

Accepted Manuscript

Non-clinical safety evaluation of biotherapeutics – Challenges, opportunities and new insights

Guenter Blaich, Andreas Baumann, Sven Kronenberg, Lolke de Haan, Peter Ulrich, Wolfgang F. Richter, Jay Tibbitts, Simon Chivers, Edit Tarcsa, Robert Caldwell, Flavio Crameri

PII: S0273-2300(16)30242-2

DOI: [10.1016/j.yrtph.2016.08.012](https://doi.org/10.1016/j.yrtph.2016.08.012)

Reference: YRTPH 3654

To appear in: *Regulatory Toxicology and Pharmacology*

Received Date: 20 August 2016

Accepted Date: 25 August 2016

Please cite this article as: Blaich, G., Baumann, A., Kronenberg, S., de Haan, L., Ulrich, P., Richter, W.F., Tibbitts, J., Chivers, S., Tarcsa, E., Caldwell, R., Crameri, F., Non-clinical safety evaluation of biotherapeutics – Challenges, opportunities and new insights, *Regulatory Toxicology and Pharmacology* (2016), doi: 10.1016/j.yrtph.2016.08.012.

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.



1 Workshop report

2 **Non-Clinical Safety Evaluation of Biotherapeutics – Challenges, Opportunities and New**
3 **Insights**

4 Guenter Blaich ^a, Andreas Baumann ^b, Sven Kronenberg ^c, Lolke de Haan ^d, Peter Ulrich ^e, Wolfgang
5 F. Richter ^c, Jay Tibbitts ^f, Simon Chivers ^g, Edit Tarcsa ^h, Robert Caldwell ⁱ, Flavio Crameri ^c

6 *^aAbbVie GmbH, Ludwigshafen, Germany; ^bBayer Pharma AG, Berlin, Germany;*

7 *^cRoche Pharmaceutical Research and Early Development, Pharmaceutical*

8 *Sciences, Roche Innovation Center Basel, Switzerland; ^dMedImmune, Cambridge,*

9 *UK; ^eNovartis Pharma, Basel, Switzerland; ^fUCB Celltech, Slough, UK; ^gADC*

10 *Therapeutics, SA; ^hAbbVie BioResearch, Worcester, USA.; ⁱAbbVie Inc., North*

11 *Chicago, USA.*

12

13 **Abstract**

14 New challenges and opportunities in nonclinical safety testing of biotherapeutics were presented and
15 discussed at the 5th European BioSafe Annual General Membership meeting in November 2015 in
16 Ludwigshafen. This article summarizes the presentations and discussions from both the main and the
17 breakout sessions.

18 The following topics were covered in six main sessions:

- 19 (i) Challenges around use of PEGylated biologics, results of BioSafe survey
- 20 (ii) Unexpected side effects of biotherapeutics
- 21 (iii) Safety testing of cell and gene therapies including vector safety and integration site
22 analysis and setting up a GLP facility in this field
- 23 (iv) Immunogenicity and PKPD including immunogenicity prediction or methodologies to
24 prevent induction of anti-drug antibodies
- 25 (v) Current approaches applied to antibody drug conjugate (ADC) development

Download English Version:

<https://daneshyari.com/en/article/5561362>

Download Persian Version:

<https://daneshyari.com/article/5561362>

[Daneshyari.com](https://daneshyari.com)