY: A technique for the treatment of genetic disease in which a gene that is absent or defective is replaced by a healthy gene, as defined by Health Canada.[ii]

MARKET AUTHORIZATION: The process of approval for a medicine to be marketed in a given country. In Canada, market approval is granted following a substantive scientific evaluation of a product's safety, efficacy, and quality, as required by the *Food and Drugs Act* and *Regulations*.[iii]

MEDICINAL INGREDIENT: A chemical or biological substance responsible for the claimed pharmacologic effect of a drug product. Sometimes referred to as a molecule, active substance, or active ingredient.[iv]

MEDICINE: A broad term encompassing both the final drug product and medicinal ingredient(s); this encompasses chemically manufactured active substances and biologics, including gene therapies. Medicines are reported at the medicinal ingredient level and can refer to a single ingredient or a unique combination of ingredients.

NEW MEDICINE: A medicinal ingredient that has not previously received market authorization by a regulator.[iv]

ORPHAN MEDICINE: A medicine used to treat a rare disease. For the purposes of this study, orphan medicine designations are sourced from GlobalData Healthcare's Drugs database, which tracks orphan designations granted by the US Food and Drug Administration (FDA), European Medicines Agency (EMA), United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA), or Japan Ministry of Health, Labour and Welfare (MHLW). For the select medicines featured in Table 7, which have a drug geography of either Canada, the US, or Europe (excluding Russia and Türkiye), orphan designations granted by the FDA or EMA are noted.

i Holford NHG, Sheiner LB. 1981. *Understanding the dose-effect relationship: Clinical application of pharmacokinetic-pharmacodynamic models.* Clin. Pharmacokinet. 6 (6): 429–453. doi: 10.2165/00003088-198106060-00002.

ii https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/health-canada-clinical-trials-database/glossary.html

iii https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products.html

iv https://www.canada.ca/en/patented-medicine-prices-review/services/npduis/analytical-studies/resources/glossary-npduis.html

PHASES OF CLINICAL TRIALS

PHASE I: These trials test an experimental medicine on a small group of people for the first time. The purpose is to look at the medicine's safety, determine a safe dosage range, and monitor if there are any side effects.

PHASE II: In this phase, the medicine is given to a larger group of people (usually 100 or more) to gather data on how well the medicine works to treat a disease or condition, check its safety on a wider range of people, and determine the best dose.[v]

PHASE III: These controlled or uncontrolled trials are conducted after preliminary evidence suggesting efficacy of the medicine has been demonstrated. They are intended to gather additional and confirmatory information about the clinical efficacy and safety of the medicine under the proposed conditions of use.[ii] Phase III trials are usually randomized with double-blind testing in several hundred to several thousand patients.

PRE-REGISTRATION: A medicine is in the pre-registration phase once all the necessary clinical trials have been completed and it is waiting for registration or approval for use by a governing body.[vi]

v https://www.canada.ca/en/health-canada/services/clinical-trials.html

vi http://www.appliedclinicaltrialsonline.com/are-phase-labels-still-relevant

Introduction

This edition of the *Meds Pipeline Monitor* (MPM) features a selection of new medicines in Phase III clinical trials or pre-registration that may gain market approval in Canada in the future.

The 2026 edition has been reorganized to emphasize medicines expected to enter the Canadian market in the near future. The Spotlight on Canada section appears immediately after the Snapshot of the Pipeline in 2025. It is followed by the table of pipeline medicines from the previous edition that have gained market authorization in the US or Europe, and then the update on medicines still in the pipeline that have been retained from previous editions. Lastly, the selected new medicines for 2026 make their debut in the final table before the appendix.

The methodology, which is detailed in the next section, uses a specific set of criteria to identify a list of new medicines in the pipeline from GlobalData Healthcare's Drugs database, as well as a list of medicines currently under review from Health Canada's Drug and Health Product Submissions Under Review (SUR) Lists. The new medicines listed in this report are selected based on a review of the literature and clinical trial outcomes[vii] to determine if the medicine addresses an unmet therapeutic need, offers a novel mechanism of action or therapeutic benefit over existing therapies, or treats a serious condition. Medicines reported on in previous editions are also reviewed and updated with newly published clinical trial results, additional regulatory designations, or other relevant developments. Additionally, this report provides an update on the medicines in the previous edition that have since received market authorization by either Health Canada, the US Food and Drug Administration (FDA), or the European Medicines Agency (EMA). New medicines selected for this report will likewise be monitored in future editions as they move through the development pipeline.

To provide context for the selection of medicines, the Snapshot of the Pipeline reports on the total number of medicines available in the global drug development pipeline, and includes a comparison with the snapshots from previous editions of the *Meds Pipeline Monitor* published from September 2021 to August 2025.

The *Meds Pipeline Monitor* is a companion publication to *Meds Entry Watch*, which analyzes medicines that received first-time approval from the US FDA, the EMA, and/or Health Canada. Together, these two PMPRB reports monitor the market continuum of late-stage pipeline medicines and new approvals, providing decision makers, researchers, patients, clinicians, and other stakeholders with information on the emerging medicines and evolving cost pressures.

vii The PMPRB does not independently assess or verify the quality or accuracy of any outcomes or claims reported in the literature or clinical trials.

Methodology

Snapshot of the Pipeline

The snapshot of the global pipeline identifies the composition of medicines in various phases of clinical development. For this analysis, a full list of pipeline medicines across all geographic areas was retrieved from GlobalData's Drugs database on March 18, 2025 and the selected medicine candidates for this year's report have been refreshed as of August 13, 2025.

New medicinal ingredients are identified as those with no prior approvals through Health Canada, the US FDA or the EMA. The distribution of new medicines by therapeutic area corresponds to the indication under evaluation, as reported by GlobalData. Note that a single new medicine may be undergoing multiple clinical studies for separate indications.

Metrics include a comparison of the number of drugs in each clinical phase of development and a breakdown of the various therapeutic areas for each phase.

Spotlight on Canada

Health Canada's Drug and Health Product Submissions Under Review (SUR) Lists are assessed using a modified approach to the selection criteria to focus on medicines that may gain market authorization in Canada in the near term. The lists used in this edition are current to July 31, 2025.

Medicines listed in the SUR include new drug submissions containing medicinal ingredients that have not been approved in Canada for any indication, in any strength or form. Unlike the selection of medicines identified in the pipeline lists, these medicines may have previously received market authorization through the US FDA or the EMA.

Additional descriptive information

The profile of each medicine under review includes the key attributes listed in Table 2, the indication and mechanism of action (sourced from the GlobalData Drugs database), as well as a summary of applicable published outcomes from clinical trials.

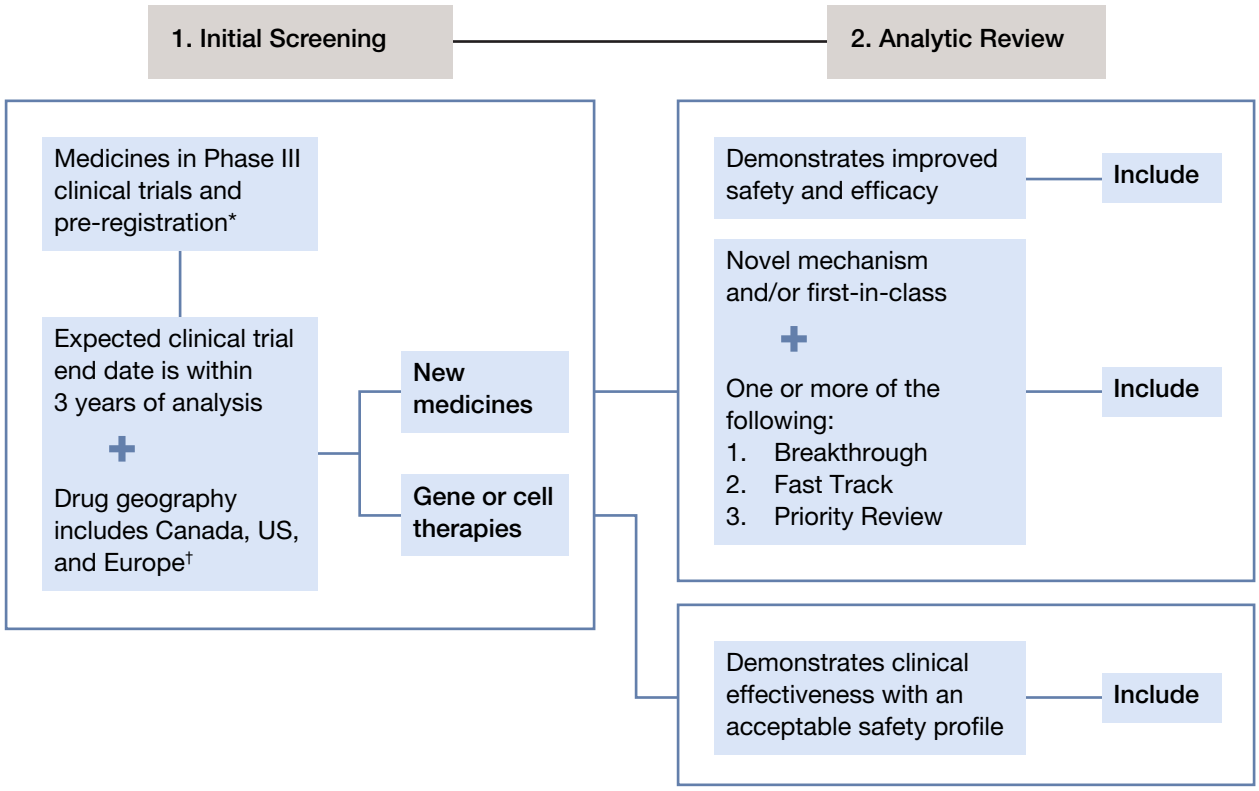
Although FDA designations for expedited development or review are not a selection criteria for this list, relevant Breakthrough, Fast Track, and Priority Review designations as noted in Table 1 are indicated where available.

Indications, therapeutic areas, mechanism of action and other information correspond to the information provided by GlobalData. The scientific description and key attributes provided are focused on the specified indication(s) for the selected medicine. For medicines under review for multiple indications, the primary indication is used.

