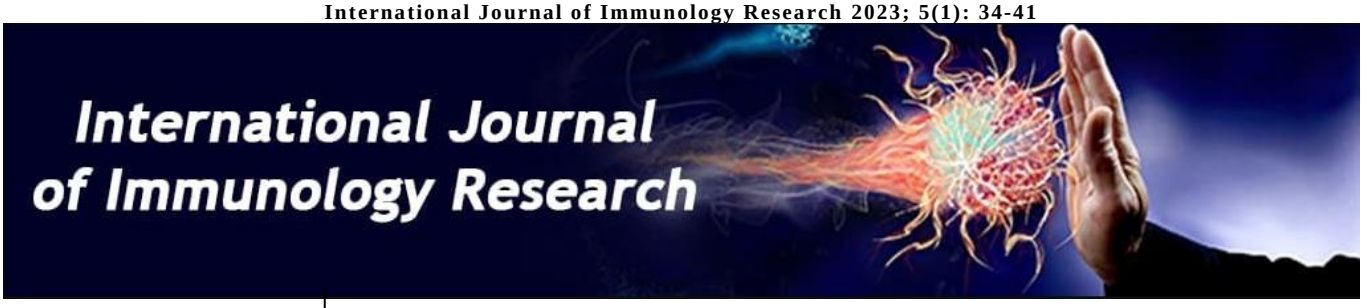

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The role of monoclonal antibodies in therapy and vaccine developments

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Abstract
The body's defense against infection is provided by the intricate network of organs, cells, and proteins known as the immune system. The two types of adaptive immune responses that enable the human body to defend itself against harmful agents such as bacteria, viruses, and other pathogens are cellular immunity and humoral immunity. Monoclonal antibodies (mAbs) are proteins that have been changed and are created by clones from an antibody-producing cell line. They are a homogeneous mixture of antibodies that are monospecific in nature and have affinity and specificity towards one epitope of a selected antigen (monovalent affinity). With the introduction of monovalent antibodies, the breadth of therapeutic and diagnostic applications has grown to include numerous sectors of biotechnology such as molecular biology, toxicology, biochemistry, and medicine. Currently, about 30 monoclonal antibodies are approved by the FDA for use in humans for treating various diseases and conditions including cancer, chronic inflammatory diseases, transplantation, infectious diseases, and cardiovascular diseases**.** With major advances in genetic sequencing and biomedical research, much research into monoclonal antibodies now focuses on identifying new targets for development and maximizing their efficacy for use in clinical practice. There are currently several treatment alternatives available, including antiviral medicines, monoclonal antibodies, and immunomodulatory drugs. Monoclonal antibodies are now established as targeted therapies for malignancies, transplant rejection, autoimmune and infectious diseases, as well as a range of new indications. Therapeutic monoclonal antibodies are a key class of biopharmaceutical products that has grown briskly in product approvals and sales, from the time when the first mAb was commercialized. In addition to targeting antigens involved in cancer cell physiology, antibodies can also function to modulate immunological pathways that are critical to immune surveillance. Generally, the aim of this paper is to compile the application of monoclonal antibodies in therapy and vaccine developments.

Keywords: Biopharmaceuticals**,** monoclonal antibodies, therapy, vaccine development

Introduction
The immune system is a complicated network of organs, cells, and proteins that protects the body from infection. The immune system preserves a record of every germ (microbe) it has ever eliminated so that if the microbe enters the body again, it can recognize and destroy it rapidly before it can multiply and make it sick (Schaller and Park, 2011) [32]. Among the immune system, adaptive immunity is made up of specialized immune cells and antibodies that target and remove foreign invaders while also remembering what those things look like and developing a new immune response to prevent illness in the future. It can continue for a few weeks or months, or it might last for a long time, even the rest of a person's life (Iwasaki and Medzhitov, 2015) [15]. Humoral immunity and cell-mediated immunity are two forms of adaptive immune responses that allow the human body to protect itself against dangerous agents including bacteria, viruses, and other pathogens. Antibodies, are the type of humoral immunity produced by B cells found in eukaryotes. Immunoglobulins exist in either soluble (blood or plasma) membrane-bound (B-cell receptor) forms. Antibodies are the major building blocks of the humoral immune system and consist of two structural units: heavy and light chains. Each heavy chain has one variable region and three constant regions, and each light chain has one variable region and one constant region (Parray *et al*., 2020) [27].
Antibodies are a type of defense mechanism that can recognize and kill invaders such as viruses and bacteria. They had a paratope (like a key), an antigen-binding site located at the top of the Y, -shaped antibody molecule (Figure1), so each could recognize a specific

antigen unique to its target. The result of this technology is that antibodies can tag microbes and infected cells, allowing them to be attacked by other components of the immune system and directly neutralizing their targets (Mohapatra and Kaur, 2021) [24].

