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ОБЗОРЫ

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Overview of drugs approved by the FDA in 2022

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The aim of the work was to conduct a review of drugs approved by the FDA in 2022.

Materials and methods. In searching for the materials to write this review article, bibliographic databases including PubMed, Google Scholar and e-library.ru were utilized. The search was conducted for the publications spanning the period from 2008 to 2023. Herewith, the following keywords and word combinations were used: new drug approval, NDA, drug authorization, approval package, breakthrough medicine.

Results. The discovery and development of drugs are among the most crucial scientific processes in healthcare. Developing a new drug is a highly intricate, expensive, and time-consuming process. Nowadays, the problem of costs reduction and the process of expedited discovering of new medications are particularly pertinent. To optimize the search for active compounds, virtual and high-throughput screenings, machine learning, artificial intelligence, cryo-electron microscopy, and drug repurposing are employed. Simultaneously, the search for original molecules to serve as the basis for innovative drugs continues. This article presents a review of medications approved by the FDA in 2022 for the treatment of various pathologies.

Conclusion. A drug development is a complex and resource-intensive process, with only a small fraction of candidates advancing to clinical trials. A drug design evolves in tandem with societal needs, and this review highlights some of the drugs approved by the FDA in 2022. Technological advancements are expected to expedite drug development, potentially reducing the time to the market. Biotechnology, including cell therapy, holds significant prospects, and achievements in genetic mapping and chip technologies will enhance the accessibility of personalized pharmacology.

Keywords: FDA; biopharmaceuticals; monoclonal antibodies; drug design trends

Abbreviations: ADMET – absorption, distribution, metabolism, excretion, and toxicity; AI – artificial intelligence; Ang2 – angiopoietin 2; ANN – artificial neural networks; CALD – cerebral adrenoleukodystrophy; CNN – convolutional neural networks; cryo-EM – cryogenic electron microscopy; CVDs – cardiovascular diseases; DL – deep learning; EMA – European Medicines Agency; FBS – fragment-based screening; HTS – high throughput screening; FDA – Food and Drug Administration; GIP – gastric inhibitory polypeptide; GLP-1 – glucagon-like peptide-1; IL – interleukin; ISMC – International Symposium on Medicinal Chemistry; JAK1 – Janus kinase 1; LDA – linear discriminant analysis; MHRA – The Medicines and Healthcare products Regulatory Agency; ML – machine learning; MLP – multilayer perceptron; NME – New Molecular Entity; NYHA – New York Heart Association; PD-1 – programmed cell death 1 receptor; PDB – Protein Data Bank; QSAR – quantitative structure-activity relationship; RF – random forest; RNN – recurrent neural networks; SBDD – structure-based drug discovery; SVM – support vector machine; TSLP – thymic stromal lymphopoietin; VEGF – vascular endothelial growth factor; VLCFAs – very long chain fatty acids; R&D – research and development; CNS – central nervous system; CT – clinical trials.

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Обзор лекарственных средств, одобренных FDA в 2022 году

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Цель. Анализ актуальных тенденций зарубежной практики в области разработки и регистрации лекарственных препаратов.

Материалы и методы. При поиске материала для написания обзорной статьи использовали реферативные базы данных PubMed, Google Scholar и e-library.ru. Поиск осуществляли по публикациям за период с 2008 по 2023 год, с использованием следующих ключевых слов: «new drug approval», «NDA», «drug authorization», «approval package», «breakthrough medicine».

Результаты. Открытие и разработка лекарственных средств являются одними из наиболее важных научных направлений в здравоохранении. Разработка нового препарата – очень сложный, дорогой и длительный процесс. Как снизить затраты и ускорить открытие новых лекарств? Этот вопрос является особенно актуальным на сегодняшний день. Для оптимизации процесса поиска активных соединений используются виртуальный и высокопроизводительный скрининг, машинное обучение, искусственный интеллект, криоэлектронная микроскопия, а также перепрофилирование существующих лекарственных средств. В то же время продолжается поиск оригинальных молекул для разработки на их основе инновационных препаратов. В данной статье представлен обзор лекарственных средств, одобренных в 2022 году Food and Drug Administration (FDA), для лечения различных патологий.

Заключение. Разработка лекарств представляет собой сложный и ресурсоемкий процесс, при котором лишь небольшая часть кандидатов доходит до клинических испытаний. Дизайн лекарств развивается вместе с потребностями общества, и в этом обзоре освещаются некоторые из препаратов, одобренных FDA в 2022 году. Ожидается, что технологические достижения ускорят разработку лекарств, потенциально сокращая время их выхода на рынок. Биотехнология, включая клеточную терапию, имеет большие перспективы, а достижения в области генетического картирования и технологий чипов повысят доступность персонализированной фармакологии.

Ключевые слова: Food and Drug Administration; FDA; биофармацевтика; моноклональные антитела; тенденции лекарственного дизайна

Список сокращений: ADMET – абсорбция, распределение, метаболизм, экскреция и токсичность; AI – искусственный интеллект; Ang2 – ангиопоэтин 2; ANN – искусственные нейронные сети; CALD – церебральная адренолейкодистрофия; CNN – сверточные нейронные сети; cryo-EM – криоэлектронная микроскопия; ССЗ – сердечно-сосудистые заболевания; DL – глубокое обучение; EMA – Европейское агентство по лекарственным средствам; FBS – фрагментарный скрининг; HTS – высокопроизводительный скрининг; FDA – Управление по контролю за продуктами и лекарствами; ГИП – глюкозозависимый инсулинотропный полипептид; ГПП-1 – глюкагоноподобный пептид-1; IL – интерлейкин; ISMC – Международный симпозиум по медицинской химии; JAK1 – янус-киназа-1; LDA – линейный дискриминантный анализ; MHRA – Агентство по регулированию лекарственных средств и товаров медицинского назначения; ML – машинное обучение; MLP – сеть многослойного персептрона; NME – новые молекулярные соединения; NYHA – Нью-Йоркская кардиологическая ассоциация; PD-1 – рецептор программируемой смерти клеток 1; PDB – Банк данных белков; QSAR – количественное соотношение структура-активность; RF – метод случайного леса; RNN – рекуррентные нейронные сети; SBDD – структура-зависимое исследование лекарственных препаратов; SVM – метод опорных векторов; TSLP – стромальный лимфопоэтин тимуса; VEGF – фактор роста эндотелия сосудов; VLCFAs – жирные кислоты с очень длинной цепью; ЛС – лекарственное средство; НИОКР – научно-исследовательские и опытно-конструкторские работы; ЦНС – центральная нервная система; КИ – клинические исследования.

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INTRODUCTION

The search for new drugs is a long and complex process, which can be roughly divided into four main phases: (i) target identification and validation; (ii) compound screening and optimisation of hit structures; (iii) pre-clinical studies; and (iv) clinical trials [1]. Completion of a typical drug development cycle from a target identification to an FDA-approved drug takes up to 14 years at an estimated cost of $800 million [2–4]. For this reason, large corporations are continually searching for new methods to accelerate this process, as well as monitoring new technologies from other areas of research [5]. Various approaches are used to optimise the process of active compounds searching: virtual screening [4], machine learning [6], artificial intelligence [1], high throughput screening [7]. Cryo-electron microscopy is a rapidly developing tool for investigating drugs based on their chemical structures [8].

Furthermore, the protracted timeline for the emergence of drug candidates has opened avenues for the repurposing and repositioning of existing medications. Drug repurposing entails the utilization of drugs previously sanctioned for treating established pathologies, as authorized by regulatory agencies such as the Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the Medicines and Healthcare products Regulatory Agency (MHRA) [9]. This paper provides a selective overview of the strides made within the global pharmaceutical industry, with a specific focus on market leaders and enterprises committing substantial financial resources to the research and development of pharmaceuticals and healthcare products.

THE AIM of this study is to analyze current trends in the development and registration of pharmaceutical drugs.

MATERIALS AND METHODS

The literature search (including results of clinical studies, literature reviews, and, in some cases, information on preclinical studies) was based on the information available on the official websites of the FDA and EMA related to the issuance of registration certificates for new pharmaceutical drugs, as well as in bibliographic databases like PubMed, Google Scholar and e-library.ru. The search encompassed publications from 2008 to 2023. The list of keywords included (but was not limited to) the following ones: new drug approval, NDA, drug authorization, approval package, breakthrough medicine. A total of 410 sources were analyzed. The exclusion criteria comprised earlier publications, non-English language articles, retracted articles, and the articles not directly relevant to the review topic. Furthermore, after a systematic categorization, 37 articles with duplicative information were removed. Following thorough the examination, 82 sources were deemed suitable for an inclusion in the review.