Pipeline Medicines 2026

The selected new medicines are chosen from the list of medicines in Phase III clinical trials or pre-registration in at least one of Canada, the United States, and Europe. Many of the pipeline candidates are first-in-class or represent novel mechanisms for treatment in a specific therapeutic area. Pipeline medicines are selected for inclusion using a two-stage process (Figure 1). The initial screening stage selects medicines in the late phases of clinical evaluation, while the analytic review stage involves a more rigorous appraisal of each potential candidate based on the selection criteria in Table 1.

Figure 1. Selection process for medicines featured in the *Meds Pipeline Monitor*



* In pre-registration with the US Food and Drug Administration (FDA).

† Has Phase III clinical trials in Canada, the United States, or geographic Europe (excluding Russia and Türkiye).

Stage 1: Initial screening

GlobalData's Drugs database is used to identify a list of medicines undergoing Phase III clinical trials or in pre-registration. These medicines serve as the basis for the initial screening stage.

The drug geography, defined as the geographical region or country in which the medicine is either marketed or in pipeline development, is restricted to Canada and other countries with similar regulatory and approval processes: the US and geographic Europe excluding Russia and Türkiye. Only new medicinal ingredients with reported data claiming increased efficacy and safety from clinical trials are considered as candidates for inclusion.

Medicines approved or sold in Canada, the US, or Europe for any other indication or in any other strength or formulation are excluded during the selection process, as are medicines whose clinical trials are inactive, suspended, withdrawn, or terminated.

Stage 2: Analytic screening

Selection criteria

Following the initial screening, the second stage of the process considers a number of selection criteria to determine the final list of pipeline candidates. These criteria are detailed in Table 1.

Earlier phases of the pipeline (i.e., Phase II) are also examined to determine if there are other medicines with the same indication or mechanism of action as the selected candidates in Phase III and pre-registration. This provides additional information on the number of medicines that are undergoing clinical evaluation in Phase II that may influence the therapeutic significance of the selected candidates in Phase III and pre-registration.

Table 1. Selection criteria for the Meds Pipeline Medicines list

Selection Criteria
Improved safety and efficacy claimed in clinical trials: a medicine with reported clinical trial data claiming increased safety, new outcome measures, or increased life expectancy or quality of life
Novel mechanism/First-in-class: a medicine that uses a new mechanism of biochemical interaction to produce a medical effect, or a medicine that would be the first in its therapeutic class if granted market authorization In addition, **the medicine must fall into one or more of the three following FDA designations** for expedited development and review:
Breakthrough – medicines intended to treat a serious condition and for which preliminary clinical evidence is accompanied by a claim that they may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s) **Fast Track –** medicines used to treat serious conditions and fill an unmet medical need
Priority Review – medicines that would provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications
Gene or cell therapy: a technique for the treatment of genetic disease in which a gene that is absent or defective is replaced by a healthy gene; or the transplantation of human cells to replace or repair damaged tissue and/or cells

Additional descriptive information

A profile of each successful pipeline candidate is provided, including the indication and mechanism of action, as well as a summary of the applicable published outcomes claimed in clinical trials. Specific attributes of each medicine are also identified. Table 2 provides a detailed description of these key attributes.

Table 2. Key attributes of new medicines selected for the *Meds Pipeline Monitor*

Attributes	Data Sources
Phase III clinical trials in Canada	GlobalData Drugs database; Health Canada Clinical Trials Database; Health Canada Drug and Health Product Submissions Under Review; National Institutes of Health (NIH) Clinical Trial Registry
Rare or orphan designation	GlobalData Drugs database, FDA orphan drug designations and approvals, EMA orphan designations
Biologic medicine	

The indications and therapeutic areas of the featured medicines correspond to their Phase III clinical trial or pre-registration stage. A single clinical trial may assess multiple indications within the same therapeutic area. These medicines may also have additional indications at various phases of clinical evaluation that are not mentioned in this report. The scientific description and key attributes provided are focused on the specified indication(s) for the selected medicines.

Medicines reported for a given year are reassessed for each following edition of the MPM. They may be retained on the MPM list if they continue to meet the selection criteria. Medicines for which clinical trials have been discontinued or for which the selection criteria is no longer met are not reported in subsequent editions.

Data Sources

The GlobalData Drugs database is the primary data source for the identification of pipeline medicines and their corresponding clinical information. GlobalData tracks medicines from pre-clinical discovery, through clinical trials, to market launch and subsequent sales. The database is a comprehensive resource of medicines under various stages of clinical development. Search capabilities allow for controlled selection of specific attributes, including but not limited to the following: phase of clinical development, therapeutic area, molecule type, indication, drug geography, mechanism of action, and regulatory designations.

Health Canada's Drug and Health Product Submissions Under Review (SUR) Lists are used to determine the featured selection of new medicines currently undergoing review by Health Canada. The SUR is a publicly available set of lists that identify pharmaceutical and biologic drug submissions containing new medicinal ingredients not previously approved in Canada that have been accepted for review. This applies to submissions accepted on or after April 1, 2015.

As this selection is restricted to new medicines, additional sources of information are cross-referenced to confirm that the candidates have not previously been approved or sold. These include recorded sales data from the IQVIA MIDAS® Database (all rights reserved); regulatory approval records from the National Institutes of Health (NIH), US FDA, the EMA, and Health Canada; and information in Health Canada's Clinical Trials database and ClinicalTrials.org.

Limitations

Unless otherwise specified, the featured lists capture the composition of the pipeline as of August 2025. Due to the unpredictability and fast-moving nature of pipeline medicines entering the market, some of the medicines listed in this edition may have been approved or marketed in Canada, the US, or Europe prior to this report's publication. Pipeline medicines that have not been included in this report due to the timing of the selection may presently meet the selection criteria; these, along with the rest of the drug pipeline, will be considered for the next edition.

This report captures a snapshot of the global pipeline. Although it is assumed to be representative of the composition of medicines over the entire year, the pipeline is fairly dynamic even within the same year. It is not possible to predict what year a product will be marketed in Canada, or if it will obtain approval in Canada at all, regardless of its status in other countries.

The selection of pipeline medicines for Table 7 is restricted to medicines under development for market in Canada, the US, and Europe. These medicines are not removed from consideration even if they have received market authorization elsewhere.

Absence of a pipeline medicine from this report should not be taken as an evaluation of its clinical effectiveness.

Some of the selected pipeline medicines may be undergoing clinical trials for additional indications; this analysis only reports on indications in the later stages of development (Phase III clinical trials or pre-registration with the US FDA) that satisfy the selection criteria set out in the methodology.

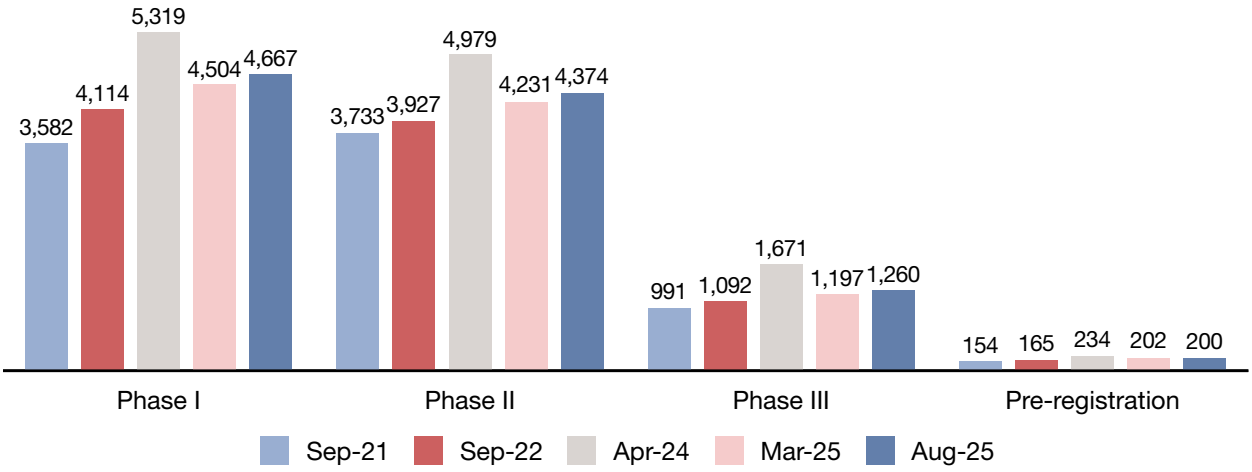
For each selected pipeline medicine, the primary manufacturer(s) and trade name, if available, are given along with the indication. In some cases, additional manufacturers, including subsidiaries, may also be involved in the development of the medicine with the primary companies, or other manufacturers may be developing the same medicine for other indications.

Snapshot of the Pipeline in 2025

The global pharmaceutical development pipeline in August 2025 had 10,501 new medicines undergoing clinical development, a decrease from the total observed in April 2024 but in line with the snapshots taken from previous years.

Figure 2 provides a comparison of pipeline snapshots taken since 2021, showing a breakdown of new medicinal ingredients not already marketed in each phase of clinical development. While the size of the pipeline is similar in Phase I and Phase II, a much smaller number of new medicines are studied in Phase III trials, with an even smaller group in pre-registration after completing required trials. The selected new medicines for this edition, as well as the medicines retained from the *Meds Pipeline Monitor 2023*, are among the 1,460 medicines in these two advanced stages of development.

