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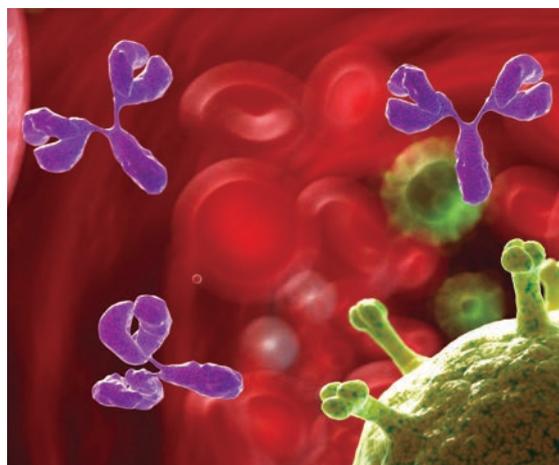
The Therapeutic Monoclonal Antibody Product Market

Dawn M. Ecker, Thomas J. Crawford, and Patti Seymour

Commercial development of therapeutic monoclonal antibodies (MAbs) began in the early 1980s, and by 1986 the first MAb product had been approved in the United States: muromonab-CD3 (trade name Orthoclone OKT3, marketed by Janssen-Cilag) for prevention of kidney-transplant rejection. Since its approval, therapeutic MAbs and antibody-related products such as Fc-fusion proteins, antibody fragments, and antibody–drug conjugates (collectively referred to herein as “MAb products”) have grown to become the dominant product class within the biopharmaceutical market. They have been approved for treating a broad range of diseases, from those with patient populations of a few thousand or less (e.g., orphan indications such as hemophagocytic lymphohistiocytosis) to those afflicting hundreds of thousands (e.g., some cancers and multiple sclerosis) or even millions of patients (diseases such as asthma and rheumatoid arthritis). With recent approvals of MAb products for infectious diseases such as those associated with *Clostridium difficile*, anthrax, and human immunodeficiency virus (HIV) infections, the potential for MAb products to combat coronavirus diseases certainly exists. However, some debate remains over just how significant a role any antibody treatment could play in treating COVID-19. (Editor’s Note: See the article by Nick Hutchinson on page 14 for more of that discussion.)

MARKET GROWTH

Sales growth and approval of additional MAb drugs



On the cover: Antibodies attack invaders such as the SARS-CoV-2 virus that causes COVID-19 illness.

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was slow until the late 1990s, when the first chimeric antibodies were approved. With the approval of such products, followed over time by that of humanized and then fully human antibodies, the rate of product approvals and sales of MAb products increased dramatically. In 2019, global sales revenue for all MAb drugs was nearly US\$163 billion (1), representing about 70% of the total sales for all biopharmaceutical products (about \$230 billion). That is a significant (~50%) increase in both sales and proportion since 2013, when it was \$75 billion (2). Continued growth in sales of currently approved MAb products, along with more than 1,200 MAb product candidates currently in development — many for multiple indications (1) — will increase sales of MAb products further in the

Figure 1: Annual approvals of monoclonal antibody products (3, 4) showing the number first approved for commercial sale in the United States or Europe each year since 1985; totals include all MAb and antibody-related products. Mammalian cell culture products are denoted in green, with products approved but subsequently removed from the market in light green; microbial-based products are in blue, none of which have been approved but subsequently withdrawn; 2020 total is as of 27 August 2020.



coming years and continue to drive the overall sales of all biopharmaceutical products.

As Figure 1 shows, the number of MAb products approved for commercial sale in the United States and Europe has grown significantly, with three to five new products approved each year between 2010 and 2014, then 10–19 new products approved each year between 2015 and 2019.

Although a total of 139 MAb products have been approved in Europe and/or the United States since 1985, 14 of these products have been withdrawn for different reasons, leaving 125 approved MAb products currently on the market (Table 1). As of 27 August 2020 (1, 3, 4), only six of those products are expressed by microbial systems whereas the remaining 119 are produced by mammalian cells. Five of the six microbial products are antibody fragments, including one fragment conjugate; also, for the first time, a full-length MAb expressed in a microbial system (*Pichia pastoris* yeast) was approved this year. Vyepti (eptinezumab-jjmr) from Lundbeck Seattle BioPharmaceuticals has been approved for prevention of migraines (5).