RESULTS AND DISCUSSION

Challenges of drug development

There has been an incredible increase in the amount of scientific information available on a wide range of areas of biology, including new findings on human physiology and the pathophysiology of human diseases. Research and development in the pharmaceutical industry is estimated to the cost over US$100 billion annually [10]. Clinical trials (CTs) of drugs account for up to 63% of this amount, while the cost of preclinical studies is only estimated at 32% [11]. In 2011, out of 5408 clinically investigational drugs worldwide, around 2000 were in phase I and phase II, and around 850 were in phase III [10]. It is worth pointing out that many medicinal products that have reached the phase are indicated for more than one treatment application [12].

In recent years, significant attention has been dedicated to the advancement of genomic and bioinformatic approaches for the discovery of novel disease biomarkers or potential drug targets [13]. The revolution in genomics and proteomics has resulted in the emergence of thousands of new drug targets [14]. These biomarkers can be regarded as indicators for measuring and evaluating normal biological processes or for influencing biological systems by certain agents, such as therapeutics, biological, or physical agents [15]. The utilization of biomarkers for patient selection in phase I/II studies may expedite the development of anticancer drugs [14, 16].

In spite of the favourable profile of pre-clinical studies, of course, drugs can fail in CTs or reach the market with delays as a result of serious side-effects [17]. Although the best efforts have been made, failures in CTs have increased dramatically over the past 20 years, with drop-out rates increasing between 1990 and 2010 for phase I from 33 to 46%, for phase II from 43 to 66% and for phase III from 20 to 30% [10]. The current reasons for phase II failures are: lack of efficacy (51%), safety issues (19%), strategic issues (29%) and pharmacokinetic/bioavailability issues (1%) [18]. The reasons for phase III failures are: lack of efficacy (66%), safety problems (21%),

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financial or commercial difficulties (7%) and other aspects (6%). Overall, the performance of new drugs in phase II is around 20% (51% ineffectiveness and 19% safety concerns) and it is around 50% in phase III (66% ineffectiveness and 21% safety concerns) [19]. Thus, although success in the execution of research and development (R&D) is important at each stage, the right choice of strategy at the earliest stage remains crucial.

Drug development trends by therapeutic areas

During the inaugural "International Symposium on Medicinal Chemistry" (ISMC) held in the 1970s, infectious diseases constituted a substantial focal point, comprising 30% of the proceedings in both 1970 and 1972 [20, 21]. However, the significance of this domain steadily declined, reaching less than 15% until 2016, followed by a resurgence in 2018. Meanwhile, deliberations related to central nervous system (CNS) disorders took precedence at ISMCs until the 2000s, accounting for 20.8% in the 1980s, 16.6% in the 1990s, and 16.8% in the 2000s. However, their prominence waned to third place in the 2010s (9.9%). This overall decline can be attributed to a dwindling number of CNS drug candidates in clinical development since the 1990s, indicative of waning pharmaceutical industry interest in CNS conditions [22]. In CNS-related research, the focus is gradually transitioning from psychiatry, which dominated the landscape until the late 1980s, toward neurology.

In the 1970s, cardiovascular diseases (CVDs) occupied the third position, commanding a notable share of 30% in 1974. Subsequently, CVDs ascended to the second spot in the 1980s (13.1%) and the 1990s (14.5%). Nevertheless, the number of CVD-related presentations plummeted significantly in the late 1990s, relegating this domain to the lower echelons with only 3.6% in the 2000s and 3.9% in the 2010s [20]. This corresponds to the diminishing focus on the pharmaceutical research and development in this area, leading to its stagnation spanning two decades [23].

The most conspicuous transformation has occurred in oncology. While this therapeutic realm was scarcely represented in the 1970s (2.7%), it experienced a remarkable surge in contributions by the 2000s and has dominated the ISMC program, occupying 21.5% in the 2010s. This evolution aligns with the consistent rise in the FDA-approved New Molecular Entities (NMEs) designated for cancer treatment and the preeminence of anti-tumour drug candidates, constituting 36.7% of the overall pharmaceutical R&D landscape [21].

In contrast, other therapeutic domains make more modest contributions to contemporary symposium programs [20]. Immunology and metabolic disorders each account for up to 10%, while analgesia issues contribute up to 7%, and respiratory diseases – only 1%. Several therapeutic areas have made sporadic appearances in ISMC curricula, including musculoskeletal diseases, gastrointestinal diseases, otorhinolaryngology, reproduction, sleep disorders, urology/nephrology, dermatology, and ophthalmology.

Strategies for drug design

Over the last 30 years, the targeted drug discovery has made it possible to significantly expand the list of chemotypes and pharmacophores for their development. New techniques such as high throughput screening (HTS), fragment-based screening (FBS), crystallography combined with molecular modelling, and combinatorial and parallel chemistry have made the generation of a considerable variety of chemical hit structures possible [24]. Moreover, this plethora of chemotypes can now be used as a source of compounds-tools to explore the undiscovered biological space and search for new drug targets or for phenotypic screening using systematic approaches to identify drug candidates in an agnostic manner.

Artificial Intelligence (AI) encompasses multiple domains of techniques, including reasoning, knowledge representation, decision mining, and machine learning (ML) [25]. ML employs algorithms capable of identifying patterns within datasets, which are subsequently classified [1]. Deep learning (DL), a subset of ML, involves artificial neural networks (ANN) [26], which consist of interconnected computational elements resembling "perceptrons", akin to biological neurons, replicating electrical impulse transmission in the human brain [27]. ANNs comprise nodes receiving distinct inputs, ultimately producing output signals, either single or multi-connected, through algorithmic processes to solve problems [28]. ANNs encompass various types, including multilayer perceptron networks (MLP), recurrent neural networks (RNNs), and convolutional neural networks (CNNs), all employing supervised or unsupervised learning procedures [29, 30]. Despite its merits, AI confronts substantial data challenges such as scale, growth, diversity, and data uncertainty. Within pharmaceutical drug development, datasets may encompass millions of compounds, posing challenges for traditional machine learning tools [31]. Quantitative structure-activity relationship (QSAR)-based computational models can swiftly generate numerous compounds or predict simple physicochemical parameters like logP or logD. However, these models fall short in predicting complex

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biological properties, including compound efficacy and side effects [32]. They also grapple with issues like small training datasets and experimental data errors. To surmount these challenges, recent AI approaches, including DL and modeling studies, have emerged for assessing drug molecule safety and efficacy through a big data analysis [33]. In 2012, Merck sponsored the QSAR ML task, evaluating DL's utility in pharmaceutical industry drug development [34, 35]. DL models have demonstrated superior predictive capabilities compared to traditional ML approaches across 15 candidate drug absorption, distribution, metabolism, excretion, and toxicity (ADMET) datasets [33, 36].

Virtual screening (VS) operates within the expansive virtual chemical space, presenting a spatial representation of molecules and their properties. VS endeavors to identify biologically active compounds within this space, facilitating the selection of molecules for a further evaluation [37]. Several publicly accessible chemical spaces, including PubChem, ChemBank, DrugBank, and ChemDB, support these efforts.

Diverse *in silico* methods for virtual screening, employing both structure- and ligand-based approaches, offer an enhanced profile analysis, an expedited removal of non-promising compounds, and a cost-effective selection of drug candidates [38]. Drug design algorithms, such as Coulomb matrices and a molecular fingerprint recognition, consider physical, chemical, and toxicological profiles to identify lead compounds [1].

Various strategies, encompassing predictive models, molecular similarity assessments, molecular generation processes, and *in silico* techniques, facilitate the prediction of desired compound chemical structures [39, 40]. Pereira et al. introduced the DeepVS system, capable of docking 40 receptors and 2 950 ligands with an exceptional performance in screening 95 000 ligands across these receptors [41]. Another approach employed a multi-criteria automated replacement algorithm to optimize the activity profile of a cyclin-dependent kinase-2 inhibitor, assessing their form similarity, biochemical activity, and physicochemical properties [42].