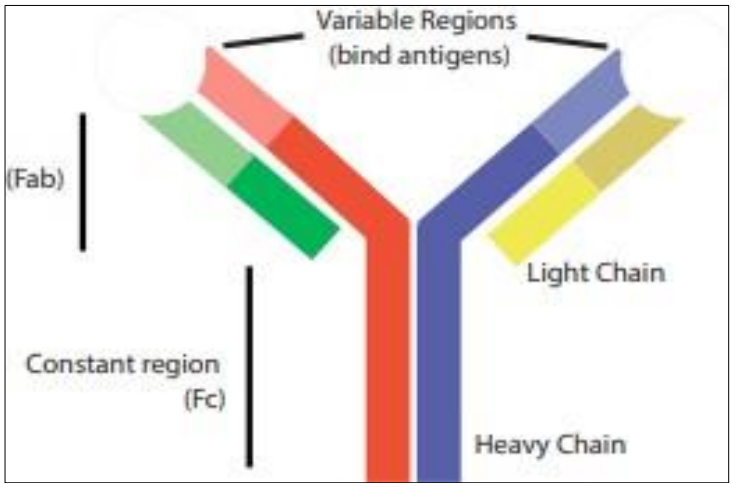

Fig 1: Antibody structure. Adopted from Nicholson (2016) [25].

Antibodies not only bind to soluble toxins and inhibit their activity, but also block surface pathogen antigens, neutralizing their ability to infect human cells or marking them for destruction. Immune cells kill pathogens through complement activation, antibody-dependent cytotoxicity (ADCC), or antibody-dependent cellular phagocytosis (ADCP). They consist of an antigen-binding fragment (Fab) that confers target specificity and a crystallizable component (Fc) that controls biological activity. Alterations in the Fab and Fc sections affect the specificity, persistence, and outcome of antibody-dependent reactions (Pecetta *et al.*, 2020) [28]. The discovery of how to isolate and clone antibodies lead to the generation of humanized and human monoclonal antibodies (mAbs) and enabled their use as therapies in the fields of oncology and autoimmunity (Hafeez *et al*., 2018) [11].

Cancer, autoimmune diseases, and chronic inflammatory diseases are most commonly treated with antibodies. However, antibody therapeutics are expanding into a wider range of human diseases, including infectious diseases, hematology, neurology, ophthalmology, metabolic diseases, musculoskeletal diseases, and transplantation.

Historical development of monoclonal antibodies

The first monoclonal antibody was produced in 1975 by Georges Kohler of West Germany and Cesar Milstein of Argentina. In the 1960s, César Milstein began investigating somatic mutation, which he hypothesized was responsible for antibody variety and specificity (Liu, 2014) [22]. The development of hybridoma technology guide to the first generation of murine antibodies against tumor cell surface antigens. The first licensed monoclonal antibody which was approved in 1986 was Orthoclone OKT3 (muromonab-CD3) for use in preventing kidney transplant rejection. It is a monoclonal mouse IgG2a antibody whose cognate antigen is CD3. It functions by attaching to and suppressing CD3 expression on T-lymphocytes. However, its use was limited to acute cases due to reported side effects (e.g. human anti-mouse antibody response) (Leavy, 2010) [20].

A variety of antibodies against solid tumors and hematologic malignancies were created and entered clinical trials after the initial clinical trials using mouse antibodies against CEA and CD3 in the 1980s. In the past 20 years, monoclonal antibody-based therapy for cancer has emerged as one of the most effective therapeutic approaches for both hematologic and solid tumors (Grimsley *et al*., 2013) [10].

B lymphocytes that can produce antibodies first arise in bone marrow as hematopoietic stem cells and differentiate into pro-B, pre-B, and immature B lymphocytes. The development of mouse hybridoma technology initiated high hopes for the production of antibodies for therapy and is the first reliable source of monoclonal antibodies and was developed for several *in vivo* therapeutic applications. The technology of mouse hybridoma was replaced by transgenic animals for the creation of human mAbs. By transgenic technology human antibody genes were introduced into mice lacking their immunoglobulin loci. These mice can be immunized with specific antigens and their B cells are used for generating hybridomas as for the generation of mouse mAbs (Nissim and Chernajovsky, 2008) [26].