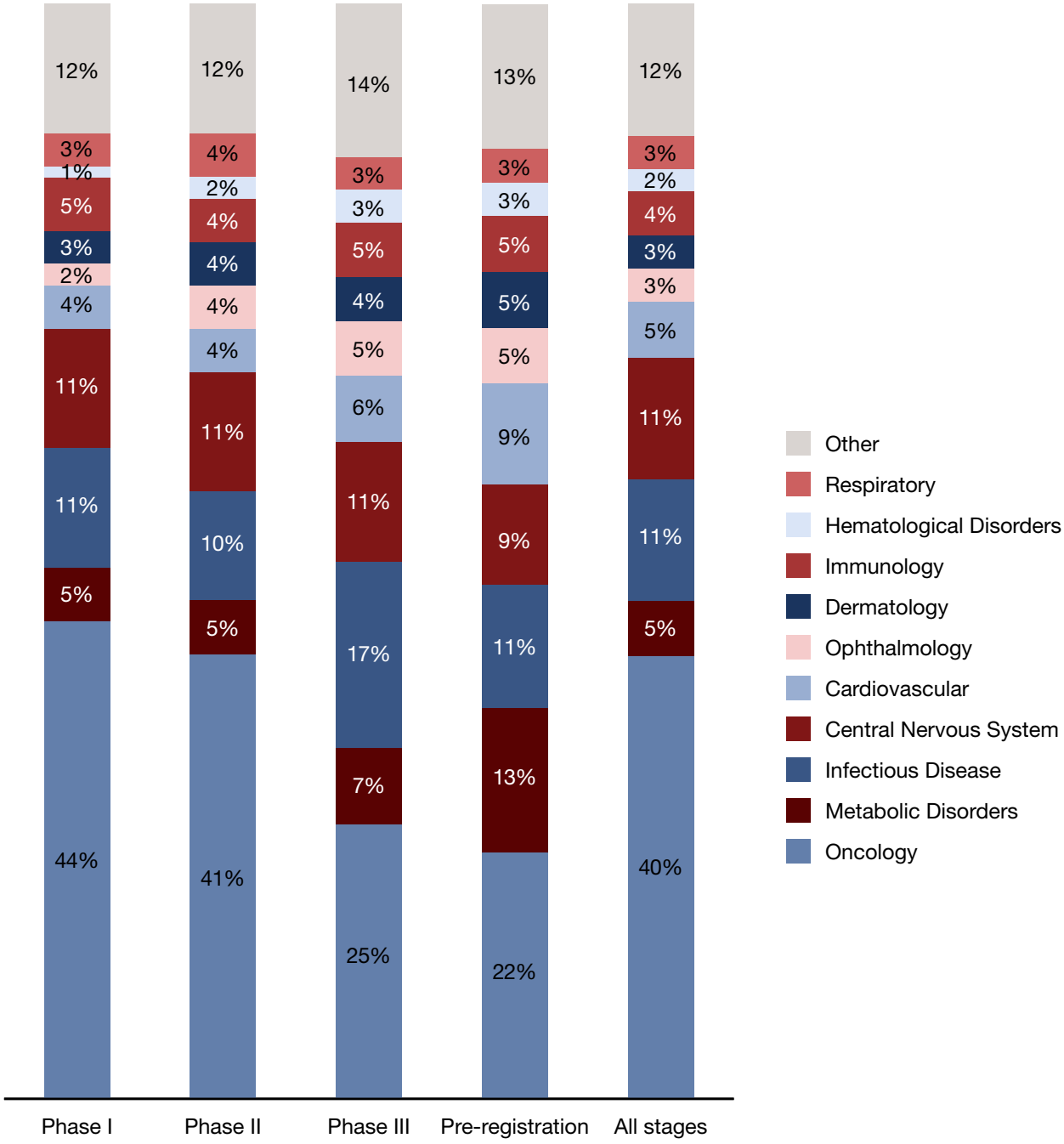
Figure 2. Number of new medicines by highest stage of development in snapshots taken from 2021 to 2025



Data source: GlobalData Drugs database (accessed 2021–2025); IQVIA MIDAS© Database.

Figure 3 illustrates the distribution of new medicines by therapeutic area from Phase I through to pre-registration. Oncology continues to be the most common therapeutic area for new drugs, accounting for 40% of the entire pipeline, and 22% of the pre-registration phase. Infectious disease medicines are the next most common class, having held second place since the 2020 snapshot. Central nervous system drugs complete the top three. While making up just 5% of the total pipeline, drugs for metabolic disorders make up a disproportionate 13% of drugs in pre-registration.

Figure 3. Therapeutic class distribution of new medicines by highest stage of development, 2025



Data source: GlobalData Drugs database (accessed August 2025).

Table 3a shows the indications with the most drugs in development selected from the top 10 largest therapeutic areas in pre-registration. For some therapeutic areas without enough instances of multiple drugs under development for the same indication, a selection was chosen to illustrate the breadth of development in that area. Table 3b shows the most common Phase III indications for these same areas.

Table 3a. Top indications for major therapeutic areas in pre-registration, 2025

Therapeutic area (% of pre-registration stage)	Indication	Medicines
Oncology (22%)	Unspecified cancer	9
	Human epidermal growth factor receptor-2-negative breast cancer (HER2– breast cancer)	4
	Non-small cell lung cancer	4
Metabolic disorders (13%)	Type 2 diabetes	8
	Diabetes	3
	Hyperlipidemia	3
Infectious disease (11%)	Unspecified influenza virus infections	3
	Influenza virus A infections	2
	Rabies	2
Central nervous system (9%)	Alzheimer's disease	2
	Insomnia	2
	Post-operative pain	2
Cardiovascular (9%)	Hypertension	3
	Critical limb ischemia	2
	Unspecified cardiovascular disorders	2
Ophthalmology (5%)	Keratoconjunctivitis sicca (dry eye)	3
	Glaucoma	2
	Wet (neovascular / exudative) macular degeneration	2
Dermatology (5%)	Unspecified dermatological disorders	3
	Acne vulgaris	2
	Atopic dermatitis (atopic eczema)	2
Immunology (5%)	Plaque psoriasis (psoriasis vulgaris)	5
	Myasthenia gravis	1
	Hereditary angioedema (HAE) (C1 esterase inhibitor [C1-INH] deficiency)	1
Hematological disorders (3%)	Anemia in chronic kidney disease (renal anemia)	2
	Idiopathic thrombocytopenic purpura (immune thrombocytopenic purpura)	2
	Fanconi anemia	1
Respiratory (3%)	Chronic obstructive pulmonary disease (COPD)	1
	Idiopathic pulmonary fibrosis	1
	Streptococcal pneumonia	1

Data source: GlobalData Drugs database (accessed August 2025).

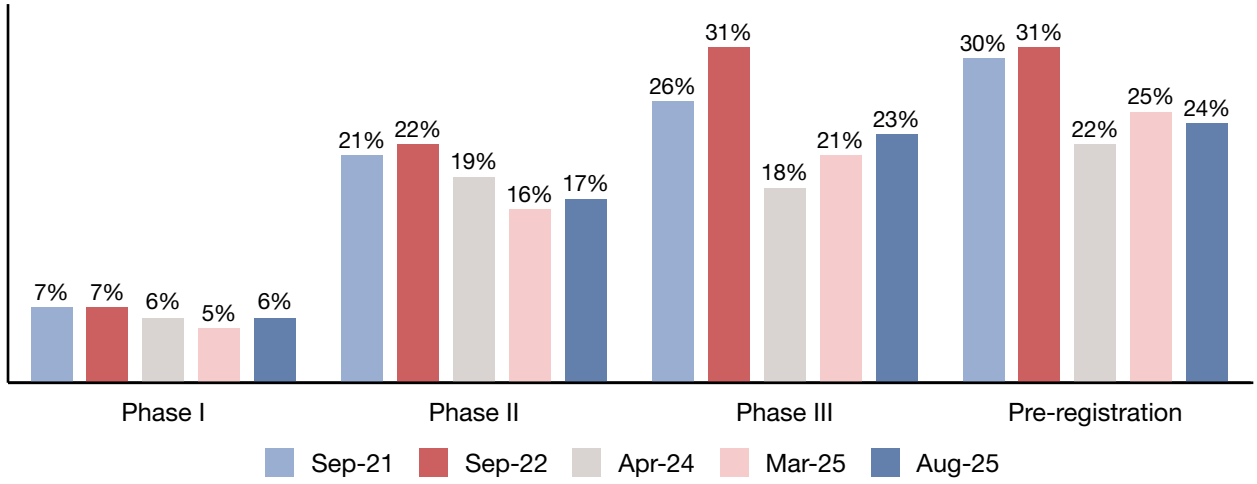
Table 3b. Top indications for major therapeutic areas in Phase III, 2025

Therapeutic area (% of pre-registration stage)	Indication	Medicines
Oncology (25%)	Non-small cell lung cancer	45
	Adenocarcinoma of the gastroesophageal junction	19
	Human epidermal growth factor receptor-2-negative breast cancer (HER2– breast cancer)	16
Metabolic disorders (7%)	Type 2 diabetes	28
	Obesity	14
	Type 1 diabetes (juvenile diabetes)	8
Infectious disease (17%)	Coronavirus disease 2019 (COVID-19)	69
	Diphtheria	6
	Poliomyelitis	6
Central nervous system (11%)	Alzheimer's disease	12
	Post-operative pain	10
	Major depressive disorder	9
Cardiovascular (6%)	Idiopathic (essential) hypertension	18
	Acute ischemic stroke	16
	Hypertension	6
Ophthalmology (5%)	Keratoconjunctivitis sicca (dry eye)	15
	Wet (neovascular / exudative) macular degeneration	7
	Diabetic macular edema	4
Dermatology (4%)	Atopic dermatitis (atopic eczema)	16
	Acne vulgaris	6
	Androgenic alopecia	4
Immunology (5%)	Plaque psoriasis (psoriasis vulgaris)	11
	Hereditary angioedema (HAE) (C1 esterase inhibitor [C1-INH] deficiency)	7
	Myasthenia gravis	4
Hematological disorders (3%)	Hemophilia A (factor VIII deficiency)	7
	Idiopathic thrombocytopenic purpura (immune thrombocytopenic purpura)	6
	Paroxysmal nocturnal hemoglobinuria	3
Respiratory (3%)	Chronic obstructive pulmonary disease (COPD)	7
	Asthma	5
	Streptococcal pneumonia	5

Data source: GlobalData Drugs database (accessed August 2025).

Orphan medicines, as denoted in GlobalData's Drugs database, accounted for an increasing share of each successive stage of the global pipeline in 2025, as shown in Figure 4. In the most recent snapshot, 24% of medicines in pre-registration and 23% in Phase III had received an orphan designation. Information on orphan medicines emerging from the pipeline can be found in the companion publication *Meds Entry Watch,* which tracks orphan designations for medicines receiving first-time approval from either Health Canada, the FDA, or EMA.[1]

Figure 4. Share of orphan medicines in the pipeline by highest phase of clinical evaluation, 2021–2025



Data source: GlobalData Drugs database (accessed 2021–2025); IQVIA MIDAS© Database.

Spotlight on Canada: Medicines under Review

This section includes a list of medicines under priority review by Health Canada that may gain market authorization in Canada in the near term. Medicines included on this list are new to Canada but may have been approved in other countries.