Table 1 – Current trends in FDA approved drugs by indication

Group of disorders	Number of approved drugs, absolute value (%)	Indications
Cancer	17 (21%)	Angiofibroma, hepatocellular carcinoma, melanoma, myelofibrosis, multiple myeloma, non-small cell lung cancer, acute myeloid leukemia, prostate cancer, ovarian cancer, follicular lymphoma, cholangiocarcinoma
CNS diseases	10 (12%)	Insomnia, Alzheimer's disease, major depressive disorder, multiple sclerosis, attention deficit hyperactivity disorder, seizures of various genes, anxiety disorder, cerebral adrenoleukodystrophy
Dermatological diseases	8 (10%)	Atopic dermatitis, plaque psoriasis, generalized pustular psoriasis, skin burns, rosacea
Infectious diseases	6 (7%)	Vaginal fungal infection, HIV infection, prevention of COVID-19, prevention of measles, mumps, rubella, prevention of recurrent *Clostridioides difficile* infection, Helicobacter infection
Metabolic disorders	6 (7%)	Acid sphingomyelinase deficiency, pyruvate kinase deficiency, urea cycle disorders, type 2 diabetes, transthyretin amyloidosis
Complications of anticancer therapy	5 (6%)	Chemotherapy-related neutropenia, prevention of cisplatin-induced ototoxicity
Diagnoses and examinations	5 (6%)	Not applicable
Ophthalmological disorders	5 (6%)	Open-angle glaucoma, macular degeneration, yellow spot oedema, glaucoma/intraocular hypertension, superficial anesthesia
Musculoskeletal disorders	4 (5%)	Amyotrophic lateral sclerosis, spasticity
Cardiological diseases	3 (4%)	Hypertention, coronary heart disease, angina pectoris, heart failure, hypertrophic cardiomyopathy
Haematological diseases	3 (4%)	Beta-thalassaemia, cold agglutinin disease, haemophilia B

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Table 2 – Drugs approved by FDA in 2022

No.	Date of approval	INN	Trade name	Manufacturer	Indications for use	Drug class / mechanism of action	Dosage form
1	07.12.22	Daridorexant	Quviviq®	Idorsia Ltd.	Insomnia	Dual orexin receptor antagonist (DORA)	Tablets
2	13.01.22	Mometasone Furoate And Olopatadine Hydrochloride	Ryaltris	Glenmark Pharmaceuticals, Inc.	Seasonal allergic rhinitis (SAR)	Combination of corticosteroids and antihistamines	Nasal spray
3	14.01.22	Abrocitinib	Cibinqo®	Pfizer Inc.	Atopic dermatitis	Janus kinase inhibitor (JAK) 1	Tablets
4	25.01.22	Tebentafusp	Kimmtrak®	Immunocore	Uveal melanoma	GP100-HLA bispecific peptide- directed activator of CD3 T cells	Solution for injection
5	28.01.22	Faricimab	Vabysmo	Genentech	Macular degeneration, diabetic macular edema	Bispecific antibody targeting (VEGF) and angiopoietin 2 (ANG- 2) pathways	Intravitreal Injection
6	31.01.22	COVID-19 vaccine	Spikevax®	Moderna, Inc.	COVID-19 prevention	mRNA-vaccine	Solution for injection
7	04.02.22	Sumimlimab	Enjaymo®	Sanofi	Cold agglutinin disease	Classical complement inhibitor	Solution for injection
8	04.02.22	Baclofen	Fleqsuvy	Azurity Pharmaceuticals, Inc.	Spasticity	GABA-derived skeletal muscle relaxants	Oral suspension
9	17.02.22	Mitapiwat	Pyrukynd®	Agios Pharmaceuticals, Inc.	Pyruvate kinase deficiency	Pyruvate kinase activator	Tablets
10	22.02.22	Technetium tc 99m succimer	NephroScan	–	Diagnosis	Radioactive diagnostic agent	Injection kit
11	24.02.22	Amlodipine besylate	Norliqva®	CMP Pharma, Inc.	High blood pressure, coronary heart disease, angina pectoris	Calcium channel blocker	Oral solution
12	25.02.22	Filgrastim	Releuko®	Kashiv BioSciences, LLC	Chemotherapy-related neutropenia	Recombinant human granulocyte colony-stimulating factor	Solution for injection
13	28.02.22	Ciltacabtagen autoleucel	Carvykti®	Janssen Pharmaceutical Companies	Multiple myeloma	BCMA-directed immunotherapy CAR-T	Intravenous suspension
14	28.02.22	Pacritinib	Vonjo®	CTI BioPharma Corp.	Myelofibrosis	JAK2/FLT3 multi-kinase inhibitor	Capsules
15	11.03.22	Donepezil	Adlarity®	Corium, Inc.	Alzheimer's	Acetylcholinesterase inhibitor	Transdermal system

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Continuation of table 2

No.	Date of approval	INN	Trade name	Manufacturer	Indications for use	Drug class / mechanism of action	Dosage form
16	17.03.22	Mometasone furoate monohydrate	Nasonex 24HR Allergy	Perrigo Company pic	Allergic rhinitis	Corticosteroid	Nasal spray
17	18.03.22	Ganaxolone	Ztalmy®	Marinus Pharmaceuticals, Inc.	Seizures associated with CDKL5 deficiency	Neuroactive steroid, positive modulator of the GABA receptor	Oral suspension
18	18.03.22	Nivolumab/ Relatlimab	Opdualag	Bristol Myers Squibb	Melanoma	A combination of antibodies blocking programmed death receptor-1 (PD-1) and antibodies blocking lymphocyte activation gene-3 (LAG-3)	Solution for injection
19	22.03.22	Dextroamphetamine	Xelstrym	Noven Pharmaceuticals, Inc.	Attention deficit hyperactivity disorder (ADHD)	CNS stimulant	Transdermal System
20	22.03.22	Sirolimus	Hyftor®	Nobelpharma America, LLC	Facial angiofibroma associated with tuberous sclerosis	mTOR inhibitor immunosuppressant	Topical gel
21	23.03.22	Gallium ga 68 gosetotide	Locametz®	Novartis Pharmaceuticals Corporation	Positron emission tomography	Radioactive diagnostic agent	Solution for injection
22	23.03.22	Lutetium lu 177 vipivotide tetraxetan	Pluvicto®	Novartis	Prostate cancer	Radioligand therapeutic agent	Solution for injection
23	28.03.22	Testosterone	Tlando®	Antares Pharma, Inc.	Hypogonadism, male	Testosterone replacement therapy	Capsules
24	05.04.22	Alpelisib	Vijoice®	Novartis	The spectrum of overgrowth associated with PIK3CA	Kinase inhibitor	Tablets
25	05.04.22	Dexmedetomidine	Igalmi	BioXcel Therapeutics, Inc.	Alarm	Alpha2-adrenoceptor agonist	Sublingual form
26	13.04.22	Bevacizumab	Alymsys®	Amneal Pharmaceuticals, Inc.	Colorectal cancer, non-small cell lung cancer, glioblastoma multiforme, renal cell cancer, cervical cancer, ovarian cancer, fallopian tube cancer, peritoneal cancer	Vascular endothelial growth factor inhibitor	Solution for injection
27	22.04.22	Benzoyl peroxide	Epsolay®	Sol-Gel Technologies, Ltd.	Rosacea	Oxidising agent for topical use	Cream

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No.	Date of approval	INN	Trade name	Manufacturer	Indications for use	Drug class / mechanism of action	Dosage form
28	26.04.22	Oteconazole	Vivjoa®	Mycovia Pharmaceuticals, Inc.	Vaginal fungal infection	Oral antifungal azole	Capsules
29	28.04.22	Mavakamten	Camzyos®	Bristol Myers Squibb	Hypertrophic cardiomyopathy	A first-in-class cardiac myosin inhibitor	Capsules
30	28.04.22	Trientine tetrahydrochlorid	Cuvrior	Orphalan SA	Wilson's disease	Copper chelator	Tablets
31	03.05.22	Amoxicillin, Clarithromycin and Vonoprazan	Voquezna® Triple Pak®	Phathom Pharmaceuticals, Inc.	Helicobacter infection	Amoxicillin (penicillin class antibiotic), clarithromycin (macrolide antimicrobial), vonoprazan (potassium-competitive acid blocker (PCAB))	Capsules+pills
32	12.05.22	Edaravon	Radicava ORS®	Mitsubishi Tanabe Pharma Corporation	Amyotrophic lateral sclerosis	Free radical scavenger	Oral suspension
33	13.05.22	Tyrzepatid	Mounjaro	Eli Lilly and Company	Type 2 diabetes mellitus	Glucose-dependent insulinotropic polypeptide (GIP) and glucagonlike peptide-1 (GLP-1) receptor agonist	Solution for injection
34	23.05.22	Tapinarof	Vtama®	Dermavant Sciences	Plaque psoriasis	An agent that modulates the local arylhydrocarbon receptor (AHR)	Cream
35	26.05.22	Pegfilgrastim	Fylnetra	Amneal Pharmaceuticals, Inc.	Chemotherapy-related neutropenia	White blood cell growth factor	Solution for injection
36	03.06.22	Live measles, mumps and rubella vaccine	Priorix®	GSK	Prevention of measles, prevention of mumps, prevention of rubella	Live attenuated vaccine	Solution for injection
37	13.06.22	Wuthrisiran	Amvuttra®	Alnylam Pharmaceuticals, Inc.	Transthyretin amyloidosis	Rnai therapeutic	Solution for injection
38	08.07.22	Sodium indigotindisulphonate	Bludigo	Provepharm	Urological and gynaecological diagnostics and examinations	Diagnostic dye	Solution for injection
39	15.07.22	Zonisamide	Zonisade®	Azurity Pharmaceuticals, Inc.	Cramps	Gabaergic blocker of potential- dependent sodium and calcium channels	Oral suspension
40	27.07.22	Undecanoate Testosterone	Kyzatrex	Marius Pharmaceuticals	Male hypogonadism	Testosterone replacement therapy	Capsules

