

## **Market Overview**

## **Antibodies for Cancer Treatment**

## SAMPLE

Type of Report: Global

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Cancer is one of the leading causes of death worldwide, affecting approximately 13 Million people in 2012 and is expected to grow to 17 Million by 2020. The dramatic increase in the size of the potential cancer market has prompted pharmaceutical players to invest in the oncology sector with major focus on monoclonal antibodies.<sup>1</sup>

Over the past several years, monoclonal antibodies have revolutionized cancer treatments. Monoclonal antibodies are laboratory-produced molecules that mimic naturally produced antibodies for oncology treatments, such as antibody drug conjugates (ADCs), biologics, and immunotherapy. Monoclonal antibodies have a variety of applications, including cancer cell marking, growth signal blocking, the delivery of chemotherapy toxins, and the reduction of new blood vessel growth. <sup>2</sup>

A bispecific antibody is a second generation immunotherapy, which some consider to be an upgraded version of monoclonal antibody, having improved structure and functionality.<sup>3</sup>

While market sizes are hard to estimate, the following describes how we arrived at an estimate for the Antibodies for Cancer Treatment Market. We estimate the market size to be approximately:

Market Niche Size			
Market Size	Growth	Base	Detailed Basis for Estimate
in Dollars	Rate	Year	
Global	7.49%	2012	The market for Monoclonal Antibodies (mAbs) for Cancer is
Cancer mAbs—	CAGR		estimated at \$23 Billion, and is expected to grow to \$33
\$23 Billion		*	Billion by 2017. <sup>4</sup> Using these figures, a Compound Annual
USD			Growth Rate of 7.49% was calculated.
Global	na	2012	The Antibody Drug Conjugates (ADC) market was estimated
ADC Market—			to be worth \$138 Million in 2012. <sup>5</sup>
\$138 Million			
USD			

<sup>&</sup>lt;sup>1</sup> "Cancer Monoclonal Antibodies Market Forecast to 2017." August 13, 2013. http://www.prnewswire.com/news-releases/cancer-monoclonal-antibodies-market-forecast-to-2017-219466121.html. (accessed April 10, 2014).

<sup>&</sup>lt;sup>2</sup> Sun, Leo. "Understanding the Massive Market Potential of Monoclonal Antibodies." August 27, 2013. http://www.fool.com/investing/general/2013/08/27/understanding-the-massive-market-potential-of-mono.aspx. (accessed April 14, 2014).

<sup>&</sup>lt;sup>3</sup> "Concise Analysis of the International Bispecific Antibody Therapeutics Market." March 5, 2014. http://www.prnewswire.com/news-releases/concise-analysis-of-the-international-bispecific-antibody-therapeutics-market-248503151.html. (accessed April 14, 2014).

<sup>&</sup>lt;sup>4</sup> "Cancer Monoclonal Antibodies Market Forecast to 2017." August 13, 2013. http://www.prnewswire.com/news-releases/cancer-monoclonal-antibodies-market-forecast-to-2017-219466121.html. (accessed April 10, 2014).

<sup>&</sup>lt;sup>5</sup> "Antibody Drug Conjugates Market." July 22, 2013. http://www.rootsanalysis.com/reports/view\_document?report\_id=21. (accessed April 14, 2014).

Bispecific	na	2023	By 2023, the bispecific antibodies market is estimated to be
Antibodies—			worth USD 4.4 billion. Oncology dominates the field of
USD 4.4 billion			bispecific antibodies. <sup>6</sup>

It is expected that the US and Europe will continue to hold significant shares of the Cancer mAbs market, and Japan will exhibit double-digit growth.<sup>7</sup>

Market size and growth rate are a function of the number of people in the market and the anticipated rate of buying. As markets transition between emerging, growth, shakeout, mature, and declining, the basis for competition and the number of competitors usually changes, along with the factors influencing adoption of innovation. The number of and growth rate for customers suggests how many units might be sold.<sup>8</sup>

Our Current View on the Phase of the Market		
Today	Trend	
Growth	Growth	

Antibody-based therapeutics is the fastest growing segment of the drugs and biologics market. Antibody-based therapy for cancer has become established over the past 15 years and is now one of the most successful and important strategies for treating patients. Currently there are a number of anti-cancer monoclonal antibodies in late phases of development, whose approvals will likely impact the market, which is expected to continue growing in upcoming years.