Table 4 highlights five medicines currently on Health Canada's Drug and Health Product Submissions Under Review (SUR) lists as of July 2025. Of the six medicines under review reported on in the 2023 edition, all but one have since received market authorization from Health Canada. The activated phosphoinositide 3-kinase delta syndrome (APDS) treatment leniolisib remains under priority review by Health Canada, as shown in the table.

Table 4. Selected new medicines currently under review by Health Canada, 2025

Selection Criteria			Key Attributes					
Increased safety and efficacy	Novel mechanism	Gene or cell therapy	Break-through	Fast Track	Priority Review	Clinical trials in Canada	Rare or orphan designation	Biologic medicine

Medicine (Trade Name) Company	Anticipated Indication(s)[†]	Description and Key Attributes
Immunological Disorders		
Leniolisib **Joenja (U.S.)** Pharming Technologies BV	Activated phosphoinositide 3-kinase delta syndrome (APDS)	• It is a phosphatidylinositol 4,5-bisphosphate 3-kinase catalytic subunit delta isoform inhibitor. • Administered orally. • Approved by the US FDA (Joenja; March 24, 2023) for the treatment of activated phosphoinositide 3-kinase delta syndrome.[2] • European Medicines Agency (EMA) review is ongoing.[3] **CLINICAL TRIALS** • Based on an interim analysis of an ongoing open-label, single-arm extension study, it was well tolerated and maintained durable outcomes with up to 5 years of exposure in 37 patients with APDS.[4] • A follow-up study tracking 6 patients from the original leniolisib dose-finding trial found positive and enduring changes over 6 years, supporting the use of leniolisib as long-term therapy for APDS in appropriate patients.[5] • There is one other drug in development for the same indication, but it is not yet in Phase II.

Medicine (Trade Name) Company	Anticipated Indication(s)[†]	Description and Key Attributes
Infectious Diseases		
Imipenem, cilastatin, and relebactam **Recarbrio (U.S., EU)** Merck Canada Inc.	Infections caused by gram-negative bacteria	• It is an inhibitor of beta lactamase, dipeptidyl peptidase 1, and penicillin binding protein. • Administered intravenously. • Approved by the US FDA (Recarbrio, 2019) for the treatment of complicated urinary tract and intra-abdominal infections caused by susceptible gram-negative bacteria.[6] • Approved by the EMA on February 13, 2020 for the treatment of hospital-acquired pneumonia, bacteraemia as a complication of pneumonia, and infections caused by Gram-negative bacteria.[7] **CLINICAL TRIALS** • A review of eight trials featuring imipenem, cilastatin and relebactam used in combination against a variety of multidrug-resistant gram-negative bacteria concluded that it was well-tolerated and non-inferior to piperacillin/tazobactam, and imipenem/cilastatin alone or with colistin, for treating complicated infections.[8] • There are 10 other drugs in Phase II development spread across three different bacterial infections treated by Recarbrio, but none with the same mechanism of action.
Metabolic Disorders		
Olezarsen sodium **Tryngolza (U.S., EU)** Theratechnologies Inc.	Familial chylomicronemia syndrome (FCS)	• It is an apolipoprotein C III inhibitor. • Administered subcutaneously. • Approved by the US FDA (Tryngolza; December 19, 2024) for the treatment of familial chylomicronemia syndrome.[9] • Approved by the EMA on September 19, 2025 for the treatment of genetically confirmed familial chylomicronemia syndrome (FCS).[10] **CLINICAL TRIALS** • A phase III trial claimed a significant triglyceride reduction in patients taking 80 mg of olezarsen after 6 months compared to placebo. After 53 weeks, 11 episodes of acute pancretitis occurred in the placebo group, and 1 episode in each olezarsen group.[11] • There are two other drugs in Phase II development for the same indication. Both share the same mechanism of action as olezarsen and plozasiran (below).

Medicine (Trade Name) Company	Anticipated Indication(s)†	Description and Key Attributes
Plozasiran Arrowhead Pharmaceuticals Inc.	Familial chylomicronemia syndrome (FCS)	• It is an apolipoprotein C III inhibitor. • Administered subcutaneously. • FDA review is ongoing.[12] • EMA review is ongoing.[13] **CLINICAL TRIALS** • In a phase III trial vs placebo, patients received either 25 mg or 50 mg injections of plozasiran, or placebo, every 3 months for 12 months. Patients who received plozasiran had significantly lower tryglyceride levels and less common severe and serious adverse events than placebo.[14] • There are two other drugs in Phase II development for the same indication. Both share the same mechanism of action as plozasiran and olezarsen (above). • Plozasiran and olezarsen have not been directly compared in a clinical trial.[15]
Sepiapterin **Sephience (U.S., EU)** PTC Therapeutics International Ltd.	Hyperphenyla-laninaemia (HPA) in adults and children with phenylketonuria (PKU)	• It is a tetrahydrobiopterin replacement. • Administered orally. • Approved by the US FDA (Sephience; July 28, 2025) for the treatment of hyperphenylalaninemia in patients with sepiapterin-responsive phenylketonuria, in conjunction with a phenylalanine-restricted diet.[16] • Approved by the EMA on June 19, 2025 for the treatment of hyperphenylalaninaemia (HPA, excessive blood levels of phenylalanine) in adults and children with phenylketonuria (PKU).[17] • A medicine with the same indication, sapropterin (Kuvan) received Notice of Compliance from Health Canada in 2010.[18] **CLINICAL TRIALS** • After 6 weeks, patients in a phase III trial treated with sepiapterin claimed significant mean reduction in blood phenylalanine concentration (-63%) compared to placebo. Sepiapterin was well-tolerated, with no serious or severe adverse events.[19] • There are no other drugs in Phase II development for the same indication.

† Health Canada's Drug and Health Product Submissions Under Review (SUR) Lists provide the therapeutic area for the medicine under review but do not specify the indication. The indication listed in Table 4 is based on the information about the medicine in the literature and/or approvals in other jurisdictions. When there is an aligned review, in some cases the indication was confirmed by the CDA Reimbursement Review report.

Pipeline Medicines 2026

The following tables include medicines featured in the previous edition that have since gained market authorization (Table 5), updates on retained medicines from previous editions of the *Meds Pipeline Monitor* (Table 6), and newly-selected medicine candidates for 2026 (Table 7).

Medicines in Phase III clinical trials or pre-registration are considered for inclusion in the *Meds Pipeline Monitor* (MPM) if they claim to address an unmet therapeutic need, offer a novel mechanism of action or therapeutic benefit over existing therapies, or treat a serious condition.

Screening new medicine candidates

Of the 43 pipeline medicines featured in the previous edition, 11 have received market authorization in Canada, the US, or Europe as of August 30, 2025 (Table 5). Six were removed from the list due to clinical trials being discontinued, filings rejected or withdrawn, or otherwise listed as inactive in GlobalData's Drugs database. Twenty-six were retained as subsequent evidence continues to claim promising clinical benefits and satisfies the selection criteria (Table 6).

Of the 1,460 new medicines under development in the Phase III and pre-registration stages of the pipeline in August 2025, 708 had a listed drug geography in Canada, the US, or Europe in the GlobalData Drugs database. Twenty-four of these were selected for inclusion in the selected new medicines list (Table 7).

Many of the selected new medicines are first-in-class or represent a novel mechanism of action. The description for each new medicine in Table 7 notes the presence of drugs in Phase II development for the same indication, and which ones have the same mechanism of action. Having insight into other drugs in an earlier stage of development can provide additional context on the potential place in therapy of the selected new pipeline candidates.

It is important to keep in mind that not all drugs in Phase II development will progress to Phase III. According to an industry analysis, Phase II clinical programs experience the lowest success rate of the development phases, with only 28.9% of developmental candidates advancing to Phase III.[20]

Biosimilars in the pipeline

Biosimilars are under development in a wide range of therapeutic areas, and their future market entry could have considerable implications for the treatment and cost landscape in Canada. Appendix A (Table A1) provides a list of biosimilars in Phase III clinical trials and a drug geography in Canada, the US, or Europe. Indications under development are listed along with the developing company, the name of the reference biologic in Canada, and whether other biosimilars have already been approved or are currently under review by Health Canada.

Table 5. Pipeline medicines featured in the 2023 *Meds Pipeline Monitor* that have since gained market authorization

Selection Criteria						Key Attributes		
Increased safety and efficacy	Novel mechanism	Gene or cell therapy	Break-through	Fast Track	Priority Review	Clinical trials in Canada	Rare or orphan designation	Biologic medicine

Medicine (Trade Name) Company	Indication(s)	Approval Status and Key Attributes
Central Nervous System		
Xanomeline-trospium (Cobenfy) Bristol Myers Squibb	Schizophrenia; Psychosis	**APPROVAL** • Approved by the US FDA September 26, 2024.[21]
Dermatology		
Prademagene zamikeracel (Zevaskyn) Abeona Therapeutics Inc.	Epidermolysis bullosa	**APPROVAL** • Approved by the US FDA April 18, 2025.[22]
Gastrointestinal Disorders		
Seladelpar lysine (Livdelzi/Lyvdelzi) CymaBay Therapeutics Inc.	Primary biliary cholangitis (primary biliary cirrhosis)	**APPROVAL** • Approved by the US FDA August 14, 2024.[23] • Conditional marketing authorisation received from the EMA February 20, 2025.[24] • Notice of Compliance from Health Canada October 16, 2025.[25]
Genito Urinary System and Sex Hormones		
Gepotidacin mesylate (Blujepa) GSK plc	Cystitis; Urinary tract infections (UTI)	**APPROVAL** • Approved by the US FDA March 25, 2025.[26]
Hematological Disorders		
Fitusiran (Qfitlia) Sanofi	Hemophilia A; Hemophilia B	**APPROVAL** • Approved by the US FDA March 28, 2025.[27]

Medicine (Trade Name) Company	Indication(s)	Approval Status and Key Attributes
Hormonal Disorders		
Palopegteriparatide (Yorvipath) Ascendis Pharma AS	Hypoparathyroidism	**APPROVAL** • Approved by the US FDA August 9, 2024.[28] • EMA marketing authorisation issued November 17, 2023.[29]
Immunological Disorders		
Garadacimab (Andembry) CSL Ltd.	Hereditary angioedema (HAE)(C1 esterase inhibitor [C1-INH] deficiency)	**APPROVAL** • Approved by the US FDA June 16, 2025.[30] • Notice of Compliance from Health Canada August 6, 2025.[31] • EMA marketing authorisation issued October 2, 2025.[32]
Oncology		
Datopotamab deruxtecan (Datroway) Daiichi Sankyo Co Ltd.	Breast cancer (HR+, HER2-)	**APPROVAL** • Approved by the US FDA January 17, 2025.[33] • EMA marketing authorisation issued April 4, 2025.[34]
Revumenib citrate (Revuforj) Syndax Pharmaceuticals Inc.	Refractory acute myeloid leukemia; Relapsed acute myeloid leukemia	**APPROVAL** • Approved by the US FDA November 15, 2024.[35]
Vorasidenib citrate (Voranigo) Les Laboratoires Servier SAS	Astrocytoma; Oligodendroglioma	**APPROVAL** • Approved by the US FDA August 6, 2024.[36] • Notice of Compliance from Health Canada August 27, 2024.[37] • EMA marketing authorisation issued September 17, 2025.[38]
Zolbetuximab (Vyloy) Astellas Pharma Inc.	Adenocarcinoma of the gastroesophageal junction; Gastric cancer	**APPROVAL** • EMA marketing authorisation issued September 19, 2024.[39] • Approved by the US FDA October 18, 2024.[40] • Notice of Compliance from Health Canada December 13, 2024.[41]

Data source: GlobalData Drugs database.

