

# Letter from the editor

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*mAbs*' September/October 2009 issue highlights the promise and challenges of antibody therapeutics development. Representing promise, our mini-review series on novel antibodies currently undergoing regulatory review or recently approved continues in this issue. Previously published articles include mini-reviews of denosumab and ustekinumab (May/June 2009 issue) and ofatumumab (July/August 2009 issue). The September/October issue features articles on golimumab, tocilizumab and motavizumab. The mini-reviews present overviews of the completed and ongoing clinical studies of these molecules. Anti-TNF $\alpha$  golimumab was approved in April 2009 by both the US Food and Drug Administration (FDA) and Health Canada as a treatment for rheumatoid arthritis (RA), psoriatic arthritis and ankylosing spondylitis; anti-IL6R tocilizumab is approved in Japan and the European Union (EU), and is currently undergoing FDA review as a treatment for RA. The juxtaposition of these two mini-reviews provides an opportunity to easily compare summaries of the available clinical results. Future issues of *mAbs* will include mini-reviews of catumaxomab, canakinumab and raxibacumab, as well as any additional antibodies that enter regulatory review in 2009 and beyond.

Specific challenges to antibody development are addressed in articles that provide thoughtful perspectives on the industrialization of antibody production technology, and the use of non-human primates (NHPs) in the preclinical development of therapeutic antibodies. In discussing the bioprocessing industry, Brian Kelley provides an authoritative overview of the current state of antibody manufacturing, and analysis of currently available capacity compared to capacity requirements under various scenarios. He also asks provocative questions concerning the need for increases in production capacity and future objectives of process development groups. On the topic of NHP studies, Kathryn Chapman and co-authors discuss results of an expert working group established by the National Center for the Replacement, Refinement and Reduction of Animals in Research. Preclinical safety data for over 100 antibodies intended as treatments for a variety of therapeutic categories from companies, contract research organizations and institutes was shared. The data was used to design suggested preclinical development pathways for hypothetical antibodies presented as examples in the article by Chapman et al.

The broad challenge of biosimilar therapeutic antibody development is also addressed in this issue of *mAbs*. Alain Beck, Harish Iyer and I present a report based on a European Medicines Agency (EMA) workshop on biosimilar monoclonal antibodies that was held on July 2, 2009 at EMA headquarters on Canary Wharf in London. Discussion focused on specific questions concerning chemistry, manufacturing and controls (CMC), non-clinical

issues, and clinical issues involved in the development of biosimilar antibody products. EMA is the world-leader in establishing guidelines for the development of biosimilars, having already issued guidelines for somatropin, insulin, granulocyte-colony stimulating factor, erythropoietins, interferon alpha and low-molecular-weight heparins. The workshop was certainly interesting, and undoubtedly informative, to the regulators, innovator and biogeneric industry representatives, and academic researchers in attendance. In addition to a narrative of the proceedings, the workshop report also includes perspectives on biosimilar product development from the EU, India, and the United States (US). The perspective from the US is further developed in Kevin McCabe's article on biosimilar and patent reform legislation pending in Congress.

*mAbs*' mission is to provide a forum for communication on all topics relevant to antibody research and development. The articles mentioned above are excellent examples of our coverage of topics important to antibody developers. In addition, our ongoing commitment to publishing high-quality research results is exemplified by the reports included in this issue. Working in the assay development area, Yin Luo and colleagues describe a surface plasmon resonance-based binding assay that can be used to evaluate Fc $\gamma$  receptor binding of monomeric, dimeric and multimeric forms of antibody molecules. Therapeutic antibodies tend to be developed as treatments for cancer, immunological and infectious disease, and this issue includes research results from each of these areas. May Kung Sutherland and colleagues present study results of lintuzumab in models of acute myeloid leukemia, and Mei-Yun Zhang and coworkers describe characterization of a chimeric anti-insulin-like growth factor type 1 receptor antibody that might have utility as an anti-cancer agent. Working in the immunological disease area, Masatoshi Maeda, Yuji Ito and colleagues discuss their studies on regulation of T-cell response using an anti-B7RP-1 antibody fragment. Donna Montgomery, Ying-Jie Wang and coworkers present results of their studies on antibodies specific for gp41 of the human immunodeficiency virus.

As with all our issues, *mAbs* readers will find thought-provoking and informative articles here. Please feel free to contact me with questions and comments, or suggestions for future issues.

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