Without the vast scientific and technological advancement made previously by numerous laboratories throughout the world, this significant accomplishment could not have been made. New methods have been developed to enhance the production of monoclonal antibodies in general and of human monoclonal antibodies in particular, even though the original hybridoma approach has been demonstrated to be remarkably reproducible (Steinitz, 2009) [37]. They are a homogeneous mixture of antibodies that are mono-specific in nature and have affinity and specificity towards one epitope of a selected antigen (monovalent affinity). In the event of the development of monovalent antibodies, the scope of therapeutic and diagnostic applications has expanded encompassing various fields of biotechnology such as molecular biology, toxicology, biochemistry, and medicine (Mitra and Tomar, 2021) [23].

Hybridoma technology and monoclonal antibodies production

The invention of hybrid cell technology is an important milestone in immunology and biomedicine. This technology has enabled scientists for the first time to generate unlimited quantities of pure, monospecific antibodies directed against virtually any antigen (Lipman *et al*., 2005) [21]. Monoclonal

antibodies are mono-specific in nature and are produced by identical B cells with high affinity and specificity for a single epitope of an antigen. The production of monoclonal antibodies was first described in 1975 by Köhler and Milstein through a procedure that involved obtaining lymphocytes from a vaccinated animal. These cells were immortalized by hybridization with an established cell line, yielding a cell line that secreted monoclonal antibodies (Cordell, 2022) [8].

Hemagglutinating virus of Japan (HVJ) and polyethyleneglycol (PEG) were used in the initial hybridoma method to somatically fuse antigen-sensitized B lymphocytes and myeloma cells to create hybridoma cells. However, these techniques lead to nonspecific fusion between many kinds of cells without control (Zhang *et al*., 2014) [45]. The successful creation of new monoclonal antibodies using hybridoma technology depends on two key factors. The first is vaccination, which helps B cells differentiate into more mature versions. The second point is a selective fusion of targeted antigen-sensitized B lymphocytes with myeloma cells. Hybridoma technology enables the creation of monoclonal antibodies with high affinity and specificity, advancing not only fundamental scientific research but also medical analyses and therapies based on precise binding between antigens and antibodies if these key requirements are met, hybridoma technology will be able to generate these antibodies (Tomita and Tsumoto, 2011) [40].

Steps of monoclonal productions

The technique was based on the fusion of spleen cells from appropriately immunized animals with myeloma cells. The primary goal is to generate a homogeneous population of mAbs towards a pre-fixed immunogen (Ansar and Ghosh, 2013) [2]. Establishing stable mAb-producing hybridomas from species that are phylogenetically distinct from the mouse is more challenging from a technological standpoint. First attempts at producing mAb should use either the mouse or rat. From the two, for the majority of xenogeneic antigens, including human antigens, the mouse is the ideal option because mice make much more antibodies than humans do, making mab to defined antigens readily available for purchase. Isotype-matched mAb, which can be used as controls in the assays of interest, are obtained easily. Not only this, the mouse is easier to handle, anti-Ig reagents specific for each mouse Ig isotype are more commonly available, and generally mouse mAb is easier than rat mAb to purify (Yokoyama *et al*., 2013) [44].

The fundamental steps are as follows (i) sufficient purification and characterization of the desired antigen, (ii) immunization of mice using the purified antigen, (iii) cultivating myeloma cells, (iv) removing spleen cells from mice and fusion with the myeloma cells, and

(v) growth of hybridomas in hypoxanthine aminopterin thymidine (HAT) medium following fusion. (vi) Hybrid cell clones are formed from a single host cell. (vii) The ability of the antibodies generated by the different clones to bind to the antigen is then evaluated using an enzyme-linked immunosorbent assay (ELISA). (viii) After that, the clone is chosen and replicated for future usage (Ansar and Ghosh, 2013) [2].