Given the large number of candidates currently in development, we expect that the number of MAb products approved each year for the coming years will be similar to the numbers approved over the past several years. In fact, nine MAb products have been granted first approvals this year as of 27 August 2020, including the first developed and manufactured MAb biosimilar from China: Zerpecap trastuzumab from Shanghai Henlius Biotech and Accord Healthcare (6).

Global sales of MAb products have **GROWN FASTER** than all other biopharmaceutical product classes over the past five years.

Currently 21 MAb products are under regulatory review, with approval decisions expected for at least two of those by the end of this year. Based on a conservative approval rate of 10 products per year, we anticipate that 180 or more MAb drugs on the global market in 2025. Additionally, we predict that within the next year, some COVID-19 MAb products, will be included within these forecasted numbers. But none of them yet has reached the biological license application (BLA) or marketing authorization application (MAA) regulatory review phase. Based on the number of novel MAb products in development for COVID-19 (1, 7), an accelerated timeline for those high-priority drugs (8), and the prospective use of MAb products as a stop-gap preventative until a successful vaccine is launched (9), we forecast that two to four novel MAb products will be approved specifically related to COVID-19.

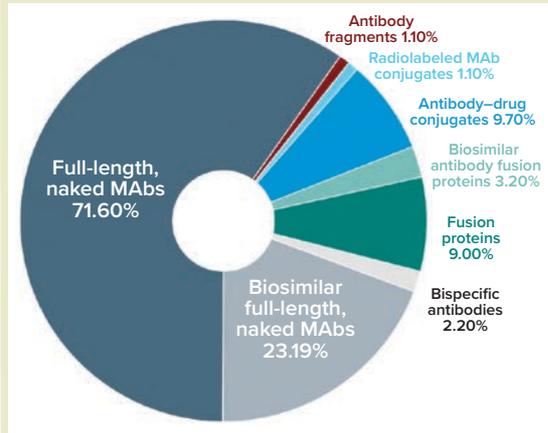
As Figure 2 shows, most of the 119 MAb products expressed in mammalian systems are full-length naked MAbs (60%), followed by biosimilar full-length naked MAbs (19%). Six other types of antibody products represent the remaining 21% of mammalian-expressed MAb products.

Global sales of MAb products have grown faster

Table 1: Currently marketed therapeutic monoclonal antibody products (*continued, next page*)

Brand Name (INN)	MAb Product Type	First Approval
Abrilada/Amsparity (EU) (adalimumab-afzb)	Antibody, biosimilar	2019 US
Abthrax (raxibacumab)	Antibody	2012 US
Actemra/RoActemra (EU) (tocilizumab)	Antibody	2009 EU
Adakveo (crizanlizumab-tmca)	Antibody	2019 US
Adcetris (brentuximab vedotin)	Antibody conjugate	2011 US
Aimovig (erenumab-aooe)	Antibody	2018 US
Ajovy (fremanezumab-vfrm)	Antibody	2018 US
Amjevita/Amgevita (EU) (adalimumab-atto)	Antibody, biosimilar	2016 US
Anthim (obiltoxaximab)	Antibody	2016 US
Arcalyst (rilonacept)	Antibody fusion protein	2008 US
Arzerra (ofatumumab)	Antibody	2009 US
Avastin (bevacizumab)	Antibody	2004 US
Avsola (infliximab-axxq)	Antibody, biosimilar	2019 US
Bavencio (avelumab)	Antibody	2017 US
Benlysta (belimumab)	Antibody	2011 US
Beovu (brolucizumab-dbli)	Antibody fragment (microbially expressed)	2019 US
Besponsa (inotuzumab ozogamicin)	Antibody conjugate	2017 EU
Blenrep (belantamab mafodotin-blmf)	Antibody conjugate	2020 US
Blincyto (blinatumomab)	Antibody, bispecific	2014 US
Cablivi (caplacizumab-yhdp)	Antibody fragment (microbially expressed)	2018 EU
Cimzia (certolizumab pegol)	Antibody fragment conjugate (microbially expressed)	2008 US
Cinqair/Cinqaero (EU) (reslizumab)	Antibody	2016 US
Cosentyx (secukinumab)	Antibody	2015 EU
Crysvita (burosumab-twza)	Antibody	2018 EU
Cyltezo (adalimumab-adbm)	Antibody, biosimilar	2017 US
Cyramza (ramucirumab)	Antibody	2014 US