Markets can also be described in terms of the basis for competition (best technological performance, best value or the price/performance tradeoff that best matches the endusers' preferences, lowest cost, or best availability or the ability to get the product

<sup>&</sup>lt;sup>6</sup> "Bispecific Antibody Therapeutics Market." October 2, 2013. <a href="http://www.prnewswire.com/news-releases/bispecific-antibody-therapeutics-market-2013---2023-226121501.html">http://www.prnewswire.com/news-releases/bispecific-antibody-therapeutics-market-2013---2023-226121501.html</a>. (accessed April 15, 2014).

<sup>7</sup> "Cancer Monoclonal Antibodies Market to 2015." March 2012. <a href="http://www.reportlinker.com/p0795425-summary/Cancer-Monoclonal-Antibodies-Market-to.html">http://www.reportlinker.com/p0795425-summary/Cancer-Monoclonal-Antibodies-Market-to.html</a>. (accessed April 15, 2014).

<sup>&</sup>lt;sup>8</sup> For a detailed discussion of the "innovativeness dimension," see Everett M. Rogers, *Diffusion of Innovations*, 4<sup>th</sup> ed. (New York: Free Press, 1995). For further readings related to market phases and innovation, see also James Utterback, *Mastering the Dynamics of Innovation* (Boston: Harvard Business School Press, 1996) and Vijay K. Jolly, *Commercializing New Technologies: Getting from Mind to Market* (Boston: Harvard Business School Press, 1997).

<sup>&</sup>lt;sup>9</sup> "Concise Analysis of the International Bispecific Antibody Therapeutics Market." March 5, 2014. http://www.prnewswire.com/news-releases/concise-analysis-of-the-international-bispecific-antibody-therapeutics-market-248503151.html. (accessed April 14, 2014).

<sup>&</sup>lt;sup>10</sup> "Antibody therapy of cancer." April 2012. <a href="http://www.nature.com/nrc/journal/v12/n4/full/nrc3236.html">http://www.nature.com/nrc/journal/v12/n4/full/nrc3236.html</a>. (accessed April 14, 2014).

<sup>&</sup>quot;Cancer Monoclonal Antibodies Market Forecast to 2017." August 13, 2013. <a href="http://www.prnewswire.com/news-releases/cancer-monoclonal-antibodies-market-forecast-to-2017-219466121.html">http://www.prnewswire.com/news-releases/cancer-monoclonal-antibodies-market-forecast-to-2017-219466121.html</a>. (accessed April 10, 2014).

<sup>&</sup>lt;sup>12</sup> "Next-gen antibody approaches to cancer treatment offer improved product profiles, greater commercial success." October 2009. <a href="http://www.ddn-news.com/index.php?newsarticle=3317">http://www.ddn-news.com/index.php?newsarticle=3317</a>. (accessed April 14, 2014).

quickly). This dimension helps to define the context in which a commercialization strategy must be developed.

Basis for Competition in the Arena		
Today	Trend	
Best Technological Performance	Lowest Cost	
Best Availability		

The cost of monoclonal antibody therapies for cancer has been very high. <sup>13</sup> Currently, such therapies command premium prices due to the huge clinical benefits they offer and the lack of alternative treatments for patients. Soon, however, they will have to be sold at competitive prices as the existing level of reimbursement will become unsustainable. <sup>14</sup>

In each market there may be stakeholders and companies with significant market share that will influence the introduction of your technology. Some organizations or companies that will likely influence the introduction of this technology are the following:

Examples of Major Competitors in the Arena			
Competitor	Relevance	Web site(s)	
Roche	This is the largest oncology company in the world, which currently has the largest portfolio of	Company web site: http://www.roche.com/	
	approved monoclonal antibody	Product web site:	
	treatments. Roche's Avastin, which generated \$6.3 billion in annual sales in 2012, is approved for the treatment of brain, colon, kidney and lung cancers. 15	http://www.avastin.com/patient	
Eli Lilly and Company	Lilly Oncology, a division of Eli Lilly and Company is developing novel treatment approaches for cancer, such as Ramucirumab, a monoclonal antibody for lung cancer.	http://www.lilly.com/	
GlaxoSmithKline (GSK)	GSK is working on a number of monoclonal antibodies for cancer, which are in various stages of development and trials.	http://www.gsk.com/	
Amgen	This company has an FDA- Approved Antibody-based Therapeutic for cancer called	Company web site: <a href="http://www.amgen.com/">http://www.amgen.com/</a>	
	Vectibix.	Product web site:	

<sup>&</sup>lt;sup>13</sup> "Controlling the cost of innovative cancer therapeutics." September 2009. http://www.isdbweb.org/documents/file/1735\_3.pdf. (accessed April 14, 2014).

<sup>&</sup>lt;sup>14</sup> "Drug Developers Drawn to Orphan Drugs Market: Financial Incentives Create Rich, Competitive Pipelines." March 25, 2014. <a href="http://www.frost.com/prod/servlet/press-release.pag?docid=289930483">http://www.frost.com/prod/servlet/press-release.pag?docid=289930483</a>. (accessed April 14, 2014).

<sup>&</sup>lt;sup>15</sup> Sun, Leo. "Understanding the Massive Market Potential of Monoclonal Antibodies." August 27, 2013. http://www.fool.com/investing/general/2013/08/27/understanding-the-massive-market-potential-of-mono.aspx. (accessed April 14, 2014).

		http://www.vectibix.com/
Bristol-Myers Squibb	BMS is heavily involved in	Company web site:
(BMS)	oncology research and has an FDA-	http://www.bms.com/
	Approved Antibody-based	Product web site:
	Therapeutic for cancer, called	http://www.yervoy.com/patient.aspx
	Yervoy.	
Seattle Genetics	Seattle Genetics is a biotechnology	http://www.seattlegenetics.com/
	company focused on developing and	
	commercializing innovative	
	antibody-based therapies for the	
	treatment of cancer. They are the	
	industry leader in antibody-drug	
	conjugates (ADCs).	
Genmab A/S	Genmab is an international	http://www.genmab.com/
	biotechnology company specializing	
	in the creation and development of	
	differentiated human antibody	
	therapeutics for the treatment of	
	cancer.	
Genetech	Genetech has an FDA-Approved	http://www.gene.com/patients/medici
	Antibody-based Therapeutic for	nes/rituxan
	cancer, called Rituxan.	

Examples of Key Stakeholders or Networking Channels with Contact Information			
Stakeholder	Relevance	Contact Information	
American Association for	"The AACR fosters research in cancer	Website: <a href="http://www.aacr.org/">http://www.aacr.org/</a>	
Cancer Research (AACR)	and related biomedical science;		
	accelerates the dissemination of new	Telephone: (215) 440-9300	
	research findings among scientists and	Toll Free Telephone: 1-866-423-	
	others dedicated to the conquest of	3965	
	cancer; promotes science education and	Email: <u>aacr@aacr.org</u>	
	training; and advances the understanding		
	of cancer etiology, prevention, diagnosis,		
	and treatment throughout the world."		
The Antibody Society	This society provides an international	Society Website:	
	forum for the field of antibody research,	http://www.antibodysociety.org/	
	engineering and related areas. mAbs is		
	the therapeutics journal of the antibody	Magazine Website:	
	society. <i>mAbs</i> is the first international	http://www.landesbioscience.co	
	peer-reviewed journal of its kind to focus	<u>m/journals/mabs/</u>	
	exclusively on monoclonal antibodies.		

Entry barriers are obstacles that remove customer segments from the market for some period of time. They limit the size of the addressable market in general or the market share that can be captured. These barriers must be overcome or avoided to have a successful market entry. Our work to date suggests the following entry barriers may prevent customer segments from buying this type of technology for some period of time.