Under typical tissue culture conditions, spleen cells die away quickly. The ability to grow myeloma cells indefinitely in culture has led to the isolation of mutants that lack the enzymes hypoxanthine guanine ribosyltransferase (azaguanine-resistant) and thymidine kinase (bromodeoxyuridine-resistant). Such mutants cannot grow in a medium containing aminopterin and supplement with hypoxanthine and thymidine (HAT medium) because they are unable to utilize the salvage pathway. The only cells that actively multiply in the HAT selective medium are hybrids between these cells and spleen cells, which can be chosen from the parental components. From the growing hybrids, individual clones can be selected that secrete the desired antibodies. Such antibodies are therefore of monoclonal origin. Like regular myeloma lines, the chosen clones can be kept alive forever (Shukla and Thömmes, 2010) [33].

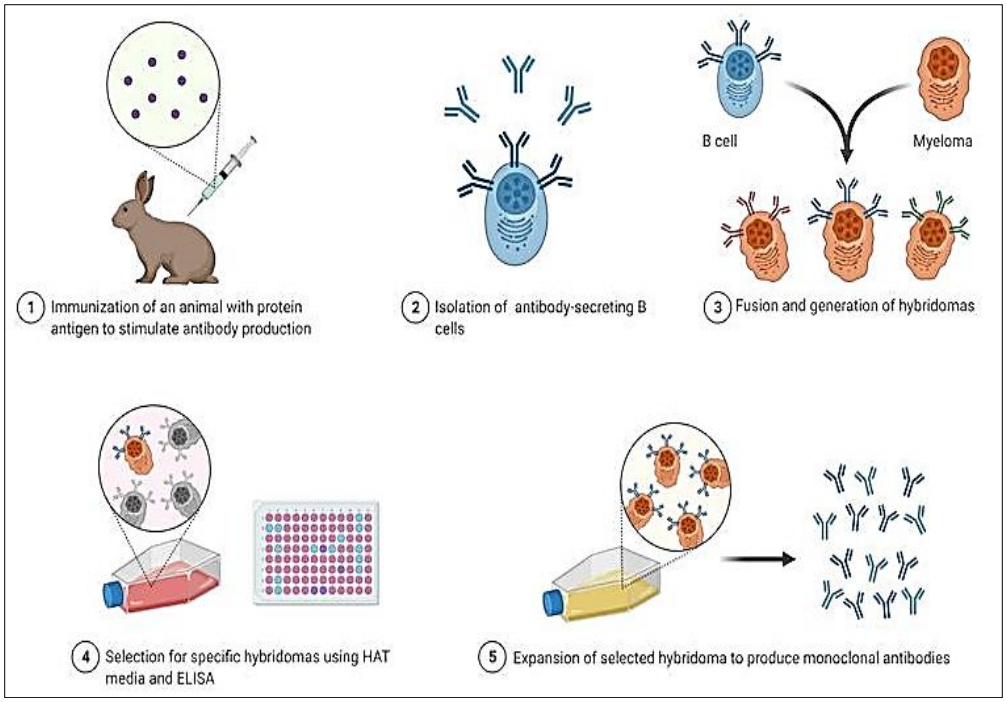

Fig 2: Steps in the generation of hybridomas for monoclonal antibody production**.** Adopted from Holzlöhner and Hanack (2017) [13]

3.2. Purification of mab

There are several types of impurities, ranging from host cell proteins (HCPs) and DNA over endotoxins and viruses to leached ligands such as protein A. Host cell proteins represent a heterogeneous mixture of hundreds of proteins, some of them having very similar adsorptive properties as the mAb leading to co-elution in non-affinity chromatography. It's crucial to remove cells, cell debris, and other insoluble components from the beginning material to avoid the chromatography column becoming clogged (Ulmer *et al.*, 2019) [41].