Figure 2: Distribution (number and percentage) of marketed MAb products expressed in mammalian systems by subtype currently approved for commercial sale in the United States or Europe as of 27 August 2020

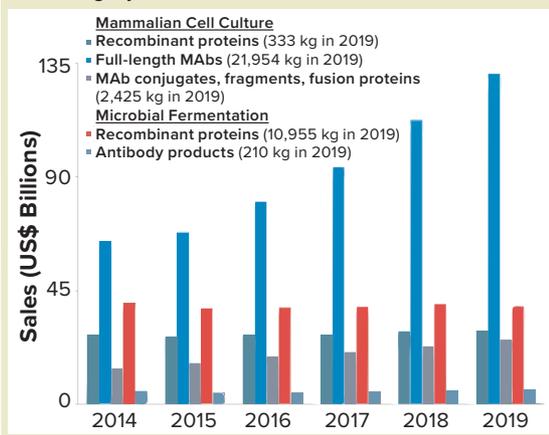


than all other biopharmaceutical product classes over the past five years. Figure 3 shows the breakdown of sales based on product type (e.g., full-length antibodies, antibody conjugates, fragments, and so on) and production system (mammalian cell culture or microbial fermentation). As the data show, sales of all MAb products (regardless of the production system or type) have grown from ~\$84 billion in 2014 to nearly \$163 billion in 2019, a 93% increase. By comparison, sales of other recombinant-protein therapeutics have remained virtually unchanged in the same time period (~\$68 billion).

Corresponding to the increasing sales of MAB products, the total quantity of these products produced annually has increased to meet the market demand. Nearly 25 metric tons of MAB products were produced around the world in 2019 — compared with about 11 metric tons of all other recombinant-protein products, regardless of expression system. The demand for mammalian-expressed MAB products has resulted in a significant amount of global manufacturing capacity devoted to their production and to significant investments in improved methods and approaches to MAB manufacturing process design and optimization (10, 11).

In 2019, 36 of the MAB products listed in Table 1 achieved annual sales of over \$1 billion, with five products reaching sales of >\$7 billion: AbbVie's Humira (adalimumab), Merck's Keytruda (pembrolizumab), Regeneron's Eylea (aflibercept), Bristol-Myers Squibb's Opdivo (nivolumab), and Genentech/Roche's Avastin (bevacizumab). AbbVie

Figure 3: Total annual sales of biopharmaceutical products are shown as a function of product type. Note that recombinant proteins produced by microbial fermentation include insulin products, which represent >40% of the sales and >85% of material produced in that category.



recorded Humira sales of about \$19 billion for two consecutive years, making that the highest selling (bio)pharmaceutical product.

Based on a review of historical sales data, company annual reports, and sales-projection data collected in our group's proprietary bioTRAK database, we determined a five-year compound annual growth rate (CAGR) of 14.1% for the MAb product market and forecast that the market feasibly could continue to grow at a CAGR of 10% or more over the next several years. With that 10% growth rate, sales of currently approved MAb products combined with those of new products approved in the coming years should drive global sales of MAb products to about \$240 billion by 2023 and nearly \$315 billion by 2025.

FACTORS CONTRIBUTING TO MARKET GROWTH

With MAb drug approvals rising over time (Figure 1) along with the demand for and revenue generated by such products (Figure 3), interest in developing them remains strong. No single specific reason can be cited for the increase in approvals or growth of this class of products, but several contributing factors have combined to create an environment that is conducive to rapidly expanding the number of approved MAb drugs. Significant funding availability, ongoing advancements in MAb technologies, expansion of MAb products into new markets, and the emergence of biosimilars all have contributed to nearly all pipeline MAb products (1), thus driving regulatory approvals, widening market

Table 1 (CONTINUED): Currently marketed therapeutic monoclonal antibody products (*continued, next page*)