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Continuation of table 2

No.	Date of approval	INN	Trade name	Manufacturer	Indications for use	Drug class / mechanism of action	Dosage form
41	29.07.22	Roflumilast	Zoryve	Arcutis Biotherapeutics, Inc.	Plaque psoriasis	Local phosphodiesterase 4 (PDE4) inhibitor	Cream
42	02.08.22	Ranibizumab	Cimerli	Coherus BioSciences, Inc.	Yellow spot degeneration, yellow spot oedema, diabetic yellow spot oedema, diabetic retinopathy, myopic chorioidal neovascularisation	(VEGF) inhibitor	Intravitreal injection
43	17.08.22	Betabeglogen autotemcel	Zynteglo®	Bluebird Bio, Inc.	Beta-thalassaemia	Gene therapy based on autologous haematopoietic stem cells	Intravenous suspension
44	18.08.22	Dextromethorphan and Bupropion	Auvelity	Axsome Therapeutics, Inc.	Major depressive disorder	NMDA receptor antagonist	Extended-release tablets
45	30.08.22	Omeprazole and sodium bicarbonate	Konvomep	Azurity Pharmaceuticals, Inc.	Gastric ulcer, gastrointestinal bleeding	Proton pump inhibitor (PPI) combination of omeprazole and sodium bicarbonate	Oral powder
46	31.08.22	Olipudase alfa	Xenpozyme	Sanofi	Acid sphingomyelinase deficiency	Hydrolytic lysosomal sphingomyelin-specific enzyme	Lyophilised powder for injection
47	01.09.22	Spesolimab	Spevigo®	Boehringer Ingelheim	Generalised pustular psoriasis	Interleukin-36 receptor antagonist	Solution for injection
48	01.09.22	Pegfilgrastim	Stimufend®	Fresenius Kabi	Chemotherapy-related neutropenia	White blood cell growth factor	Solution for injection
49	07.09.22	Daxitulinotoxin A	Daxxify®	Revance Therapeutics, Inc.	Glabellar lines	Acetylcholine release inhibitor and neuromuscular blocker	Lyophilised powder for injection
50	09.09.22	Deukravacitinib	Sotyktu	Bristol Myers Squibb	Plaque psoriasis	Tyrosine kinase inhibitor 2 (TYK2)	Tablets
51	09.09.22	Eflapegrastim	Rolvedon®	Spectrum Pharmaceuticals, Inc.	Chemotherapy-related neutropenia	White blood cell growth factor	Solution for injection
52	14.09.22	Terlipressin	Terlivaz®	Mallinckrodt pic	Hepatorenal syndrome	Vasopressin receptor agonist	Lyophilised powder for injection
53	16.09.22	Aprepitant	Aponvie	Heron Therapeutics, Inc.	Nausea/vomiting in the postoperative period	P/neurokinin-1 receptor antagonist (NK1)	Solution for injection

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Continuation of table 2

No.	Date of approval	INN	Trade name	Manufacturer	Indications for use	Drug class / mechanism of action	Dosage form
54	16.09.22	Elivaldogen autotemsel	Skysona®	Bluebird bio, Inc.	Cerebral adrenoleukodystrophy	Functional copies of the ABCD1 gene added to the patient's stem cells and created using the patient's own blood stem cells	Intravenous suspension
55	20.09.22	Sodium thiosulphate	Pedmark®	Fennec Pharmaceuticals Inc.	Prevention of cisplatin-induced ototoxicity	Cisplatin-neutralising agent	Solution for injection
56	21.09.22	Gadopilenol	Elucirem	Guerbet	Paramagnetic contrast agent for magnetic resonance imaging	Macrocyclic gadolinium-based contrast agent (GBCA)	Solution for injection
57	22.09.22	Omidenepag isopropyl	Omlonti®	Santen Inc.	Glaucoma/intraocular hypertension	A relatively selective prostaglandin E2 receptor agonist (EP2)	Ophthalmic solution
58	27.09.22	Chloroprocaine hydrochloride	Iheezo	Harrow	Superficial eye anaesthesia	Ether anaesthetic	Ophthalmic gel
59	27.09.22	Bevacizumab	Vegzelma®	Celltrion USA	Colorectal cancer, non-small cell lung cancer, glioblastoma multiforme, renal cell cancer, cervical cancer, ovarian cancer, fallopian tube cancer, peritoneal cancer	Vascular endothelial growth factor (VEGF) inhibitor	Solution for injection
60	29.09.22	Sodium phenylbutyrate and taurursodiol	Relyvrio	Amylyx Pharmaceuticals, Inc.	Amyotrophic lateral sclerosis	Oral fixed-dose combination therapy for the treatment of adults with bass	Oral powder
61	30.09.22	Futibatinib	Lytgobi®	Taiho Oncology, Inc.	Cholangiocarcinoma	Irreversible tyrosine kinase inhibitor FGFR1, 2, 3 and 4	Tablets
62	07.10.22	Furosemide	Furoscix®	scPharmaceuticals, Inc.	Heart failure	Loop diuretic	Solution for injection
63	21.10.22	Tremelimumab	Imjudo®	AstraZeneca	Hepatocellular carcinoma	Antibody blocking cytotoxic t- lymphocyte-associated antigen 4 (CTLA-41)	Solution for injection
64	25.10.22	Teclistamab	Tecvayli®	Janssen Pharmaceutical Companies of Johnson & Johnson	Multiple myeloma	Bispecific B-cell maturation antigen (BCMA) targeting CD3 T-cells	Solution for injection
65	14.11.22	Mirvetuximab soravtansine	Elahere	ImmunoGen, Inc.	Ovarian cancer, fallopian tube cancer, peritoneal cancer	Antibody conjugate against folic acid receptor alpha (fra) and microtubule inhibitor	Solution for injection

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Continuation of table 2

No.	Date of approval	INN	Trade name	Manufacturer	Indications for use	Drug class / mechanism of action	Dosage form
66	17.11.22	Teplizumab	Tzield®	Provention Bio, Inc.	Delaying the onset of type 1 diabetes at stage 3	CD3-directed antibody	Solution for injection
67	17.11.22	Sodium phenobarbital	Sezaby	Sun Pharmaceutical Industries Limited	Neonatal seizures	GABA mimetic	Injection powder
68	22.11.22	Etranacogene dezaparvovec	Hemgenix®	CSL	Haemophilia B	Adeno-associated virus vector-based gene therapy	Intravenous suspension
69	30.11.22	Faecal microbiota, live	Rebyota®	Ferring Pharmaceuticals Inc.	Prevention of recurrent clostridioides difficile infection	Live biotherapeutic based on microbiota	Rectal suspension
70	01.12.22	Olutazidenib	Rezlidhia	Forma Therapeutics	Acute myeloid leukaemia	Isocitrate dehydrogenase inhibitor-1 (IDH1)	Capsules
71	12.12.22	Adagracib	Krazati®	Mirati Therapeutics, Inc.	Non-small cell lung cancer	Low molecular weight inhibitor KRAS g12c	Tablets
72	13.12.22	Latanoprost	Iyuzeh	Thea Pharma, Inc.	Intraocular hypertension, open- angle glaucoma,	Prostaglandin F2α analogue	Ophthalmic solution
73	13.12.22	Adalimumab	Idacio®	Fresenius Kabi	Rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, Bechterew disease, Crohn's disease, ulcerative colitis, plaque psoriasis	Tumour necrosis factor (TNF) blocker	Solution for injection
74	16.12.22	Nadofaragen firaden	Adstiladrin®	Ferring Pharmaceuticals	Bladder cancer	Gene therapy based on a non-replicating adenovirus vector	Suspension for intravesicular use
75	22.12.22	Lenacapavir	Sunlenca®	Gilead Sciences, Inc.	HIV infection	Long-acting HIV-1 capsid inhibitor	Injectable solution and tablets
76	22.12.22	Mosunetuzumab	Lunsumio	Genentech	Follicular lymphoma	Bispecific CD20-directed activator of CD3 T cells	Solution for injection
77	22.12.22	Sodium phenylbutyrate	Olpruva	Acer Therapeutics Inc.	Urea cycle disorders	Nitrogen-binding agent	Oral suspension
78	23.12.22	Xe 129 hyperpolarised	Xenoview	Polarean Imaging plc	Diagnosis	Hyperpolarised contrast agent	Inhalation agent
79	28.12.22	Ublituximab	Briumvi	TG Therapeutics, Inc.	Multiple sclerosis	CD20-directed cytolytic antibody	Solution for injection
80	28.12.22	Anacaulase	NexoBrid®	MediWound Ltd.	Skin burns	Proteolytic enzyme concentrate	Topical gel

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Table 3 – Combinations of chemotherapeutic drugs with evacizumab to treat different types of cancer.