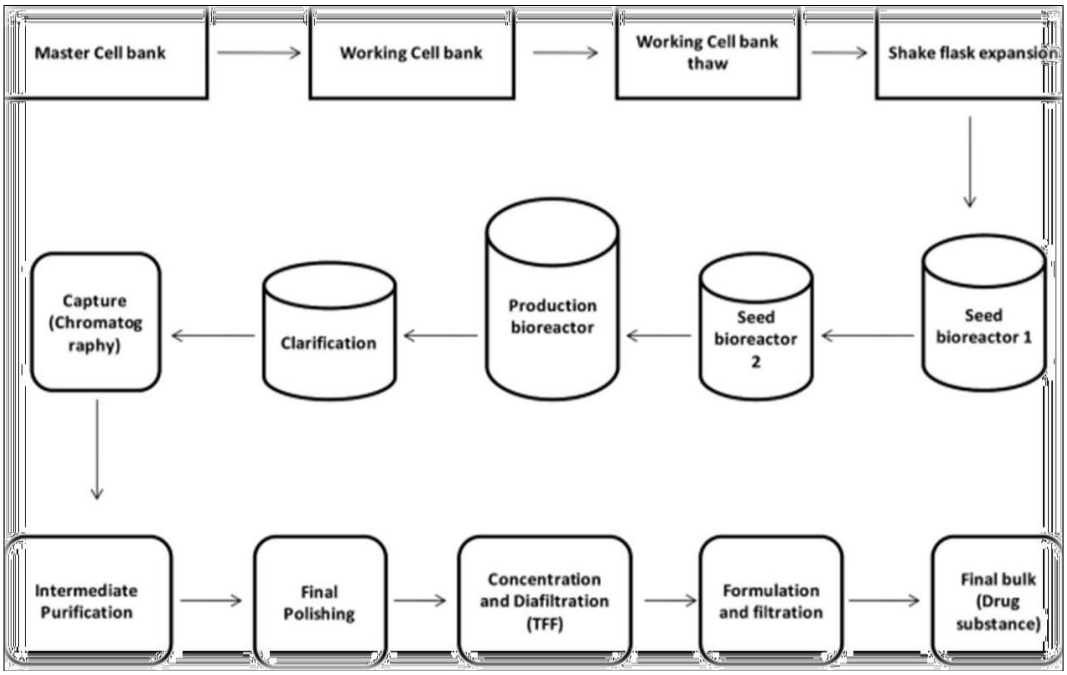

Fig 3: The generalized process flow for therapeutic molecule production to the final drug Adopted from Chahar *et al.* (2020) [7]

At the production scale, continuous centrifugation, depth filtration, or tangential flow filtration (TFF) have been utilized as primary clarifying procedures to remove the majority of big particles, cell debris, and whole cell contaminants (Somasundaram *et al*., 2018) [34]. In the pharmaceutical industry, Protein An affinity chromatography is a well-known process because of its high binding affinity and the purity levels that can be obtained with it. The purification procedure involves loading the cleared cell culture containing the target antibodies at neutral pH on the immobilized Protein A support, which allows the ligands to interact. The protein is then isolated from contaminants such as host cell proteins (HCP), and product desorption is accomplished by lowering the mobile phase pH. In the platform, polishing procedures such as ion exchange chromatography are typically used after the chromatographic process. Finally, virus removal is achieved by employing membrane steps (ultrafiltration, diafiltration, and nanofiltration), solvent/detergent treatments (Ramos-de-la-Peña *et al*., 2019) [30].

Application of monoclonal antibodies

Monoclonal antibodies are of great pharmaceutical interest because their functions make them promising alternative therapeutics in viral diseases, cancer, rheumatic diseases, and other neurological diseases (Ramos-de-la-Peña *et al*., 2019) [30].

Monoclonal Antibodies in Therapy

Monoclonal antibodies (mAb)-based therapeutics are playing an increasingly crucial role in the treatment or prevention of many important diseases such as cancers, autoimmune disorders, and infectious diseases. Multi-domain mAbs are far more complex than small-molecule drugs with intrinsic heterogeneities (Wang *et al.*, 2018) [43]. Immune system proteins known as monoclonal antibodies, are derived from a single-cell lineage and exhibit a strong affinity for their target cell. Monoclonal antibodies have been established as targeted treatments for a variety of neoplastic disorders, autoimmune, post-transplant immunosuppression, and infectious diseases thanks to significant advancements in molecular engineering. (Hansel *et al*., 2010) [12].

The application of monoclonal antibodies is a new era in infectious disease prevention that overcomes numerous shortcomings associated with serum treatment and intravenous immunoglobulin preparations in terms of specificity, purity, the minimal danger of blood-borne pathogen contamination, and safety. They are a versatile class of pharmaceuticals that have been successfully used by the pharmaceutical industry and can provide an efficient therapeutic intervention with a highly specific treatment against a particular disease. It provided an enormous opportunity for the examination of a range of previously elusive issues. For example, monoclonal antibodies agreeing used in radioimmunoassay, enzyme-linked immune sorbent assays, immunocytopathology, and flow for *in vitro* and *in vivo* diagnosis and immunotherapy of human and animal diseases. Additionally, it has mostly been used in clinical settings for the detection and treatment of cancer, for altering the immune system to generate immunological suppression in the treatment of autoimmune diseases, and for preventing allograft rejection (Waldmann, 1991) [42]. Many therapeutic strategies have been explored using mAbs or their derivatives in cancer treatment and some promising therapeutic possibilities have emerged, some of them are summarized and presented in Table 1 (Breedveld, 2000) [6].