Brand Name (INN)	MAb Product Type	First Approval
Darzalex (daratumumab)	Antibody	2015 US
Dupixent (dupilumab)	Antibody	2017 US
Emgality (galcanezumab-gnlm)	Antibody	2018 US
Empliciti (elotuzumab)	Antibody	2015 US
Enbrel (etanercept)	Antibody fusion protein	1998 US
Enhertu (fam-trastuzumab deruxtecan-nxki)	Antibody conjugate	2019 US
Enspryng (satralizumab-mwge)	Antibody	2020 US
Entyvio (vedolizumab)	Antibody	2014 US
Erbitux (cetuximab)	Antibody	2004 US
Erelzi (etanercept-szsz)	Antibody fusion protein, biosimilar	2016 US
Eticovo/Benepali (EU) (etanercept-ykro)	Antibody fusion protein, biosimilar	2016 EU
Evenity (romosozumab-aqqg)	Antibody	2019 US
Eylea (afibercept)	Antibody fusion protein	2011 US
Fasenra (benralizumab)	Antibody	2017 US
Gamifant (emapalumab-lzsg)	Antibody	2018 US
Gazyva/Gazyvaro (EU) (obinutuzumab)	Antibody	2013 US
Hadlima/Imraldi (EU) (adalimumab-bwwd)	Antibody, biosimilar	2017 EU
Hemlibra (emicizumab-kxwh)	Antibody, bispecific	2017 US
Herceptin (trastuzumab)	Antibody	1998 US
Herzuma (trastuzumab-pkrb)	Antibody, biosimilar	2018 EU
Hulio (adalimumab-fkjp)	Antibody, biosimilar	2018 EU
Humira (adalimumab)	Antibody	2002 US
Hyrimoz/Halimatoz (EU), Hefiya (EU) (adalimumab-adaz)	Antibody, biosimilar	2018 EU
Idacio (EU) (adalimumab)	Antibody, biosimilar	2019 EU
Ilaris (canakinumab)	Antibody	2009 US
Ilumya/Ilumetri (EU) (tildrakizumab-asmn)	Antibody	2018 US
Imfinzi (durvalumab)	Antibody	2017 US

Table 1 (CONTINUED): Currently marketed therapeutic monoclonal antibody products (*continued, next page*)

Brand Name (INN)	MAb Product Type	First Approval
Inflectra (infliximab-dyyb)	Antibody, biosimilar	2013 EU
Kadcyla (ado-trastuzumab emtansine)	Antibody conjugate	2013 US
Kanjinti (trastuzumab-anns)	Antibody, biosimilar	2018 EU
Kevzara (sarilumab)	Antibody	2017 US
Keytruda (pembrolizumab)	Antibody	2014 US
Lemtrada (alemtuzumab)	Antibody	2013 EU
Libtayo (cemiplimab-rwlc)	Antibody	2018 US
Lucentis (ranibizumab)	Antibody fragment (microbially expressed)	2006 US
Lumoxiti (moxetumomab pasudotox-tdfk)	Antibody fusion protein (microbially expressed)	2018 US
Monjuvi (tafasitamab-cxix)	Antibody	2020 US
Mvasi (bevacizumab-awwb)	Antibody, biosimilar	2017 US
Mylotarg (gemtuzumab ozogamicin)	Antibody conjugate	2000 US
Nepexto (EU) (etanercept)	Antibody fusion protein, biosimilar	2020 EU
Nucala (mepolizumab)	Antibody	2015 US
Nulojix (belatacept)	Antibody fusion protein	2011 US
Ocrevus (ocrelizumab)	Antibody	2017 US
Ogivri (trastuzumab-dkst)	Antibody, biosimilar	2017 US
Ontruzant (trastuzumab-dttb)	Antibody, biosimilar	2017 EU
Opdivo (nivolumab)	Antibody	2014 US
Orencia (abatacept)	Antibody fusion protein	2005 US
Padcev (enfortumab vedotin-ejfv)	Antibody conjugate	2019 US
Perjeta (pertuzumab)	Antibody	2012 US
Polivy (polatuzumab vedotin-piiq)	Antibody conjugate	2019 US
Portrazza (necitumumab)	Antibody	2015 US
Poteligeo (mogamulizumab-kpkc)	Antibody	2018 US
Praluent (alirocumab)	Antibody	2015 US

Companies maximizing cell culture titers through combined increases in cell density, specific productivity, and culture duration have seen **INCREASES** in impurity levels and the percentage of solids present in their cell culture fluids.

reach, and increasing revenues for this class of products.