Indication	Drug administered in combination with bevacizumab
Metastatic colorectal cancer	Fluorouracil (1st–2nd line) Fluoropyrimidine+irinotecan or Fluoropyrimidine+oxaliplatin (2nd line)
Non-small cell lung cancer	Carboplatin+paclitaxel (1st line)
Metastatic renal cell cancer	Interferon alpha
Persistent, recurrent or metastatic cervical cancer	Paclitaxel+cisplatin or Paclitaxel+topotecan
Epithelial cancer of the ovaries, fallopian tubes or primary peritoneal cancer	Paclitaxel

QSAR modeling tools have evolved into AI-based QSAR approaches, such as a linear discriminant analysis (LDA), support vector machines (SVMs), random forest (RF), and decision trees, accelerating a QSAR analysis [43–45].

Cryogenic electron microscopy. Until 2014, cryogenic electron microscopy (cryo-EM) rarely provided the resolution below 4.0 Å, often necessary for a structure-based drug discovery (SBDD) [46]. However, the tremendous advances in the methodology over the latest few years have led to a higher availability of high-resolution structural data. "The quantum leap" of cryo-EM is due to many advances, such as direct electron detectors for image recording, improved computational methods and a hardware parallelisation for processing large datasets [47]. Furthermore, the nature of cryo-EM as a direct imaging technique allows a rapid diagnosis of biochemical problems such as aggregation and instability of samples, leading to the rapid improvement through genetic and biochemical modifications [48]. As a result, the number of cryo-EM structures deposited in the Protein Data Bank (PDB) with a resolution of 4.0 Å or higher increased from 16 before 2014 to 1753 new structures deposited in 2020 alone. The proportion of newly deposited structures with resolutions better than 4.0 and 3.5 Å increased from 36 and 12% in 2015 to 75 and 50% in 2020 [8]. Perhaps most impressively, the proportion of deposited structures above 3.0 and 2.5 Å resolution in 2020, previously almost non-existent, is now a significant 18 and 3% respectively [8, 49].

Drug repositioning. Drug repositioning has a number of interrelated benefits [50]. Essentially, they include the simplification of regulatory procedures to bring a previously approved drug to the market, especially in some countries such as the US [51]. This procedure considers previously obtained data, in particular on the safety and toxicity of the drug, which can significantly speed up the initial stages of development of a new drug [52] and hence make it cheaper (by more than 80% according to Naylor) [53], and increase the chances of it reaching the market. One important consideration, however, is that because the level of safety required for a medicine is highly dependent on its indication, the side effects of a medicine will be proportionately less acceptable if it is repositioned to treat a less serious disease than its original indication [54, 55]. Any change in the formulation, dosage or route of administration would require a reassessment of the safety profile of the drug in this new setting, as it would be a new pharmaceutical product.

Current state of FDA-approved drugs

According to the analysis of recent developments, drugs with an anticancer activity (21%), CNS disorders (12%), and dermatological conditions (8%) are most frequently approved (Table 1). It is worth pointing out that about 22% of the approved drugs are biotech products, which may indicate current trends in the drug design (Table 2).

Spikevax® is an mRNA vaccine that can be used for an active immunization against COVID-19 in persons aged 12 years and older. The FDA-approved vaccine Spikevax® (monovalent) and the emergency-approved (EUA) vaccine Moderna COVID19 (monovalent) contain the same mRNA component of the original SARS-CoV-2 strain, but when used with the FDA approval, the vaccine is labeled Spikevax® and when used under the EUA – Moderna COVID19 vaccine. Moderna COVID19, a bivalent vaccine, differs from the original Moderna COVID19 (monovalent) vaccine and Spikevax® because it contains two SARS-CoV-2 mRNA components. The efficacy of the vaccine has been confirmed by numerous studies [56–58].

Opdualag® (nivolumab and relatlimab) is an antibody combination indicated for the treatment of unresectable or metastatic melanoma in adults and children from 12 years of age [59]. Nivolumab is an antibody that blocks programmed death-1 receptor (PD-1), first approved under the brand name of Opdivo for the treatment of unresectable or metastatic melanoma in 2014. Lymphocyte activation gene-3

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(LAG-3) is a cell surface molecule expressed on effector T cells and regulatory T cells, and it is associated with the T cell depletion and resistance to immunotherapies such as antibodies that block PD-1 [60]. Relatlimab is an LAG-3 blocking antibody that binds to LAG-3 on T cells, thereby restoring the effector function of depleted T cells and potentially promoting an anti-tumour response [61]. The combination of nivolumab and relatlimab leads to an increased T-cell activation compared to the activity of either antibody alone. The FDA approval of Opdualag® is based on the results of the phase 2/3 RELATIVITY-047 trial, in which a fixed combination of relatlumab and nivolumab demonstrated a statistically significant and clinically relevant progression-free survival benefit compared to nivolumab monotherapy [62].

Alymsys® (bevacizumab) is a vascular endothelial growth factor (VEGF) inhibitor intended to treat several types of cancer, including metastatic colorectal cancer; non-small cell lung cancer; glioblastoma; metastatic renal cell carcinoma; cervical cancer; epithelial ovarian, fallopian tube or primary peritoneal cancer [63–66] (Table 3). Instead of directly targeting cancer cells, bevacizumab affects the tumour microenvironment, characterised by complex interactions between cancer cells, normal cells and the extracellular matrix. Moreover, VEGF plays additional roles independent of angiogenesis in the complex tumour microenvironment, including a modulation of anticancer immune response. Since the initial approval of bevacizumab, a number of targeted cancer therapies have become available, changing the treatment landscape for many solid tumour indications and providing opportunities for new approaches to combination therapy. Notably, the approval of bevacizumab in combination with immune checkpoint inhibitors for non-small cell lung cancer treatment has recently occurred, with additional CTs demonstrating clinical benefits in renal cell cancer patients in combination with PARP inhibitors for ovarian cancer treatment [67].

Camzyos® (mavacamten) is a first-in-class cardiac myosin inhibitor for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy of class II-III according to the New York Heart Association (NYHA) classification [68]. Hypertrophic cardiomyopathy is a type of a heart disease characterised by thickening of the heart muscle and the left ventricular stiffness. The obstruction occurs when the thickened septum causes a narrowing that can block or reduce a blood flow from the left ventricle to the aorta, making it difficult for the heart to expand normally and fill with blood. Camzyos® is an allosteric, reversible and selective inhibitor of cardiac myosin [69]. It is thought to work by reducing the cardiac muscle contractility by inhibiting an excessive formation of myosin-actin cross-links. The drug has an embryo-fetal toxicity.

Fleqsuvy is an oral baclofen suspension for the treatment of spasticity caused by multiple sclerosis, especially for the relief of flexor spasms and the associated pain, clonus and muscle stiffness. Fleqsuvy may also be useful for patients with a spinal cord disease, including trauma. It is increasingly used off-label for the treatment of skeletal muscle pain, a gastroesophageal reflux disease and alcohol dependence [70–72].

Mounjaro (tirzepatide) is a glucose-dependent insulinotropic polypeptide (IGP) receptor and a glucagon-like peptide-1 (GFP-1) receptor agonist shown as a supplement to diet and exercise to improve a glycaemic control in adults with type 2 diabetes. Mounjaro works by activating the body's receptors for GIP and GFP-1, which are naturally occurring incretin hormones [73–75]. The drug is administered subcutaneously once a week. Patients with diabetic retinopathy should take the drug with caution as taking Mounjaro may exacerbate the condition.