Table 1: Monoclonal antibodies approved for therapy

Name (USAN)	Target	Isotype	Species	Indication Class
Synagis (palivizumab)	RSV F prot	IgG1K	Humanized	Antiinfective
Amevive (alefacept)	CD2	IgG1 fusion		Immunomodulatory
Enbrel (etanercept)	TNF alpha	IgG1 fusion		Immunomodulatory
Humira (adalimumab)	TNF alpha	IgG1K	Human	Immunomodulatory
OKT3 (muromonab-CD3)	CD3	IgG2a	Murine	Immunomodulatory
Raptiva (efalizumab)	CD11a	IgG1kappa	Humanized	Immunomodulatory
Remicade (infliximab)	TNF alpha	IgG1K	Chimeric	Immunomodulatory
ReoPro (abciximab)	GP 2b/3a	IgG1K Fab	Chimeric	Immunomodulatory
Simulect (basiliximab)	CD25	IgG1	Humanized	Immunomodulatory
Xolair (omalizumab)	IgE	IgG1 kappa	Humanized	Immunomodulatory
Zenapax (daclizumab)	CD25	IgG1	Humanized	Immunomodulatory
Tysabri (natalizumab)	a4 integrin	IgG4	Humanized	Immunomodulatory
Orencia (abatacept)	CTLA4-Ig	IgG1	Human	Immunomodulatory
Avastin (bevacizumab)	VEGF	IgG1 kappa	Humanized	Oncology
Bexxar (tositumaomb)	CD20	IgG2a	Murine	Oncology
Campath (alemtuzumab)	hu CD52	IgG1	Humanized	Oncology
Erbitux (cetuximab)	hu EGFr	IgG1kappa	Chimeric	Oncology
Herceptin (trastuzumab)	Her2	IgG1K	Humanized	Oncology
Vectabix (panitumumab)	EGFR	IgG2	Humanized	Oncologic
Mylotarg (gemtuzumab ozogamicin)	hu CD33	IgG4kappa	Humanized	Oncology
Rituxan (rituximab)	CD20	IgG1K	Chimeric	Oncology
Zevalin (ibritumomab tiuxetan)	hu CD20	IgG1kappa	murine	Oncology

Rituximab (Mabthera)

Rituximab (Rituxan and MabThera) is a pharmaceutical used to treat some instances of vasculitis and rheumatoid arthritis that has not responded to other types of therapy. It functions by disabling a portion of the immune system that autoimmune illnesses cause to malfunction. It is the first mAb approved for the treatment of cancer. It is a chimeric IgG-1 mAb directed against CD20 which is a transmembrane protein on pre-B and mature B lymphocytes. This treatment is not exactly specific; rather, it involves removing a certain lineage of cancerous and comparable normal cells in the hope that normal cells may rebuild from normal stem cells (Frampton, 2020) [9].

Rituximab is given as an infusion into the vein. The infusion typically lasts between two and four hours, but on rare occasions, it may take longer. A course of rituximab for rheumatoid arthritis usually consists of two 1000 mg doses given 15 days apart and often repeated within six months. It is approved for the treatment of blood B cell cancers as well as non-hematologic B cell-mediated diseases, including autoimmune disorders (Bergantini *et al*., 2020) [4]. To treat vasculitis, a smaller dose is given once a week for four weeks in a row. There are three main mechanisms by which rituximab induces B- cell lysis, namely complement activation and membranolytic attack complex formation, antibody-dependent cellular cytotoxicity on CD20 B-cells, and apoptosis. The lysis via complement activation appears to be the fastest-acting mechanism based on the occurrence of symptoms related to „cytokine release syndrome" noted rarely in some patients immediately after the first infusion. Although less efficient, rituximab opsonization on B-cells activates Antibody-dependent cellular cytotoxicity (ADCC) through the recruitment of natural killer (NK) cells and macrophages that express Fcg receptors (FcgRs). Rituximab is also capable of inducing apoptosis by forcing CD20 into lipid-raft environments, resulting in altered calcium flux into B-cells (Kosmidis and Dalakas, 2010) [19].