Table 6. Update on pipeline medicines retained from the 2023 *Meds Pipeline Monitor*

Selection Criteria						Key Attributes		
Increased safety and efficacy	Novel mechanism	Gene or cell therapy	Break-through	Fast Track	Priority Review	Clinical trials in Canada	Rare or orphan designation	Biologic medicine

Medicine (Trade Name) Company	Indication(s)	Update
Cardiovascular		
Abelacimab Anthos Therapeutics Inc.	Deep vein thrombosis (DVT); Pulmonary embolism; Atrial fibrillation	**CLINICAL TRIALS** • According to a cost-effectiveness study, abelacimab could offer a potential cost-savings of $50,000 USD and improvements of 1.5 quality-adjusted life years (QALYs) per person over a lifetime horizon as compared to rivaroxaban, a direct oral anticoagulant.[42] • Two Phase III trials in cancer-associated venous thromboembolism (VTE) are ongoing, with estimated primary completion in December 2026 for both.[43,44] • A Phase III trial for patients with atrial fibrillation (AF) is ongoing, with primary completion estimated in August 2026.[45]
Aficamten Cytokinetics Inc.	Hypertrophic cardiomyopathy	**CLINICAL TRIALS** • It has similar efficacy to mavacamten (Camzyos), also a cardiac myosin inhibitor, but has a shorter half-life and fewer drug-drug interactions,[46] suggesting improved safety. The shorter half-life allows for the dose to be uptitrated quickly, resulting in earlier symptomatic relief.[47] • Phase III trials SEQUOIA-HCM and MAPLE-HCM have been completed, respectively claiming "substantial improvements across a broad range of clinically relevant efficacy measures",[48] and that "aficamten monotherapy was superior to metoprolol monotherapy in improving peak oxygen uptake and hemodynamics and decreasing symptoms."[49] • One Phase III trial is currently active.[50]

Medicine (Trade Name) Company	Indication(s)	Update
Etripamil Milestone Pharmaceuticals Inc.	Supraventricular tachycardia	**CLINICAL TRIALS** • A Phase III trial was completed in December 2024.[51] • Results from a completed Phase III trial claim etripamil was well tolerated and effective, with a consistent safety profile.[52] • One Phase III trial is enrolling patients with tachycardia,[53] while another trial for atrial fibrillation is planned to start in 2026.[54] • It has been submitted to the US FDA for review.[55]
Nerinetide NoNO Inc.	Acute ischemic stroke	**CLINICAL TRIALS** • Three Phase III trials have been completed.[56,57,58] • Meta-analysis of completed trials found a sub-population of patients with clinically significant benefits from nerinetide treatment, suggesting a focus for future trials.[59]
Obicetrapib NewAmsterdam Pharma Company	Dyslipidemia; Heterozygous familial hypercholestero-lemia (HeFH); Atherosclerosis	**CLINICAL TRIALS** • Three Phase III trials have been completed. Obicetrapib was found to have "significantly slowed AD biomarker progression over 12 months in participants with [atherosclerotic cardiovascular disease]",[60] and in combination with ezetimibe "significantly reduced LDL cholesterol."[61] • An additional three Phase III trials are ongoing.[62]
Pelacarsen sodium Novartis AG	Cardiovascular disease; Hyperlipidemia	**CLINICAL TRIALS** • One Phase III trial has been completed; results are not yet available. Five others are active or recruiting.[63]
Central Nervous System		
Fosigotifator Calico Life Sciences LLC	Amyotrophic lateral sclerosis (ALS)	**CLINICAL TRIALS** • A Phase III trial has been completed, evaluating safety and efficacy for the treatment of ALS.[64] Another is ongoing, with estimated completion in April 2026.[65]

Medicine (Trade Name) Company	Indication(s)	Update
Latozinemab (previously AL-001) Alector Inc.	Frontotemporal dementia (FTD)	**CLINICAL TRIALS** • In a Phase II study, latozinemab treatment for frontotemporal dementia claimed no significant impact on disease progression, although the treatment was generally safe and well-tolerated.[66] • The Phase III trial is still ongoing; it is targeted to be completed in August 2027.[67] A Phase III continuation study has been initiated and is enrolling patients.[68]
ND-0612 (levodopa/carbidopa for subcutaneous infusion) Neuroderm, a Mitsubishi Tanabe Pharma Corp subsidiary	Parkinson's disease (PD)	**CLINICAL TRIALS** • Positive results from Phase III trials have been reported[69] and published.[70] • A Phase III trial is ongoing, with estimated completion in February 2027.[71]
Resiniferatoxin Grunenthal GmbH	Osteoarthritis pain	**CLINICAL TRIALS** • Three Phase III trials for pain associated with knee osteoarthritis have been completed; results are not yet available.[72]
Valiltramiprosate (previously ALZ-801) Alzheon Inc.	Alzheimer's disease (AD)	**CLINICAL TRIALS** • The Phase III trial has been completed. Results in the early Alzheimer's Disease population did not claim "significant clinical efficacy at 78 weeks", but did claim "significant brain atrophy slowing."[73] • A long-term Phase III extension study is ongoing.[74]
Gastrointestinal Disorders		
Efruxifermin Akero Therapeutics Inc.	Metabolic dysfunction-associated steatohepatitis (MASH)	**CLINICAL TRIALS** • A new Phase III trial is recruiting patients.[75] One other is also recruiting.[76] • A Phase III trial is active, with targeted study completion in October 2026.[77]
Obefazimod Abivax SA	Ulcerative colitis	**CLINICAL TRIALS** • Two Phase III trials have been completed.[78] A third long-term safety trial is active, with estimated study completion in May 2030.[79]

Medicine (Trade Name) Company	Indication(s)	Update
Genetic Disorders		
Fazirsiran sodium Arrowhead Pharmaceuticals Inc.	Alpha-1 antitrypsin deficiency (A1AD)	**CLINICAL TRIALS** • Two Phase III trials are recruiting.[80] A long-term extension study is active, with estimated completion in 2033.[81]
Genito Urinary System and Sex Hormones		
Inaxaplin (VX19-147) Vertex Pharmaceuticals Inc.	Focal segmental glomerulosclerosis (FSGS); Chronic kidney disease (chronic renal failure)	**CLINICAL TRIALS** • Adaptive Phase II/III trial is ongoing, with estimated completion in June 2026.[82]
Hematological Disorders		
Bentracimab SFJ Pharmaceuticals Inc.	Bleeding and clotting disorders	• Orphan designation received March 18, 2025 from the FDA.[83] **CLINICAL TRIALS** • A Phase III trial was completed in September 2024.[84] Results presented at a 2025 conference claim that it "restored platelet function in minutes and was not linked to serious allergic reactions or discontinuations due to side effects."[85]
Infectious Diseases		
Zoliflodacin Innoviva Inc.	Uncomplicated cervical and urethral gonorrhea	• Priority review granted by FDA in June 2025.[86] **CLINICAL TRIALS** • Results from the Phase III trial have been positive.[87] Zoliflodacin "demonstrated non-inferiority in achieving microbiological cure at the urogenital site of infection" and "was generally well-tolerated".[86]
Metabolic Disorders		
Clemidsogene lanparvovec (RGX-121) RegenxBio Inc.	Mucopolysaccharidosis II (MPS II) (Hunter syndrome)	• Priority review granted by FDA in May 2025.[88] **CLINICAL TRIALS** • CAMPSIITE Phase I/II/III trial is ongoing, with an estimated completion date in August 2025.[89]

Medicine (Trade Name) Company	Indication(s)	Update
Oncology		
Bemarituzumab Amgen Inc.	Adenocarcinoma of the gastroesophageal junction; Gastric cancer; Bladder cancer; Gastroesophageal (GE) junction carcinomas	• Orphan designation granted by EMA August 21, 2024.[90] **CLINICAL TRIALS** • Two Phase III trials are ongoing, with estimated completion in June 2026[91] and January 2027.[92]
Gemcitabine (GemRIS) Johnson & Johnson	Non-muscle invasive bladder cancer (NMIBC) (superficial bladder cancer); Muscle invasive bladder cancer (MIBC)	• Orphan designation received July 1, 2025 from the FDA.[93] **CLINICAL TRIALS** • A Phase III trial for MIBC has a target completion date in December 2028.[94] • Two Phase III trials for NMIBC are active, with estimated completion in 2029[95] and 2031.[96]
Navitoclax dihydrochloride AbbVie Inc.	Myelofibrosis	**CLINICAL TRIALS** • A Phase III trial was completed in January 2025.[97] Another is ongoing, with estimated completion in December 2026.[98]
Patidegib hydrochloride Sol-Gel Technologies Ltd.	Gorlin syndrome (basal cell nevus syndrome/ nevoid basal cell carcinoma syndrome)	**CLINICAL TRIALS** • A Phase III trial is ongoing, with estimated completion in August 2026.[99] • Results from a Phase II trial suggest that patidegib reduced basal cell carcinomas with minimal adverse events.[100]
Rusfertide acetate Protagonist Therapeutics Inc.	Polycythemia vera (PV)	**CLINICAL TRIALS** • Another Phase III trial has commenced, in addition to the one ongoing, with respective estimated completion dates in April and June 2027.[101,102]