Between 2015 and 2018, fundraising through venture capital, initial public offerings (IPOs), and follow-ons has exceeded such funding in 2010–2014 (12) and provided financial support for advancing our understanding of disease at a molecular level. Although failing to meet some observers' initially high expectations, genomics, proteomics, and other systems-biology tools do continue to provide important new targets for modulating disease (13). MAb products often provide the most direct route to a clinical proof-of-concept for activating, inhibiting, or blocking those new targets. Timelines for developing a lead product to investigational new drug application (IND) have shortened while production timelines for clinical products have lengthened (8).

MAb products and industry technologies also have expanded product types from basic “naked” MAbs to more complex structures such as conjugates that deliver targeted cytotoxic or radiologic materials and bispecific antibodies that can bind multiple targets. Because production of most MAb products is easily amenable to efficient platform-based approaches for both discovery and manufacture, and because antibodies are generally well-tolerated and highly specific, the risk of unexpected safety issues is lower in human clinical trials of MAb products than with many other types of therapeutic products. Thus, for many novel targets, MAb products often are the first product candidates advancing into clinical studies. If the initial proof-of-concept results are successful, these products can make rapid progress toward commercialization, providing a “first-to-market” advantage.

Also fueling the growth in MAb product sales is the global market expansion of the pharmaceutical market overall, which results from an increasing

Biosimilars are discussed often as an aid to lowering healthcare costs and a vehicle by which larger patient populations could receive needed treatments — but they actually represent a **SMALL PORTION** of the development pipeline.

and aging worldwide population along with improved standards of living in emerging markets. In addition, continued evaluation of MAb products for new and expanded clinical indications contributes to demand for clinical study materials and subsequent sales in newly approved indications. As the biopharmaceutical industry continues to mature, the number and types of diseases that will be treated economically with MAb products will increase. Driven in part by the need for cost-effective supply of large quantities of products for such cost-sensitive indications as rheumatology and asthma, recent improvements in MAb production technologies have improved process yields and reduced actual manufacturing costs substantially. As a result, these products have an ever-increasing opportunity to penetrate relatively cost-sensitive indications and markets.

As patents providing exclusive rights to many of high-profile and blockbuster MAb products expire, interest in biosimilar development has grown (Figure 2). In September 2013, the first biosimilar monoclonal antibodies — sold under the brand names Remsima (marketed by Celltrion) and Inflectra (marketed by Pfizer) — were approved for commercial sale in Europe. These biosimilar versions of Janssen’s blockbuster MAb product Remicade (infliximab) were the first of 32 MAb product biosimilars currently approved, and in the coming years, many more biosimilar MAb products certainly will be approved for commercial sale in both the United States and Europe.

Biosimilars have received significant attention in the press and are discussed often as an aid to lowering healthcare costs and a vehicle by which larger patient populations could receive needed treatments. However, these products actually represent a small portion of the development pipeline. But we do anticipate modest acceleration of sales growth for all MAb products as biosimilars

Table 1 (CONTINUED): Currently marketed therapeutic monoclonal antibody products (*continued, next page*)