Market Entry Barriers	
Name of Barrier	Description/Why
Regulatory approvals	Regulatory approvals (such as those imposed by the FDA) can be stringent for technologies in this market and thus create a barrier for entry. <sup>16</sup>
New products entering the market	Currently there are a number of anti-cancer monoclonal antibodies in advanced phases of development/ trials whose approvals may make entering the market more difficult. <sup>17</sup>
High cost of R&D	It costs on average \$1.2 billion to bring a new biologic to the market. <sup>18</sup> The high cost will make it challenging to enter this market.
Market Consolidation	While research and innovation in the field of cancer monoclonal antibodies have been growing greatly, the industry has witnessed a large number of consolidation activities. <sup>19</sup>

As with most drug markets, hopeful new entrants into the Cancer mAb market may face challenges in obtaining funds for research and development in order to meet standards and receive regulatory approvals. Additionally, the strong current competitors and possible new competitors may also make entering this market difficult.

Market drivers are forces that strengthen or weaken the importance of end-user needs over time.

Market Drivers		
Name of Driver	Why Significant	
Increase in number of	Cancer cases worldwide are predicted to increase by 70% over the next	
cancer cases	two decades, from 14 million in 2012 to 25 million new cases a year,	
	according to the World Health Organization. <sup>20</sup> This increase may	
	strengthen the need for therapeutics such as antibodies.	
Pricing and Patent factors	In the US cancer treatment market the pricing trends are favorable for	
are favorable in the US	market participants. This is coupled with the strength of the existing	
	patent landscape where existing patents will remain in force for some	
	time – keeping generics out of play. <sup>21</sup>	

<sup>&</sup>lt;sup>16</sup> "FDA Oncology Drug Approval." FDA web site.

http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ucm103366.pdf. (accessed April 15, 2014).

<sup>&</sup>lt;sup>17</sup> "Cancer Monoclonal Antibodies Market Forecast to 2017." August 13, 2013. http://www.prnewswire.com/news-releases/cancer-monoclonal-antibodies-market-forecast-to-2017-219466121.html. (accessed April 10, 2014).

<sup>18 &</sup>quot;Controlling the cost of innovative cancer therapeutics." September 2009. http://www.isdbweb.org/documents/file/1735 3.pdf. (accessed April 14, 2014).

<sup>&</sup>lt;sup>19</sup> "Cancer Monoclonal Antibodies Market to 2015." March 2012. <a href="http://www.reportlinker.com/p0795425-summary/Cancer-Monoclonal-Antibodies-Market-to.html">http://www.reportlinker.com/p0795425-summary/Cancer-Monoclonal-Antibodies-Market-to.html</a>. (accessed April 15, 2014).

<sup>&</sup>lt;sup>20</sup> Boseley, Sarah. "Worldwide cancer cases expected to soar by 70% over next 20 years." Guardian News web site. <a href="http://www.theguardian.com/society/2014/feb/03/worldwide-cancer-cases-soar-next-20-years">http://www.theguardian.com/society/2014/feb/03/worldwide-cancer-cases-soar-next-20-years</a>. (accessed April 14, 2014).

<sup>&</sup>lt;sup>21</sup> "Monoclonal Antibodies Market in Colorectal Cancer to 2019 - Favorable Pricing Policy in the US and Rising Prevalence in Europe and Japan Ensures Market Growth," April 3, 2014, Reportbuyer.com,

Here are some additional sources that can help you better understand the market.

Link	Description
http://www.ncbi.nlm.nih.gov	This is an article titled "Bispecific antibodies for cancer therapy."
/pmc/articles/PMC2791310/	
http://www.insightpharmare	This is a report titled "Monoclonal Antibodies: Pipeline Analysis and
ports.com/uploadedFiles/sa	Competitive Assessment," which contains information on the antibodies
mple pages(1).pdf	that are in clinical trials for cancer.

http://www.abc12.com/story/25155332/monoclonal-antibodies-market-in-colorectal-cancer-to-2019-favorable-pricing-policy-in-the-us-and-rising-prevalence-in-europe-and-japan-ensures-market (accessed April 17, 2014).