Letter to Editor

Risk evaluation and mitigation strategy for approved therapeutic antibodies

Abbreviations: mAb, monoclonal antibody; MSPA, Moderate to Severe Persistent Asthma; CIU, Chronic Idiopathic Urticaria; α4, α4-Subunit of α4β1 and α4β7 Integrins; MS, Multiple Sclerosis; CD, Crohn's Disease; PML, Progressive Multifocal Leukoencephalopathy; PNH, Paroxysmal Nocturnal Hemoglobinuria; aHUS, Atypical Hemolytic Uremic Syndrome; p40, p40 Subunit of IL-12 and IL-23; Ps, Psoriasis; PsA, Psoriatic Arthritis; RPLS, Reversible Posterior Leukoencephalopathy Syndrome; RA, Rheumatoid Arthritis; PJIA, Polyarticular Juvenile Idiopathic Arthritis; SJIA, Systemic Juvenile Idiopathic Arthritis; CTLA-4, Human Cytotoxic T-lymphocyte Antigen-4; UMM, Unresectable Or Metastatic Melanoma; SFIMAR, Severe and Fatal Immune-Mediated Adverse Reactions such as Enterocolitis; REMS, Risk Evaluation And Mitigation Strategy

Volume 1 Issue 5 - 2014

Henry Hongrong Cai
Pharmacovigilance and drug safety, EMD Serono and InVentive Health Clinical, USA

Correspondence: Henry Hongrong Cai, Medical Director, Ventive Health Clinical, 95 Cynthia Road Newton, MA 02459, USA, Tel 617-581-5161, Email DrCai66@gmail.com

Received: October 31, 2014 | **Published:** December 11, 2014

Letter to editor

In 1975, Monoclonal antibody (mAb) technique was created by Georges Kohler, Cesar Milstein, and NielsKaj Jerne by using mouse x mouse hybridoma, they shared the Nobel Prize in Physiology or Medicine in 1984 for the discovery. 8 years later, in 1992 FDA approved first therapeutic mAbMuromonab-CD3 (trade name Orthoclone OKT3) for to reduce acute rejection in patients with organ transplants, since then, as of December 2014, FDA has approved 42 therapeutic mAbs. Among them 6 need risk evaluation and mitigation strategy (REMS) (Table 1). These therapeutic mAb targets at components of immune system, soluble or membrane to achieve therapeutic effect, inevitably causing immune-mediated adverse reaction.[1-6] REMS includes medication guide and elements to assure safe use to maintain the benefit overweight the risk.

Table 1 Approved therapeutic mAb with risk evaluation and mitigation strategy (REMS)

Approval date	MAH	Drug name	mAb	Target	Indication	REMS
June 20 2003	GENENTECH	Xolair	Omalizumab	IgE	MSPA, CIU	Anaphylaxis
Nov 23 2004	BIOGENIDEC	Tysabri	Natalizumab	α4	MS, CD	PML
Mar 16 2007	ALEXION	Soliris	Eculizumab	C5	PNH, aHUS	Meningococcal infections
Sept 25 2009	CENTOCOR ORTHO	Stelara	Ustekinumab	p40	Ps, PsA	RPLS
Jan 08 2009	GENENTECH	Actemra	Tocelizumab	IL-6R	RA, PJIA, SJIA	Serious infection
Mar 25 2011	BMS	Yervoy	Ipilimumab	CTLA-4	UMM	SFIMAR

According to the law Food and Drug Administration Amendments Act- sometimes called "FDAAA"-enacted in 2007, FDA may require a REMS as part of the approval of a new product, or for an approved product when new safety information arises. Essentially, REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use. REMS assessments will be submitted to FDA at 18 months, 3 years, 5 years, and 7 years after approval of the original REMS. On Dec 22, 2011 Xolair was successfully release from the REMS.[7]

Acknowledgements

None.

Conflicts of Interest

There is no conflict of interest.

Funding

None.

References

1. http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/103976s5161lbl.pdf
2. http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/125104s840s847s889lbl.pdf
3. http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125166s368s380lbl.pdf
4. http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125261s114lbl.pdf
5. http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/125276s092lbl.pdf

6. http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/125377s055lbl.pdf

7. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm393231.htm

Citation: Cai HH. Risk evaluation and mitigation strategy for approved therapeutic antibodies. *MOJ Immunol.* 2014;1(5):11–12.
DOI: 10.15406/moji.2014.01.00028