Brand Name (INN)	MAb Product Type	First Approval
Praxbind (idarucizumab)	Antibody fragment	2015 US
Prolia (denosumab)	Antibody	2010 EU
Qarziba (EU) (dinutuximab beta)	Antibody	2017 EU
Reblozyl (luspatercept-aamt)	Antibody fusion protein	2019 US
Remicade (infliximab)	Antibody	1998 US
Remsima (EU) (infliximab)	Antibody, biosimilar	2013 EU
Renflexis/Flixabi (EU) (infliximab-abda)	Antibody, biosimilar	2016 EU
Repatha (evolocumab)	Antibody	2015 EU
Rituxan/MabThera (EU) (rituximab)	Antibody	1997 US
Rixathon (EU), Riximyo (EU) (rituximab)	Antibody, biosimilar	2017 EU
Ruxience (rituximab-pvvr)	Antibody, biosimilar	2019 US
Sarclisa (isatuximab-irfc)	Antibody	2020 US
Siliq/Kyntheum (EU) (brodalumab)	Antibody	2017 US
Simponi (golimumab)	Antibody	2009 US
Simulect (basiliximab)	Antibody	1998 US
Skyrizi (risankizumab-rzaa)	Antibody	2019 US
Soliris (eculizumab)	Antibody	2007 US
Stelara (ustekinumab)	Antibody	2009 EU
Strensiq (asfotase alfa)	Antibody fusion protein	2015 EU
Sylvant (siltuximab)	Antibody	2014 US
Synagis (palivizumab)	Antibody	1998 US
Takhzyro (lanadelumab-flyo)	Antibody	2018 US
Taltz (ixekizumab)	Antibody	2016 US
Tecentriq (atezolizumab)	Antibody	2016 US
Tepezza (teprotumumab)	Antibody	2020 US
Trazimera (trastuzumab-qyyp)	Antibody, biosimilar	2018 EU
Tremfya (guselkumab)	Antibody	2017 US

gain market acceptance. Interest in them continues surge in the markets of Latin America, China, Southeast Asia, India, and Russia. Several MAb products already have been approved in these regions. Introduction of biosimilars in those markets is likely to have a large impact on the global sales of MAb products as biosimilar MAbs are approved in regions that currently have no access to expensive innovator products.

A BRIGHT FUTURE AHEAD

MAb products will continue to be a dominant therapeutic modality for treatment of a broad range of diseases in the foreseeable future. The potential impact of MAb therapeutics in the race to build up COVID-19 vaccine treatments is uncertain. But in spite of the ongoing pandemic, global MAb approvals and sales will continue to increase over the next five years. As approvals of biosimilar products initially bite into MAb innovator sales, adoption of biosimilars is expected to increase overall access to antibody product types for a net increase in the overall number of patients (and hence, sales) for this biopharmaceutical industry segment. Manufacturing capacity to make MAb products continues to expand to meet the continually growing demand as well.

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Table 1 (CONTINUED): Currently marketed therapeutic monoclonal antibody products

Brand Name (INN)	MAb Product Type	First Approval
Trodelyv (sacituzumab govitecan-hziy)	Antibody conjugate	2020 US
Trogarzo (ibalizumab-uiyk)	Antibody	2018 US
Trulicity (dulaglutide)	Antibody fusion protein	2014 US
Truxima (rituximab-abbs)	Antibody, biosimilar	2017 EU
Tysabri (natalizumab)	Antibody	2004 US
Ultomiris (ravulizumab-cwvz)	Antibody	2018 US
Unituxin (dinutuximab)	Antibody	2015 US
Uplinza (inebilizumab-cdon)	Antibody	2020 US
Vectibix (panitumumab)	Antibody	2006 US
Vyepti (eptinezumab-jjmr)	Antibody (microbially expressed)	2020 US
Xgeva (denosumab)	Antibody	2010 US
Xolair (omalizumab)	Antibody	2003 US
Yervoy (ipilimumab)	Antibody	2011 US
Zaltrap (ziv-aflibercept)	Antibody fusion protein	2012 US
Zercepac (EU) (trastuzumab)	Antibody, biosimilar	2020 EU
Zessly (EU) (infliximab)	Antibody, biosimilar	2017 US
Zevalin (ibritumomab tiuxetan)	Antibody conjugate	2002 US
Zinplava (bezlotoxumab)	Antibody	2016 US
Zirabev (bevacizumab-bvzr)	Antibody, biosimilar	2019 EU

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Corresponding author **Dawn M. Ecker** is the managing director of *bioTRAK Database Services*, **Thomas J. Crawford** is a *bioTRAK database senior associate*, and **Patti Seymour** is managing director at *BioProcess Technology Group — Life Sciences Practice*, BDO USA, LLP, One International Place, Boston, MA 02110; <https://www.bdo.com/industries/life-sciences/bioprocess-technology>; decker@bdo.com. 

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