Cibinqo® (abrocitinib) is indicated for the treatment of adults and children from 12 years of age with moderate to severe refractory atopic dermatitis refractory to other treatments. Cibinqo® selectively inhibits Janus kinase-1 (JAK1) [76]. The inhibition of JAK1 is thought to modulate several cytokines involved in the pathophysiology of atopic dermatitis, including interleukin IL-4, IL-13, IL-31, IL-22 and thymic stromal lymphopoietin (TSLP) [77]. The study published in The Lancet assessed the effectiveness and safety of abrocitinib in comparison to dupilumab [78]. Abrocitinib, administered at a daily dose of 200 mg, demonstrated a superior efficacy to dupilumab in adults with moderate to severe atopic dermatitis who were receiving topical therapy, resulting in rapid alleviation of itching and improvement in atopic dermatitis symptoms. Cibinqo® is administered orally once daily.

Adstiladrin® (nadofaragen firadenovec) is a non-replicative gene-based adenoviral vector designed to treat adult patients with Bacillus Calmette-Guerin (BCG) unresponsive non-muscle invasive bladder cancer with or without papillary tumours [79]. Adstiladrin® acts by delivering the interferon alfa-2b gene into bladder wall cells, resulting in the increased secretion of interferon alfa-2b protein, a native cancer-fighting agent [80]. Adstiladrin® is injected into the bladder once every three months.

Skysona® (elivaldogen autotemcel) is a single-dose gene therapy administered intravenously to treat the underlying cause of cerebral adrenoleukodystrophy (CALD). Skysona® is indicated for slowing the progression of a neurological dysfunction in boys aged

4–17 years with early active CALD. This indication was approved in a fast-track procedure after the evidence of a 24-month survival rate without major functional impairments [68].

CALD is a genetic disorder caused by mutations in the ABCD1 gene that lead to an accumulation of very long chain fatty acids (VLCFAs) in the brain. VLCFAs can destroy the myelin coating of nerve cells and cause brain damage [81]. Skysona® is made specifically for each patient using the patient's own blood stem cells. Functional copies of the ABCD1 gene are added to the patient's stem cells, which can then help the body to degrade VLCFAs to slow the progression of brain damage and slow the decline in a neurological function [82]. Skysona packets are administered intravenously over less than 60 min each.

CONCLUSION

Drug development is obviously a very time-consuming and labour-intensive process requiring a huge number of resources. A small proportion of pharmaceuticals undergoing the preclinical research cycle reach the stage of CTs. Drug design trends are not static and changing according to the demands of the society. This review presents only a few of the most promising drugs approved by the FDA in 2022. As the technology advances, the speed of drug development will increase, resulting in a shorter time for the drugs to reach the market. Biotechnology-based pharmaceuticals, particularly cell-based therapies, have great a potential and demand, while genetic mapping and improved chipping technologies (cell / tissue / organ on a chip) will increase the availability of personalized treatment strategies.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

AUTHORS CONTRIBUTION

Denis V. Kurkin – conception and planning of the work's content; Dmitry A. Bakulin, Yuliya V. Gorbunova, Yury A. Kolosov, Marina A. Dzhavakhyan – data collection and drafting of the manuscript; Evgeniy I. Morkovin, Andrey V. Strygin – data collection, editing the final version of the manuscript; Igor E. Makarenko, Roman V. Drai, Andrew V. Zaborovsky, Olga V. Shatalova, Vladimir I. Petrov, Anatoliy P. Pleten, Aleksei A. Prokopov, Tatiana Yu. Tatarenko-Kozmina – consulting, editing, and approval of the final version of the manuscript. All authors made a substantial contribution to the conception of the work, acquisition, analysis, interpretation of data for the work, drafting and revising the work, final approval of the version to be published and agree to be accountable for all aspects of the work.

REFERENCES

1. Chan HCS, Shan H, Dahoun T, Vogel H, Yuan S. Advancing Drug Discovery via Artificial Intelligence. Trends Pharmacol Sci. 2019;40(8):592–604. DOI: 10.1016/j.tips.2019.06.004
2. Batool M, Ahmad B, Choi S. A Structure-Based Drug Discovery Paradigm. Int J Mol Sci. 2019;20(11):2783. DOI: 10.3390/ijms20112783
3. Moore TJ, Zhang H, Anderson G, Alexander GC. Estimated Costs of Pivotal Trials for Novel Therapeutic Agents Approved by the US Food and Drug Administration, 2015-2016. JAMA Intern Med. 2018;178(11):1451–7. DOI: 10.1001/jamainternmed.2018.3931
4. Lavecchia A, Di Giovanni C. Virtual screening strategies in drug discovery: a critical review. Curr Med Chem. 2013;20(23):2839–60. DOI: 10.2174/09298673113209990001
5. Berdigaliyev N, Aljofan M. An overview of drug discovery and development. Future Med Chem. 2020;12(10):939–47. DOI: 10.4155/fmc-2019-0307
6. Vamathevan J, Clark D, Czodrowski P, Dunham I, Ferran E, Lee G, Li B, Madabhushi A, Shah P, Spitzer M, Zhao S. Applications of machine learning in drug discovery and development. Nat Rev Drug Discov. 2019;18(6):463–77. DOI: 10.1038/s41573–019-0024-5
7. Markel U, Essani KD, Besirlioglu V, Schiffels J, Streit WR, Schwaneberg U. Advances in ultrahigh-throughput screening for directed enzyme evolution. Chem Soc Rev. 2020;49(1):233–62. DOI: 10.1039/c8cs00981c
8. Robertson MJ, Meyerowitz JG, Skiniotis G. Drug discovery in the era of cryo-electron microscopy. Trends Biochem Sci. 2022;47(2):124–35. DOI: 10.1016/j.tibs.2021.06.008.
9. Parvathaneni V, Kulkarni NS, Muth A, Gupta V. Drug repurposing: a promising tool to accelerate the drug discovery process. Drug Discov Today. 2019;24(10):2076–85. DOI: 10.1016/j.drudis.2019.06.014
10. Mignani S, Huber S, Tomás H, Rodrigues J, Majoral JP. Why and how have drug discovery strategies in pharma changed? What are the new mindsets? Drug Discov Today. 2016;21(2):239–49. DOI: 10.1016/j.drudis.2015.09.007
11. Paul D, Sanap G, Shenoy S, Kalyane D, Kalia K, Tekade RK. Artificial intelligence in drug discovery and development. Drug Discov Today. 2021;26(1):80–93. DOI: 10.1016/j.drudis.2020.10.010
12. Shih HP, Zhang X, Aronov AM. Drug discovery effectiveness from the standpoint of therapeutic mechanisms and indications. Nat Rev Drug Discov. 2018;17(1):19–33. DOI: 10.1038/nrd.2017.194
13. He X, Hui Z, Xu L, Bai R, Gao Y, Wang Z, Xie T, Ye XY.

Medicinal chemistry updates of novel HDACs inhibitors (2020 to present). Eur J Med Chem. 2022;227:113946. DOI: 10.1016/j.ejmech.2021.113946