Medicine (Trade Name) Company	Indication(s)	Update
SGX-301 Hypericin sodium (synthetic hypericin) Soligenix Inc.	Cutaneous T-cell lymphoma (CTCL)	**CLINICAL TRIALS** • The company filed an NDA in December 2022 with the US FDA. Upon preliminary review, the FDA determined that the NDA was not sufficiently complete to permit substantive review.[103] After discussion with the FDA, a confirmatory Phase III trial is being undertaken.[104,105] • Confirmatory Phase III trial is recruiting patients, with estimated study completion in October 2026.[106]
Respiratory		
AD-109 (atomoxetine + R-oxybutynin) Apnimed, Inc.	Obstructive sleep apnea (OSA)	**CLINICAL TRIALS** • Two Phase III trials have been completed.[107,108] A third is enrolling patients, with estimated study completion in June 2026.[109]
Brensocatib Insmed Inc.	Bronchiectasis	• Priority review granted by FDA in February 2025.[110] **CLINICAL TRIALS** • Completed Phase III trial for COVID-19 treatment claimed no improvement in clinical status for hospitalized patients.[111] • Phase III trial for bronchiectasis was completed in October 2024.[112] Brensocatib taken once a day "led to a lower annualized rate of pulmonary exacerbations than placebo, and the decline in [forced expiratory volume in 1 second] was less with the 25 mg dose of brensocatib than with placebo."[113]

Data source: GlobalData Drugs database.

Table 7. Selected new pipeline medicines for the 2026 *Meds Pipeline Monitor*

Selection Criteria						Key Attributes		
Increased safety and efficacy	Novel mechanism	Gene or cell therapy	Break-through	Fast Track	Priority Review	Clinical trials in Canada	Rare or orphan designation	Biologic medicine

Medicine (Trade Name) Company	Indication(s)	Description and Key Attributes
Central Nervous System		
Bexicaserin Longboard Pharmaceuticals Inc.	Dravet syndrome (severe myoclonic epilepsy of infancy); Developmental epileptic encephalopathy (DEE); Lennox-Gastaut syndrome	• Bexicaserin (LP-352) acts as a 5-hydroxytryptamine receptor 2C (5-HT2C) agonist. • 5-HT2C is a G protein-coupled receptor (GPCR).[114] • Administered orally. **CLINICAL TRIALS** • Phase III trials unpublished to date. • Phase II PACIFIC study (1b/2a) was a double-blind trial in patients with Dravet Syndrome and other DEEs (unpublished).[115] • DEEp SEA is a multicenter, double-blind, Phase III trial expecting to enroll 320 patients (2 to 65 years of age) to receive bexicaserin or placebo for 12-weeks. Eligible patients completing this study can enroll in a 52-week extension trial (announced October 2024). The study is actively recruiting patients.[116] • There is one drug in Phase II treating Dravet syndrome and one for Lennox-Gastaut syndrome. Neither has the same mechanism of action as bexicaserin.
Tanruprubart Annexon Inc.	Guillain-Barré syndrome	• Tanruprubart (ANX005) is a monoclonal antibody that inhibits C1q, which is the molecule that initiates the classical complement cascade leading to neuroinflammation and nerve damage.[117] • Administered as an intravenous infusion. **CLINICAL TRIALS** • A phase III trial was held with 241 subjects in Bangladesh and the Philippines[118] who received doses of either ANX005 30 mg/kg or 75 mg/kg. Annexon Biosciences released results claiming the 30 mg/kg dose suppressed C1q for one week and the higher dose for 2 to 3 weeks, according to unpublished data.[119] • There are no drugs with this indication in Phase II.

Medicine (Trade Name) Company	Indication(s)	Description and Key Attributes
Dermatology		
SkinTE Regen ETP Inc., PolarityBio	Diabetic foot ulcers	• It is a personalized autologous regenerative cell therapy. • Administered topically. **CLINICAL TRIALS** • FDA Breakthrough designation was granted following results from a Phase II trial demonstrating efficacy. 70% of patients receiving SkinTE plus standard of care (SOC) had wound closure at 12 weeks compared to 34% of patients receiving only SOC. Percentage Area Reduction (PAR) for the SkinTE arm was significantly greater as well, at 80.7% vs 26.8%, without resulting in more adverse events than SOC.[120] • There is an ongoing Phase III trial with results expected in 2026.[121] • Expanded access treatment protocol approved by FDA and opened by manufacturer in September 2025 to permit access to SkinTE to patients with Wagner 1 diabetic foot ulcers.[122] • There are five drugs with this indication in Phase II. None have the same mechanism of action as SkinTE.
Gastrointestinal Disorders		
Pegozafermin 89bio Inc.	Metabolic dysfunction-associated steatohepatitis (MASH or NASH) and related complications	• Pegozafermin (BIO89-100) is a glycopegylated fibroblast growth factor 21 (FGF21) analog which acts as a FGFR1c, 2c and 3c agonist in the presence of beta klotho. • Administered subcutaneously. **CLINICAL TRIALS** • In a Phase IIb trial, the percentage of patients who met the criteria for NASH resolution was 2% in the placebo group, 37% in the 15 mg pegozafermin group (difference vs. placebo, 35 percentage points; 95% CI, 10 to 59), 23% in the 30 mg pegozafermin group (difference, 21 percentage points; 95% CI, 9 to 33), and 26% in the 44 mg pegozafermin group (difference, 24 percentage points; 95% CI, 10 to 37).[123] • There is one ongoing Phase III trial[124] and two others in recruitment.[125,126] • There are 12 drugs with this indication in Phase II. None have the same mechanism of action as pegozafermin.

Medicine (Trade Name) Company	Indication(s)	Description and Key Attributes
Genetic Disorders		
Copper histidinate Sentynl Therapeutics Inc.	Menkes disease (kinky hair disease)	• It is a replacement therapy that enhances the levels of copper in the brain, avoiding gastrointestinal absorption. • Administered subcutaneously. **CLINICAL TRIALS** • Findings from a small Phase I/II trial and a larger Phase III open-label single-arm trial were studied against historical untreated cohorts and statistically significant benefits were observed in overall survival.[127,128] • There are no drugs with this indication in Phase II.
Efsudenermin alfa EspeRare Foundation	X-linked hypohidrotic ectodermal dysplasia (XLHED)	• It is a recombinant fusion protein that acts as an ectodysplasin A receptor (EDAR) agonist. • Administered intravenously and intra-amniotically. **CLINICAL TRIALS** • Phase II EDELIFE trial (NCT04980638) is currently recruiting to assess the safety and efficacy of ER-004 as an intra-amniotic treatment for unborn male X-linked hypohidrotic ectodermal dysplasia (XLHED) subjects. The estimated completion dates are February 2027 (primary) and December 2032 (full). A five-year long-term follow-up phase will follow the initial trial period.[129] • There are no drugs with this indication in Phase II.
Setrusumab Ultragenyx	Osteogenesis imperfecta (brittle bone disease)	• It is an anti-sclerostin monoclonal antibody. Sclerostin is a protein that inhibits bone formation. • Administered intravenously. **CLINICAL TRIALS** • FDA Breakthrough designation received in October 2024 based on results claiming a "rapid and clinically meaningful decrease in fracture rate" from the Phase II portion of an ongoing study.[130] • Three Phase III trials are active to assess reduction in fracture rate for pediatric patients receiving setrusumab,[131] patients receiving setrusumab versus placebo,[132] and pediatric patients receiving setrusumab versus IV bisphosphonates.[133] • There are no drugs with this indication in Phase II.

Medicine (Trade Name) Company	Indication(s)	Description and Key Attributes
Immunology		
Navenibart Astria Therapeutics Inc.	Hereditary angioedema	• It is monoclonal antibody that inhibits plasma kallikrein, which interferes with the blood clotting process in the brain. • Administered subcutaneously. **CLINICAL TRIALS** • Final results from ALPHA-STAR, a dose-ranging proof-of-concept trial conducted in adult patients with type 1 hereditary angioedema, demonstrated reduction in the mean monthly attack rate of 90-95% at 6 months and favorable safety profile.[134] • A multicenter, randomized, double-blind, placebo-controlled Phase III trial is recruiting. Dosage will be every three months or every six months.[135] • There are no drugs with this indication in Phase II.
Infectious Diseases		
Bepirovirsen sodium GSK plc	Hepatitis B	• It is an antisense oligonucleotide targeting all hepatitis B virus (HBV) RNAs, including HBV messenger RNA and pregenomic RNA. • Administered subcutaneously. **CLINICAL TRIALS** • Fast Track designation from FDA received in February 2024. Bepirovirsen is the only medicine in Phase III that has "shown the potential to achieve clinically meaningful cure response" based on results in Phase II trials.[136] • Two Phase III trials are underway.[137,138] • There are six drugs with this indication in Phase II. None have the same mechanism of action as bepirovirsen sodium.
Enibarcimab Adrenomed AG	Sepsis; Septic shock; Cardiogenic shock	• It is a humanized monoclonal anti-adrenomedullin antibody. • Administered intravenously. **CLINICAL TRIALS** • Fast Track designation from the FDA received in April 2024. The AdrenOSS Phase IIa trial included 301 patients with early septic shock.[139] In a subgroup of patients with specific biomarkers, it claimed a 60% reduction in relative 28-day mortality vs placebo and could potentially be the "first effective targeted treatment against septic shock".[140] • Phase III trial for treatment of cardiogenic shock did not improve survival at days 30 or 90 but was well-tolerated.[141] • There are no drugs with this indication in Phase II.