Bapineuzumab

Bapineuzumab is a humanized N-terminal–specific monoclonal antibody in clinical development and developed by collaborations of Wyeth and Elan, and later acquired by Pfizer and Janssen for the treatment of Alzheimer's disease. It binds with high affinity to the N- terminus of amyloid

beta (Aβ1--5], particularly when the Aβ is already deposited in senile plaques. The rationale of this passive immunotherapy approach is that antibody binding will clear excess Aβ. Bapineuzumab is an IgG1 antibody that binds fibrillar and soluble Aβ and activates microglial phagocytosis and cytokine production. A tiny portion of peripherally administered antibodies enters the CNS of PDAPP and other mouse models of Aβ amyloidosis (Tayeb *et al*., 2013) [39].

Solanezumab

Solanezumab is a humanized monoclonal IgG1 antibody that binds to the central region of β- amyloid, a peptide believed to play a key role in the pathogenesis of Alzheimer's disease. It is directed against the mid-domain of the Aβ peptide and recognizes soluble monomeric, not fibrillar, Aβ. The therapeutic rationale is that it may exert benefit by sequestering Aβ, shifting equilibrium between different species of Aβ, and removing small soluble species of Aβ that are directly toxic to synaptic function. It was created by Eli Lilly & Co. for the treatment of mild-to-moderate Alzheimer's disease using an intravenous formulation of solanezumab (Imbimbo *et al*., 2012) [14].

Monoclonal Antibodies in vaccine development

Monoclonal antibodies have been used to detect new vaccine antigens and to clarify the nature and conformation of protective epitopes, allowing for vaccine design and development. The identification of the cytomegalovirus (CMV) pentamer-complex and the respiratory syncytial virus (RSV) Pre-Fusion (Pre-F) conformation of the fusion (F) protein are two successful examples of human mAbs playing a crucial role in vaccine development (Andreano *et al*., 2019) [1].

Nirsevimab

Nirsevimab is an investigational single-dose long-acting antibody designed to help protect all infants from birth through their first RSV season and for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. Through the duration of the RSV season, it aids in preventing RSV disease in all infant populations (including healthy term, late preterm, and preterm infants, as well as infants with particular health conditions) that necessitate medical attention, such as doctor visits, urgent care visits, and hospitalizations (Bergeron and Tripp, 2022) [5]. It has been developed to offer newborns and infants direct RSV protection via an antibody to help prevent lower respiratory tract infection (LRTI) caused by RSV and do not require the activation of the immune system to help offer timely, rapid and direct protection against disease (Keam, 2023) [17].

Palivizumab

Palivizumab is a humanized mouse monoclonal immunoglobulin G1, comprising 95% human and 5% murine amino acid sequences. It is produced by recombinant DNA technology and directed against an epitope of the F glycoprotein of RSV. Palivizumab binds to this glycoprotein and stops the virus from invading the airway's host cells. This reduces viral activity and cell-to-cell transmission and blocks the fusion of infected cells. It is administered intramuscularly at a dose of 15 mg/kg once every 30 days in a series of 5 monthly intramuscular injections to infants and children during the RSV season (Rogovik *et al*., 2010) [31].

Monoclonal Antibodies in disease diagnosis

Monoclonal antibodies are crucial parts of test kits for the detection of ovulation, pregnancy, or menopause on the diagnostic front. They are also used to diagnose illnesses by testing bodily fluids and to identify whether a heart attack has occurred (Quinteros *et al*., 2016) [29]. The invention of potent monoclonal antibody (mAb)-based tests or diagnostic imaging techniques for detecting antigens and small chemicals generated by malignant cells would considerably improve modern cancer diagnostic treatment. Despite mAb technology is still in its early stages, new developments in recombinant antigen synthesis and antibody creation techniques have significantly expanded its potential in cancer diagnosis. In comparison to other approaches, mAb-based assays may provide geographical, immediate, accurate, and quantitative information for disease diagnosis (Zhang *et al*., 2014) [45].

Radioimmuno detection (RID)

Refers to the employment of mAbs for imaging that is commonly labeled with indium-Ill or technetium-99m. This procedure is frequently exceedingly sensitive in discovering lesions that would have been missed by conventional diagnostic approaches. Under light microscopy, they are utilised in immune histopathology for the differential diagnosis of solid tumours (Baquiran *et al*., 1996) [2].