14. Geronikaki A. Recent Trends in Enzyme Inhibition and Activation in Drug Design. Molecules. 2020;26(1):17. DOI: 10.3390/molecules26010017
15. Wooller SK, Benstead-Hume G, Chen X, Ali Y, Pearl FMG. Bioinformatics in translational drug discovery. Biosci Rep. 2017;37(4):BSR20160180. DOI: 10.1042/BSR20160180
16. Carden CP, Sarker D, Postel-Vinay S, Yap TA, Attard G, Banerji U, Garrett MD, Thomas GV, Workman P, Kaye SB, de Bono JS. Can molecular biomarker-based patient selection in Phase I trials accelerate anticancer drug development? Drug Discov Today. 2010;15(3–4):88–97. DOI: 10.1016/j.drudis.2009.11.006
17. Hauser AS, Attwood MM, Rask-Andersen M, Schiöth HB, Gloriam DE. Trends in GPCR drug discovery: new agents, targets and indications. Nat Rev Drug Discov. 2017;16(12):829–42. DOI: 10.1038/nrd.2017.178
18. MacLean F. Knowledge graphs and their applications in drug discovery. Expert Opin Drug Discov. 2021;16(9):1057–69. DOI: 10.1080/17460441.2021.1910673
19. Arrowsmith J. Trial watch: Phase II failures: 2008-2010. Nat Rev Drug Discov. 2011;10(5):328–9. DOI: 10.1038/nrd3439
20. Differding E. Trends in drug discovery over five decades – The European Federation for Medicinal Chemistry International Symposium on Medicinal Chemistry (EFMC-ISMC). Chem Med Chem. 2020;15(24):2352–8. DOI: 10.1002/cmdc.202000840
21. Kinch MS. An analysis of FDA-approved drugs for oncology. Drug Discov Today. 2014;19(12):1831–5. DOI: 10.1016/j.drudis.2014.08.007
22. Kesselheim AS, Hwang TJ, Franklin JM. Two decades of new drug development for central nervous system disorders. Nat Rev Drug Discov. 2015;14(12):815–6. DOI: 10.1038/nrd4793
23. Fordyce CB, Roe MT, Ahmad T, Libby P, Borer JS, Hiatt WR, Bristow MR, Packer M, Wasserman SM, Braunstein N, Pitt B, DeMets DL, Cooper-Arnold K, Armstrong PW, Berkowitz SD, Scott R, Prats J, Galis ZS, Stockbridge N, Peterson ED, Califf RM. Cardiovascular drug development: is it dead or just hibernating? J Am Coll Cardiol. 2015;65(15):1567–82. DOI: 10.1016/j.jacc.2015.03.016
24. Velmurugan D, Pachaiappan R, Ramakrishnan C. Recent trends in drug design and discovery. Curr Top Med Chem. 2020;20(19):1761–70. DOI: 10.2174/1568026620666200622150003
25. Yang X, Wang Y, Byrne R, Schneider G, Yang S. Concepts of artificial intelligence for computer-assisted drug discovery. Chem Rev. 2019;119(18):10520–94. DOI: 10.1021/acs.chemrev.8b00728
26. Jiménez-Luna J, Grisoni F, Weskamp N, Schneider G. Artificial intelligence in drug discovery: recent advances and future perspectives. Expert Opin Drug Discov. 2021;16(9):949–59. DOI: 10.1080/17460441.2021.1909567
27. Beneke F, Mackenrodt MO. Artificial Intelligence and Collusion. IIC 50. 2019:109–34. DOI: 10.1007/s40319-018-00773-x
28. Steels L, Brooks R. (ed.). The artificial life route to artificial intelligence: Building embodied, situated agents. UK: Taylor & Francis Group; 2018. 296 p.
29. Bielecki A. Models of Neurons and Perceptrons: Selected Problems and Challenges. Germany: Springer International Publishing; 2018, 156 p.
30. Tekade RK. The future of pharmaceutical product development and research. Netherlands: Academic Press; 2020. 976 p.
31. Paul SM, Mytelka DS, Dunwiddie CT, Persinger CC, Munos BH, Lindborg SR, Schacht AL. How to improve R&D productivity: the pharmaceutical industry's grand challenge. Nat Rev Drug Discov. 2010;9(3):203–14. DOI: 10.1038/nrd3078
32. Gupta R, Srivastava D, Sahu M, Tiwari S, Ambasta RK, Kumar P. Artificial intelligence to deep learning: machine intelligence approach for drug discovery. Mol Divers. 2021;25(3):1315–60. DOI: 10.1007/s11030-021-10217-3
33. Zhu H. Big data and artificial intelligence modeling for drug discovery. Annu Rev Pharmacol Toxicol. 2020;60:573–89. DOI: 10.1146/annurev-pharmtox-010919-023324
34. Vatansever S, Schlessinger A, Wacker D, Kaniskan HÜ, Jin J, Zhou MM, Zhang B. Artificial intelligence and machine learning-aided drug discovery in central nervous system diseases: State-of-the-arts and future directions. Med Res Rev. 2021;41(3):1427–73. DOI: 10.1002/med.21764
35. You Y, Lai X, Pan Y, Zheng H, Vera J, Liu S, Deng S, Zhang L. Artificial intelligence in cancer target identification and drug discovery. Signal Transduct Target Ther. 2022;7(1):156. DOI: 10.1038/s41392-022-00994-0
36. Ciallella HL, Zhu H. Advancing computational toxicology in the big data era by artificial intelligence: data-driven and mechanism-driven modeling for chemical toxicity. Chem Res Toxicol. 2019;32(4):536–47. DOI: 10.1021/acs.chemrestox.8b00393
37. Hessler G, Baringhaus KH. Artificial intelligence in drug design. Molecules. 2018;23(10):2520. DOI: 10.3390/molecules23102520
38. Mak KK, Pichika MR. Artificial intelligence in drug development: present status and future prospects. Drug Discov Today. 2019;24(3):773–80. DOI: 10.1016/j.drudis.2018.11.014
39. Brown N. In silico medicinal chemistry: computational methods to support drug design. UK: Royal Society of Chemistry; 2015, 232 p.
40. Sellwood MA, Ahmed M, Segler MH, Brown N. Artificial intelligence in drug discovery. Future Med Chem. 2018;10(17):2025–8. DOI: 10.4155/fmc-2018-0212
41. Pereira JC, Caffarena ER, Dos Santos CN. Boosting docking-based virtual screening with deep learning. J Chem Inf Model. 2016;56(12):2495–506. DOI: 10.1021/acs.jcim.6b00355
42. Firth NC, Atrash B, Brown N, Blagg J. MOARF, an Integrated Workflow for Multiobjective Optimization: Implementation, Synthesis, and Biological Evaluation. J Chem Inf Model. 2015;55(6):1169–80. DOI: 10.1021/acs.jcim.5b00073
43. Carpenter KA, Huang X. Machine learning-based virtual screening and its applications to alzheimer's drug discovery: a review. Curr Pharm Des. 2018;24(28):3347–58. DOI: 10.2174/1381612824666180607124038