Medicine (Trade Name) Company	Indication(s)	Description and Key Attributes
Ganaplacide + lumefantrine Novartis AG	Malaria	• It is a non-artemisinin plasmodium falciparum inhibitor. Ganaplacide targets the plasmodium internal protein secretory pathway and lumefantrine inhibits the parasite conversion of toxic heme to non-toxic hemozoin. • Administered orally. • Reports of strains of malaria resistant to artemisinin-based therapies (ACTs) have emerged and, as the mainstay of treatment has been ACTs, the development of new medications to combat resistance is an area of focus according to the WHO.[142] **CLINICAL TRIALS** • Phase IIb KALUMI trial (randomized, open label, noninferiority) evaluated efficacy and safety of this combination compared with artemether-lumefantrine in children aged 6 months to 12 years. Both achieved a 99% success rate at day 29.[143] • Phase III KALUMA trial (active, not currently recruiting) and PLATINUM trial (currently recruiting) are ongoing. These trials will compare ganaplicide + lumefantrine oral treatment versus standard of care anti-malarials.[144,145] • There are three drugs with this indication in Phase II. None have the same mechanism of action as ganaplacide + lumefantrine.
LMN-201 Lumen Bioscience Inc.	*C. difficile* infection	• It is a biologic cocktail of therapeutic proteins that neutralizes the *C. difficile* bacterium.[146] • Administered orally. • *C. difficile* infection is an antimicrobial resistance "Urgent Threat" according to the U.S. CDC, with growing resistance to the main antibiotic used in CDI treatment.[147] **CLINICAL TRIALS** • Part A of RePreve trial is complete. Twenty-one patients with *C. difficile* infection were enrolled. All participants in this open-label cohort received LMN-201 in addition to antibiotics, starting within 7 days of diagnosis. All patients (21/21) achieved initial clinical resolution.[148] • Phase III arm of RePreve trial has begun.[149] • There is one drug with this indication in Phase II. It does not have the same mechanism of action as LMN-201.

Medicine (Trade Name) Company	Indication(s)	Description and Key Attributes
VLA-15 (Lyme disease vaccine) Valneva SE	Lyme disease	• It is a multivalent, outer surface protein A (OspA)-based protein subunit vaccine. • Administered by intramuscular injection. **CLINICAL TRIALS** • VLA-15 has had a favourable safety profile in clinical trials to date. Subject to positive data in the VALOR trial, Pfizer plans to submit applications to the FDA and EMA in 2026.[150] • A Phase III trial to study safety in pediatric patients was completed in July 2025.[151] • Phase III VALOR trial is currently active and is expected to be completed in December 2025.[152] • There are no drugs with this indication in Phase II.
Metabolic Disorders		
Diamyd Diamyd Medical AB	Type 1 diabetes (juvenile diabetes)	• It is a recombinant human glutamic acid decarboxylase 65-isoform (GAD65) which acts by targeting pancreatic beta cell autoantigen in autoimmune diabetes. • Administered through the subcutaneous, intra-inguinal, and intralymphatic route. **CLINICAL TRIALS** • FDA Fast Track designation granted in February 2024 following Phase IIb results claiming statistically significant change in stimulated C-peptide and reduction in the number and severity of hyperglycemic events.[153] Investigators found the treatment was well-tolerated and constituted a "disease-modifying treatment for T1D."[154] • One Phase III trial is ongoing, with estimated completion in 2027.[155] • There are two drugs with this indication in Phase II. Neither has the same mechanism of action as Diamyd.
Pariglasgene brecaparvovec Ultragenyx Pharmaceuticals	Glycogen Storage Disease Type 1A	• It is an adeno-associated virus vector (AAV) gene therapy that activates the glucose-6-phosphatase (G6Pase) enzyme. • Administered intravenously. **CLINICAL TRIALS** • A Phase I/II safety and dose-finding study in adults with Glycogen Storage Disease Type 1a (GSDIa) claimed positive efficacy and safety profile after 1 year.[156,157] • A Phase III trial is underway, with estimated completion in 2026.[158] • There are no drugs with this indication in Phase II.

Medicine (Trade Name) Company	Indication(s)	Description and Key Attributes
Musculoskeletal Disorders		
RGX-202 RegenxBio	Duchenne muscular dystrophy	• It is an adeno-associated virus serotype 8 (AAV8) vector which contains a transgene encoding a novel microdystrophin gene. • Administered intravenously. **CLINICAL TRIALS** • Interim clinical data claims RGX-202 was well tolerated at both dose levels and "demonstrated robust RGX-202 microdystrophin expression in boys with DMD 4-12 years of age."[159] • Phase I/II/III open-label AFFINITY trial is currently recruiting, with estimated study completion in August 2028. The purpose is to assess "safety, tolerability, and clinical efficacy of a one-time intravenous (IV) dose of RGX-202".[160] • There are two drugs with this indication in Phase II. Neither has the same mechanism of action as RGX-202.
TPX-115 Tego Science Inc.	Partial thickness rotator cuff tear	• It is an injection of allogeneic fibroblasts for cell therapy. • Administered intratendinously. **CLINICAL TRIALS** • FDA allowed direct progression to Phase II trials in the US without Phase I results, based on results of a Phase I/II study in South Korea.[161] • Phase IIb/III trial is currently recruiting, with estimated completion in January 2027.[162] • There are no drugs with this indication in Phase II.
Oncology		
Aglatimagene besadenovec (PancAtak) Candel Therapeutics Inc.	Pancreatic ductal adenocarcinoma	• It is a DNA polymerase inhibitor. • Administered intratumourally. **CLINICAL TRIALS** • Active Phase II trial in combination with valacyclovir or acyclovir for patients with borderline resectable pancreatic carcinoma who are being treated with neoadjuvant chemoradiation or stereotactic body radiation therapy. No published results to date; study completion estimated July 2026.[163] • Also in an active Phase III trial for prostate cancer, with estimated completion in 2030.[164] • There are 131 drugs with this indication in Phase II. One has the same mechanism of action as aglatimagene besadenovec.

Medicine (Trade Name) Company	Indication(s)	Description and Key Attributes
Berubicin hydrochloride CNS Pharmaceuticals Inc.	Recurrent glioblastoma multiforme (GBM)	• It is an anthracycline derivative that acts as a DNA topoisomerase II inhibitor. • Administered intravenously, orally, and vaginally as a powder or solution. **CLINICAL TRIALS** • A Phase II trial for patients with recurrent GBM after failure of standard first-line therapy is underway, with estimated completion in March 2026.[165] • It is the first anthracycline that appears able to cross the blood-brain barrier to treat GBM. Interim analysis of data from the Phase II trial found comparable efficacy to lomustine in terms of overall survival.[166] • There are 36 drugs with this indication in Phase II. None have the same mechanism of action as berubicin hydrochloride.
Bria-IMT BriaCell Therapeutics Corp	Breast cancer (HER2-, HER2+, triple-negative)	• It is a granulocyte macrophage colony stimulating factor activator (GM-CSF). • Administered intradermally. **CLINICAL TRIALS** • Phase II survival data suggests Bria-IMT "may offer a valuable therapeutic option for patients who have exhausted multiple prior lines of therapy" in combination with an immune checkpoint inhibitor (CPI). Median overall survival (OS) was higher than published data for comparator treatments for triple-negative breast cancer and hormone receptor-positive disease.[167] • A Phase III trial for treatment of advanced metastatic or locally recurrent breast cancer is currently recruiting, with estimated completion in June 2026.[168] • There are 105 drugs in Phase II with a HER2- indication, 44 with a HER2+ indication, and 182 with a triple-negative (TNBC) indication. One drug has the same mechanism of action as Bria-IMT and is indicated for the same three types of breast cancer. Another drug with the same mechanism of action only shares the TNBC indication.

Medicine (Trade Name) Company	Indication(s)	Description and Key Attributes
Darovasertib Ideaya Biosciences Inc.	Uveal melanoma; Metastatic uveal melanoma	• It is a protein kinase C inhibitor. • Administered orally. **CLINICAL TRIALS** • Phase II trial generated positive clinical data supporting darovasertib as potential "first systemic therapy for the neoadjuvant treatment of primary uveal melanoma". 37.5% of patients recommended for enucleation and 44.7% of patients eligible for plaque brachytherapy had a reduction in tumor size ≥30%.[169] • Two Phase III trials are currently recruiting, one studying use in patients with metastatic uveal melanoma, and the other for primary non-metastatic uveal melanoma. The planned study completion dates are in 2028 and 2031, respectively.[170,171] • There are 17 drugs in Phase II indicated for uveal melanoma, and 15 indicated for metastatic uveal melanoma. None share the same mechanism of action as darovasertib.
Intismeran autogene Moderna Inc.	Various cancers (vaccine) including melanoma, metastatic melanoma, non-small cell lung cancer, squamous non-small cell lung cancer, locally resectable advanced cutaneous squamous cell carcinoma (LA cSCC), and small-cell lung cancer	• It is an mRNA vaccine. • Administered by intramuscular injection. **CLINICAL TRIALS** • Phase IIb trial KEYNOTE-942 interim results claimed "adjuvant treatment with mRNA-4157 (V940) in combination with KEYTRUDA continued to demonstrate a clinically meaningful and durable improvement in recurrence-free survival (RFS), the primary endpoint of the study, reducing the risk of recurrence or death by 49%".[172] • There are multiple ongoing Phase II and III trials. Almost all involve intismeran autogene in combination with pembrolizumab. • Two active Phase III trials are for treatment of locally resectable advanced cutaneous squamous cell carcinoma (estimated completion March 2026)[173] and high-risk melanoma (September 2030).[174] • Recruitment is underway for Phase III trials in margin negative, completely resected Stage II, IIIA, IIIB (with nodal involvement [N2]) non-small cell lung cancer (NSCLC)[175] and non-small cell lung cancer.[176] Completion of these trials tracking disease-free survival will be in 2035 and 2038, respectively. • There are eight other mRNA vaccines in Phase II sharing at least one indication with intismeran autogene. All elicit an immune response against cancer cells similar to intismeran autogene.