Additionally, the nucleocapsid protein of rabies and rabies-related viruses protein, as well as the antigenic characterization of viruses, are both detected by monoclonal antibodies. Due to the tests using mAb as diagnostic reagents, polyclonal antibodies' limitations in the immunodiagnosis of protozoal and parasitic disorders have been greatly addressed (Siddiqui, 2010) [34].

Other roles of Monoclonal Antibodies

mAbs have a long history of usage in prognostic procedures. They are also utilized as a marker for the identification of HCV antigens, thus a quick, easy, and inexpensive test to find anti-HCV antibodies (Table *et al*., 2015) [38].

Challenge and progress of monoclonal antibodies

Monoclonal antibodies are expensive and the number of doses needed to treat patients is high. For example, therapeutic doses should be expressed in grams for various cancer monoclonal antibodies. Therefore, monoclonal antibodies must be produced in large quantities to meet the needs of the world population (Chahar *et al*., 2020) [7]. There have been ongoing attempts to create human therapeutic monoclonal antibodies due to the great clinical potential initially associated with these molecules. Today, these advancements are heavily influenced by the pharmacological industry. Current methods for producing human monoclonal antibodies are still insufficient, as evidenced by ongoing efforts to advance techniques. Moreover, the methods offered today to test the *in vivo* efficacy and effectiveness of human monoclonal antibodies are not satisfactory. Finally, the use of only a few fully humanized monoclonal antibodies in clinical settings today shows that the field is still in its early stages (Steinitz, 2009) [37]. Combinations of monoclonal antibodies may exhibit more potent antiviral action, enhancing the efficacy of

therapy and preventing viral escape. The large-scale production of monoclonal antibodies is labor-intensive, expensive, and time-consuming, which outweighs the clinical application of monoclonal antibodies, especially those against the emerging pathogen, even though several monoclonal antibodies showed promising results in neutralizing SARS-CoV and MERS-CoV infection (Sparrow *et al*., 2017) [36].

Monoclonal antibody manufacture and use have shown various problems, including standardization, patient safety, availability, and access. These difficulties have prompted researchers to consider replacing polyclonal antibodies with monoclonal antibodies (mAbs), which can be manufactured using recombinant deoxyribonucleic acid technologies. Creating mAbs used to be difficult and expensive. However, the growing use of mAbs in cancer, autoimmune, and other chronic disease therapies has resulted in expanded production capacity and improved manufacturing techniques. These improvements have made mAbs potentially cost-competitive with blood-derived polyclonal antibodies, while also contributing to increased global supply (Kelly, 2009) [18].

Despite having components that the receiver may mistake for being alien and which may trigger innate and immunological responses, monoclonal antibodies are often well tolerated in humans. Acute responses after mAb infusions can be brought on by several different mechanisms, including serum sickness, tumor lysis syndrome (TlS), cytokine release syndrome (CRS), and acute anaphylactic (IgE-mediated) and anaphylactoid reactions against the mAb). Clinical manifestations can include pyrexia, an influenza-like illness, localized skin reactions at the injection site, acute anaphylaxis, and systemic inflammatory response syndrome, all of which have a potentially fatal outcome (Hansel *et al*., 2010) [12].

Conclusion

Antibodies are a type of defense mechanism that can recognize and prevent invaders such as viruses and bacteria. They had a paratope (like a key), an antigen-binding site located at the top of the Y-shaped antibody molecule, so each could recognize a specific antigen unique to its target. Monoclonal antibodies (mAbs) are proteins that have been changed and are created by clones from an antibody-producing cell line. They are a homogeneous mixture of antibodies that are mono-specific in nature and have affinity and specificity towards one epitope of a selected antigen (monovalent affinity). They are now established as targeted therapies for malignancies, transplant rejection, autoimmune and infectious diseases, as well as a range of new indications. Therapeutic monoclonal antibodies are a key class of biopharmaceutical products that has grown rapidly in product approvals and sales, from the time when the first mAb was commercialized. Monoclonal antibodies are of great pharmaceutical interest because their functions make them promising alternative therapeutics in viral diseases, cancer, rheumatic diseases, and other neurological diseases. Not only these, but it has also been used to detect new vaccine antigens and to clarify the nature and conformation of protective epitopes, allowing for vaccine design and development.

Conflict of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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