ISSN 2307-9266 e-ISSN 2413-2241

Scientific and Practical Journal
PHARMACY & PHARMACOLOGY

44. Patel L, Shukla T, Huang X, Ussery DW, Wang S. Machine learning methods in drug discovery. Molecules. 2020;25(22):5277. Published 2020 Nov 12. DOI: 10.3390/molecules25225277
45. Zhang L, Tan J, Han D, Zhu H. From machine learning to deep learning: progress in machine intelligence for rational drug discovery. Drug Discov Today. 2017;22(11):1680–5. DOI: 10.1016/j.drudis.2017.08.010
46. de Oliveira TM, van Beek L, Shilliday F, Debreczeni JÉ, Phillips C. Cryo-EM: The Resolution Revolution and Drug Discovery. SLAS Discov. 2021;26(1):17–31. DOI: 10.1177/2472555220960401
47. Renaud JP, Chari A, Ciferri C, Liu WT, Rémigy HW, Stark H, Wiesmann C. Cryo-EM in drug discovery: achievements, limitations and prospects. Nat Rev Drug Discov. 2018;17(7):471–92. DOI: 10.1038/nrd.2018.77
48. Saur M, Hartshorn MJ, Dong J, Reeks J, Bunkoczi G, Jhoti H, Williams PA. Fragment-based drug discovery using cryo-EM. Drug Discov Today. 2020;25(3):485–90. DOI: 10.1016/j.drudis.2019.12.006
49. Van Drie JH, Tong L. Cryo-EM as a powerful tool for drug discovery. Bioorg Med Chem Lett. 2020;30(22):127524. DOI: 10.1016/j.bmcl.2020.127524
50. Kale MA, Shamkuwar PB, Mourya VK, Deshpande AB, Shelke PA. Drug repositioning: a unique approach to refurbish drug discovery. Curr Drug Discov Technol. 2022;19(1):e140122192307. DOI: 10.2174/1570163818666210316114331
51. Jourdan JP, Bureau R, Rochais C, Dallemagne P. Drug repositioning: a brief overview. J Pharm Pharmacol. 2020;72(9):1145–51. DOI: 10.1111/jphp.13273
52. Nosengo N. Can you teach old drugs new tricks? Nature. 2016;534(7607):314–6. DOI: 10.1038/534314
53. Naylor DM, Kauppi DM, Schonfeld JM. Therapeutic drug repurposing, repositioning and rescue. Drug Discovery. 2015;57. [Internet]. Available from: https://www.researchgate.net/profile/Stephen-Naylor-2/publication/282951546_Therapeutic_drug_repurposing_repositioning_and_rescue_Part_II_Business_review/links/568c102208ae71d5cd04abdc/Therapeutic-drug-repurposing-repositioning-and-rescue-Part-II-Business-review.pdf
54. Dudley J, Berliocchi L. (ed.). Drug repositioning: approaches and applications for neurotherapeutics. USA: CRC press; 2017, 313 p.
55. Langhans SA. Three-dimensional in vitro cell culture models in drug discovery and drug repositioning. Front Pharmacol. 2018;9:6. DOI: 10.3389/fphar.2018.00006
56. Meo SA, Bukhari IA, Akram J, Meo AS, Klonoff DC. COVID-19 vaccines: comparison of biological, pharmacological characteristics and adverse effects of Pfizer/BioNTech and Moderna Vaccines. Eur Rev Med Pharmacol Sci. 2021;25(3):1663–9. DOI: 10.26355/eurrev_202102_24877
57. Patel R, Kaki M, Potluri VS, Kahar P, Khanna D. A comprehensive review of SARS-CoV-2 vaccines: Pfizer, Moderna & Johnson & Johnson. Hum Vaccin Immunother. 2022;18(1):2002083. DOI: 10.1080/21645515.2021.2002083
58. Xia X. Detailed dissection and critical evaluation of the Pfizer/BioNTech and Moderna mRNA Vaccines. Vaccines (Basel). 2021;9(7):734. DOI: 10.3390/vaccines9070734
59. Au L, Larkin J, Turajlic S. Relatlimab and nivolumab in the treatment of melanoma. Cell. 2022;185(26):4866–9. DOI: 10.1016/j.cell.2022.12.003
60. Chen XY, Li YD, Xie Y, Cao LQ, Ashby CR Jr, Zhao H, Chen ZS. Nivolumab and relatlimab for the treatment of melanoma. Drugs Today (Barc). 2023;59(2):91–104. DOI: 10.1358/dot.2023.59.2.3509756
61. Amaria RN, Postow M, Burton EM, Tetzlaff MT, Ross MI, Torres-Cabala C, Glitza IC, Duan F, Milton DR, Busam K, Simpson L, McQuade JL, Wong MK, Gershenwald JE, Lee JE, Goepfert RP, Keung EZ, Fisher SB, Betof-Warner A, Shoushtari AN, Callahan M, Coit D, Bartlett EK, Bello D, Momtaz P, Nicholas C, Gu A, Zhang X, Korivi BR, Patnana M, Patel SP, Diab A, Lucci A, Prieto VG, Davies MA, Allison JP, Sharma P, Wargo JA, Ariyan C, Tawbi HA. Neoadjuvant relatlimab and nivolumab in resectable melanoma. Nature. 2022;611(7934):155–60. DOI: 10.1038/s41586-022-05368-8
62. Tawbi HA, Schadendorf D, Lipson EJ, Ascierto PA, Matamala L, Castillo Gutiérrez E, Rutkowski P, Gogas HJ, Lao CD, De Menezes JJ, Dalle S, Arance A, Grob JJ, Srivastava S, Abaskharoun M, Hamilton M, Keidel S, Simonsen KL, Sobiesk AM, Li B, Hodi FS, Long GV; RELATIVITY-047 Investigators. Relatlimab and Nivolumab versus Nivolumab in untreated advanced melanoma. N Engl J Med. 2022;386(1):24–34. DOI: 10.1056/NEJMoa2109970
63. Diaz RJ, Ali S, Qadir MG, De La Fuente MI, Ivan ME, Komotar RJ. The role of bevacizumab in the treatment of glioblastoma. J Neurooncol. 2017;133(3):455–67. DOI: 10.1007/s11060-017-2477-x
64. Halmos B, Burke T, Kalyvas C, Vandormael K, Frederickson A, Piperdi B. Pembrolizumab+chemotherapy versus atezolizumab+chemotherapy+/-bevacizumab for the first-line treatment of non-squamous NSCLC: A matching-adjusted indirect comparison. Lung Cancer. 2021;155:175–82. DOI: 10.1016/j.lungcan.2021.03.020
65. Li M, Kroetz DL. Bevacizumab-induced hypertension: Clinical presentation and molecular understanding. Pharmacol Ther. 2018;182:152–60. DOI: 10.1016/j.pharmthera.2017.08.012
66. Rosen LS, Jacobs IA, Burkes RL. Bevacizumab in Colorectal Cancer: Current Role in Treatment and the Potential of Biosimilars. Target Oncol. 2017;12(5):599–610. DOI: 10.1007/s11523-017-0518-1
67. Garcia J, Hurwitz HI, Sandler AB, Miles D, Coleman RL, Deurloo R, Chinot OL. Bevacizumab (Avastin®) in cancer treatment: A review of 15 years of clinical experience and future outlook. Cancer Treat Rev. 2020;86:102017. DOI: 10.1016/j.ctrv.2020.102017
68. Keam SJ. Mavacamten: First Approval. Drugs. 2022;82(10):1127–35. DOI: 10.1007/s40265-022-01739-7
69. Langley PC. Concerns with Patient Reported Outcome Measurement and Value Claims for Therapy Response: The Case of Mavacamten and Symptomatic Hypertrophic Cardiomyopathy (SHCM). Innov Pharm. 2022;13(2):10.24926/iip.v13i2.4861. DOI: 10.24926/iip.v13i2.4861

70. Kent CN, Park C, Lindsley CW. Classics in Chemical Neuroscience: Baclofen. ACS Chem Neurosci. 2020;11(12):1740–55. DOI: 10.1021/acschemneuro.0c00254
71. McCormick ZL, Chu SK, Binler D, Neudorf D, Mathur SN, Lee J, Marciniak C. Intrathecal Versus Oral Baclofen: A Matched Cohort Study of Spasticity, Pain, Sleep, Fatigue, and Quality of Life. PM R. 2016;8(6):553–62. DOI: 10.1016/j.pmrj.2015.10.005
72. Romito JW, Turner ER, Rosener JA, Coldiron L, Udipi A, Nohrn L, Tausiani J, Romito BT. Baclofen therapeutics, toxicity, and withdrawal: A narrative review. SAGE Open Med. 2021;9:20503121211022197. DOI: 10.1177/20503121211022197
73. Chavda VP, Ajabiya J, Teli D, Bojarska J, Apostolopoulos V. Tirzepatide, a New Era of Dual-Targeted Treatment for Diabetes and Obesity: A Mini-Review. Molecules. 2022;27(13):4315. DOI: 10.3390/molecules27134315
74. Gettman L. New Drug: Tirzepatide (Mounjaro™). Sr Care Pharm. 2023;38(2):50–62. DOI: 10.4140/TCP.n.2023.50
75. Syed YY. Tirzepatide: First Approval. Drugs. 2022;82(11):1213–20. DOI: 10.1007/s40265-022-01746-8
76. Bieber T, Simpson EL, Silverberg JI, Thaçi D, Paul C, Pink AE, Kataoka Y, Chu CY, DiBonaventura M, Rojo R, Antinew J, Ionita I, Sinclair R, Forman S, Zdybski J, Biswas P, Malhotra B, Zhang F, Valdez H; JADE COMPARE Investigators. Abrocitinib versus Placebo or Dupilumab for Atopic Dermatitis. N Engl J Med. 2021;384(12):1101–12. DOI: 10.1056/NEJMoa2019380
77. Deeks ED, Duggan S. Abrocitinib: First Approval. Drugs. 2021;81(18):2149–57. DOI: 10.1007/s40265-021-01638-3
78. Reich K, Thyssen JP, Blauvelt A, Eyerich K, Soong W, Rice ZP, Hong HC, Katoh N, Valenzuela F, DiBonaventura M, Bratt TA, Zhang F, Clibborn C, Rojo R, Valdez H, Kerkmann U. Efficacy and safety of abrocitinib versus dupilumab in adults with moderate-to-severe atopic dermatitis: a randomised, double-blind, multicentre phase 3 trial. Lancet. 2022;400(10348):273–82. DOI: 10.1016/S0140-6736(22)01199-0
79. Narayan VM, Dinney CPN. Intravesical Gene Therapy. Urol Clin North Am. 2020;47(1):93–101. DOI: 10.1016/j.ucl.2019.09.011
80. Lee A. Nadofaragene Firadenovec: First Approval. Drugs. 2023;83(4):353–7. DOI: 10.1007/s40265-023-01846-z
81. Eichler F, Duncan C, Musolino PL, Orchard PJ, De Oliveira S, Thrasher AJ, Armant M, Dansereau C, Lund TC, Miller WP, Raymond GV, Sankar R, Shah AJ, Sevin C, Gaspar HB, Gissen P, Amartino H, Bratkovic D, Smith NJC, Paker AM, Shamir E, O'Meara T, Davidson D, Aubourg P, Williams DA. Hematopoietic Stem-Cell Gene Therapy for Cerebral Adrenoleukodystrophy. N Engl J Med. 2017;377(17):1630–8. DOI: 10.1056/NEJMoa1700554
82. Ma CY, Li C, Zhou X, Zhang Z, Jiang H, Liu H, Chen HJ, Tse HF, Liao C, Lian Q. Management of adrenoleukodystrophy: From pre-clinical studies to the development of new therapies. Biomed Pharmacother. 2021;143:112214. DOI: 10.1016/j.biopha.2021.112214

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