Medicine (Trade Name) Company	Indication(s)	Description and Key Attributes
Ophthalmology		
4D-150 4D Molecular Therapeutics Inc.	Diabetic macular edema; Wet (neovascular / exudative) macular degeneration	• It is a Vascular Endothelial Growth Factor inhibitor (VEGF-A, B, C, and placenta growth factor). • Administered by intravitreal injection. **CLINICAL TRIALS** • Interim results from an ongoing Phase II trial for patients with diabetic macular edema claimed "notable efficacy, achieving sustained visual acuity gains (+8.4 letters) and central subfield thickness (CST) reductions (-194 µm) through 32 weeks." No intraocular inflammation or serious safety concerns were observed.[177] Trial completion is estimated in February 2029.[178] • Phase III trials for treatment of age-related macular degeneration are recruiting.[179,180] • There are 36 drugs indicated for diabetic macular edema in Phase II; 17 have the same mechanism of action as 4D-150.
Gildeuretinol acetate Alkeus Pharmaceuticals	Juvenile macular degeneration (Stargardt Disease); Geographic atrophy	• It is a vitamin A enriched with deuterium (D3-vitamin A). • Administered orally. **CLINICAL TRIALS** • It received Rare Pediatric Disease and Fast Track designation from the FDA in November 2024 for the treatment of Stargardt disease, which has no approved treatment.[181] • Interim results from Phase II TEASE study tracking five early-stage Stargardt patients claimed less loss in ellipsoid zone (EZ) area, and that "overall disease remained relatively stable while on therapy ranging between two to seven years".[182] • A Phase II/III trial for treatment of geographic atrophy secondary to age-related macular degeneration was completed in June 2024.[183] Results claim a reduction in the primary endpoint of GA lesion growth rate at 24 months. Safety profile was consistent with other studies for Stargardt disease.[184] • There are three drugs with this indication in Phase II. None have the same mechanism of action as gildeuretinol acetate.

Data source: GlobalData Drugs database.

Appendix A

Table A1: Biosimilars in Phase III or pre-registration for reference biologics marketed in Canada

Medicine	Reference product in Canada	Company selling reference product in Canada	Other biosimilars marketed in Canada at this time (Y/N)	Companies with biosimilars under review by Health Canada	Companies developing a biosimilar in Phase III or pre-registration	Biosimilar indications
Adalimumab	Humira	AbbVie Corporation	Y	JAMP Pharma Corporation (supplemental submission)	Outlook Therapeutics Inc.	Plaque psoriasis (psoriasis vulgaris)
Aflibercept	Eylea	Bayer Inc.	Y	Celltrion Inc. Samsung Bioepis Co., Ltd. Sandoz Canada Inc. Formycon AG JAMP Pharma Corporation	Alteogen Inc. Alvotech SA Biolitec Pharma Ltd.	Choroidal neovascularization
					Alteogen Inc. Alvotech SA Biolitec Pharma Ltd.	Diabetic macular edema
					Alvotech SA	Diabetic retinopathy
					Alteogen Inc.	Macular edema
					Alvotech SA	Retinal vein occlusion

Medicine	Reference product in Canada	Company selling reference product in Canada	Other biosimilars marketed in Canada at this time (Y/N)	Companies with biosimilars under review by Health Canada	Companies developing a biosimilar in Phase III or pre-registration	Biosimilar indications
Aflibercept	Eylea	Bayer Inc.	Y	Celltrion Inc. Samsung Bioepis Co., Ltd. Sandoz Canada Inc. Formycon AG JAMP Pharma Corporation	Alteogen Inc. Alvotech SA Biolitec Pharma Ltd. Kissei Pharmaceutical Co., Ltd.	Wet (neovascular / exudative) macular degeneration
Bevacizumab	Avastin	Hoffmann-La Roche Limited	Y	Curateq Biologics Pvt Ltd.	Curateq Biologics Pvt Ltd	Metastatic colorectal cancer
					Curateq Biologics Pvt Ltd Prestige BioPharma Ltd	Non-small cell lung cancer
					Zhaoke (Guangzhou) Ophthalmology Pharmaceutical Ltd	Wet (neovascular / exudative) macular degeneration
Daratumumab	Darzalex	Janssen Inc.	N	–	Celltrion Inc.	Refractory multiple myeloma
					Celltrion Inc.	Relapsed multiple myeloma
Denosumab	Prolia	Amgen Canada Inc.	Y	Apotex Inc. Biosimilar Collaborations Ireland Limited Celltrion Inc. Fresenius Kabi Canada Ltd. Mantra Pharma Inc. Samsung Bioepis Co., Ltd. Shanghai Henlius Biotech Inc.	Shanghai Henlius Biotech Inc.	Giant cell tumor of bone

Medicine	Reference product in Canada	Company selling reference product in Canada	Other biosimilars marketed in Canada at this time (Y/N)	Companies with biosimilars under review by Health Canada	Companies developing a biosimilar in Phase III or pre-registration	Biosimilar indications
Denosumab	Prolia	Amgen Canada Inc.	Y	Apotex Inc. Biosimilar Collaborations Ireland Limited Celltrion Inc. Fresenius Kabi Canada Ltd. Mantra Pharma Inc. Samsung Bioepis Co., Ltd. Shanghai Henlius Biotech Inc.	Alvotech SA Curateq Biologics Pvt Ltd. Shanghai Henlius Biotech Inc. Teva Pharmaceutical Industries Ltd.	Postmenopausal osteoporosis
Dulaglutide	Trulicity	Eli Lilly Canada Inc.	N	-	Shandong Boan Biotechnology Co., Ltd.	Type 2 diabetes
Golimumab	Simponi	Janssen Inc.	N	JAMP Pharma Corporation	Bio-Thera Solutions Ltd. Alvotech SA Bio-Thera Solutions Ltd. Bio-Thera Solutions Ltd.	Ankylosing spondylitis (Bekhterev's disease) Rheumatoid arthritis Ulcerative colitis Psoriatic arthritis
Insulin aspart	NovoRapid	Novo Nordisk Canada Inc.	Y	-	Amphastar Pharmaceuticals Inc. Amphastar Pharmaceuticals Inc.	Type 1 diabetes (juvenile diabetes) Type 2 diabetes
Nivolumab	Opdivo	Bristol-Myers Squibb Canada	N	-	Shandong Boan Biotechnology Co., Ltd. Shandong Boan Biotechnology Co., Ltd.	Adenocarcinoma of the gastroesophageal junction Colorectal cancer

Medicine	Reference product in Canada	Company selling reference product in Canada	Other biosimilars marketed in Canada at this time (Y/N)	Companies with biosimilars under review by Health Canada	Companies developing a biosimilar in Phase III or pre-registration	Biosimilar indications
Nivolumab	Opdivo	Bristol-Myers Squibb Canada	N	-	Shandong Boan Biotechnology Co., Ltd.	Esophageal squamous cell carcinoma (ESCC)
					Shandong Boan Biotechnology Co., Ltd.	Gastric cancer
					Shandong Boan Biotechnology Co., Ltd.	Gastroesophageal (GE) junction carcinomas
					Shandong Boan Biotechnology Co., Ltd.	Head And Neck Squamous Cell Carcinoma (HNSC)
					Shandong Boan Biotechnology Co., Ltd.	Hepatocellular Carcinoma
					Shandong Boan Biotechnology Co., Ltd.	Hodgkin Lymphoma (B-Cell Hodgkin Lymphoma)
					Shandong Boan Biotechnology Co., Ltd.	Malignant Pleural Mesothelioma
					Shandong Boan Biotechnology Co., Ltd.	Melanoma
					Shandong Boan Biotechnology Co., Ltd.	Non-Small Cell Lung Cancer
					Shandong Boan Biotechnology Co., Ltd.	Renal Cell Carcinoma
					Shandong Boan Biotechnology Co., Ltd.	Transitional Cell Carcinoma (Urothelial Cell Carcinoma)

Medicine	Reference product in Canada	Company selling reference product in Canada	Other biosimilars marketed in Canada at this time (Y/N)	Companies with biosimilars under review by Health Canada	Companies developing a biosimilar in Phase III or pre-registration	Biosimilar indications
Ocrelizumab	Ocrevus	Hoffmann-La Roche Limited	N	–	Celltrion Inc.	Relapsing remitting multiple sclerosis (RRMS)
Omalizumab	Xolair	Novartis Pharmaceuticals Canada Inc.	Y	-	Kashiv BioSciences, LLC	Allergic asthma
					Kashiv BioSciences, LLC	Chronic urticaria or hives
					Kashiv BioSciences, LLC	Rhinosinusitis
OnabotulinumtoxinA	Botox	AbbVie Corporation	N	-	Aquavit Pharmaceuticals Inc.	Unspecified neurologic disorders
Pembrolizumab	Keytruda	Merck Canada Inc.	N	-	Celltrion Inc.	Non-small cell lung cancer
Pertuzumab	Perjeta	Hoffmann-La Roche Limited	N	Shanghai Henlius Biotech Inc.	Shanghai Henlius Biotech Inc.	Human epidermal growth factor receptor-2-positive breast cancer (HER2+ breast cancer)
Ranibizumab	Lucentis	Novartis Pharmaceuticals Canada Inc.	Y	-	Lupin Ltd.	Wet (neovascular/exudative) macular degeneration
Secukinumab	Cosentyx	Novartis Pharmaceuticals Canada Inc.	N	-	Bio-Thera Solutions Ltd.	Plaque psoriasis (psoriasis vulgaris)
Teriparatide	Forteo	Eli Lilly Canada Inc.	Y	-	MiGenTra GmbH	Osteoporosis

Medicine	Reference product in Canada	Company selling reference product in Canada	Other biosimilars marketed in Canada at this time (Y/N)	Companies with biosimilars under review by Health Canada	Companies developing a biosimilar in Phase III or pre-registration	Biosimilar indications
Tocilizumab	Actemra	Hoffmann-La Roche Limited	Y	Biogen Canada Inc. Celltrion Inc.	Gedeon Richter Plc.	Coronavirus disease 2019 (COVID-19)
					Gedeon Richter Plc.	Cytokine release syndrome (cytokine storm)
					Gedeon Richter Plc.	Giant cell arteritis (temporal arteritis/cranial arteritis/ Horton disease)
					Gedeon Richter Plc.	Polyarticular juvenile idiopathic arthritis (PJIA)
					Gedeon Richter Plc. Mochida Pharmaceutical Co., Ltd.	Rheumatoid arthritis
					Gedeon Richter Plc.	Systemic-onset juvenile idiopathic arthritis (Still disease)
Trastuzumab	Herceptin	Hoffmann-La Roche Limited	Y	3 products under review, company names not available (submissions accepted pre-Oct 2018)	Tanvex BioPharma Inc.	Human epidermal growth factor receptor-2-positive breast cancer (HER2+ breast cancer)
					Qilu Pharmaceutical Co., Ltd.	Metastatic breast cancer

Data source: GlobalData Drugs database, Health Canada Drug Product Database, Health Canada Submissions Under Review (SUR) lists.

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