Accepted Manuscript

The predictive value of the rodent neurofunctional assessment for commonly reported adverse events in Phase I clinical trials

Andrew N. Mead, Hamid R. Amouzadeh, Kathryn Chapman, Lorna Ewart, Alessandra Giarola, Samuel J. Jackson, Philip Jarvis, Pierre Jordaan, Will Redfern, Martin Traebert, Jean-Pierre Valentin, Hugo M. Vargas

PII: S0273-2300(16)30105-2

DOI: 10.1016/j.yrtph.2016.05.002

Reference: YRTPH 3562

To appear in: Regulatory Toxicology and Pharmacology

Received Date: 4 January 2016

Revised Date: 20 April 2016

Accepted Date: 2 May 2016

Please cite this article as: Mead, A.N., Amouzadeh, H.R., Chapman, K., Ewart, L., Giarola, A., Jackson, S.J., Jarvis, P., Jordaan, P., Redfern, W., Traebert, M., Valentin, J.-P., Vargas, H.M., The predictive value of the rodent neurofunctional assessment for commonly reported adverse events in Phase I clinical trials, *Regulatory Toxicology and Pharmacology* (2016), doi: 10.1016/j.yrtph.2016.05.002.

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.



ACCEPTED MANUSCRIPT

1 The Predictive Value Of The Rodent Neurofunctional Assessment For

2 Commonly Reported Adverse Events In Phase I Clinical Trials

3

- 4 Andrew N. Mead^a, Hamid R. Amouzadeh^b, Kathryn Chapman^c, Lorna Ewart^d, Alessandra
- 5 Giarola^e, Samuel J Jackson^{c*}, Philip Jarvis^f, Pierre Jordaan^f, Will Redfern^g, Martin Traebert^h,
- 6 Jean-Pierre Valentini Hugo M. Vargasb.

7

- 8 Affiliations:
- ^a Pfizer Inc., Eastern Point Road, Groton, CT 06340, USA^I.
- b Amgen Inc., Integrated Discovery & Safety Pharmacology, Thousand Oaks CA, 91320,
- 11 USA
- ^c National Centre for the Replacement, Refinement and Reduction of Animals in Research
- 13 (NC3Rs), Gibbs Building, 215 Euston Road, London, NW1 2BE, UK;
- ^d AstraZeneca R&D Mölndal, Drug Safety and Metabolism, Pepparedsleden 1, 431 83,
- 15 Mölndal, Sweden
- ^e GlaxoSmithKline, Safety Assessment Department, Park Road, Ware, UK
- ^f Novartis DS&E and Oncology OGD, Postfach, CH-4002, Basel, Switzerland
- ⁹ AstraZeneca R&D, Drug Safety & Metabolism, Alderley Park, SK10-4TG, Macclesfield, UK.
- ^h Novartis Institutes of Biomedical Research, Safety Pharmacology, CH-4057 Basel,
- 20 Switzerland
- ¹ AstraZeneca R&D, Drug Safety & Metabolism, Alderley Park, SK10-4TG, Macclesfield,
- 22 UK^{II}.
- *Corresponding author: Samuel J Jackson, National Centre for the Replacement,
- 24 Refinement and Reduction of Animals in Research (NC3Rs), Gibbs Building, 215 Euston
- 25 Road, London, NW1 2BE, UK

-

¹ Current affiliation: AstraZeneca R&D, Drug Safety and Metabolism, Cambridge, CB4 0WG, LIK

^{II} Current affiliation: UCB Biopharma, Non-Clinical Development, Chemin du Foriest, Braine l'Alleud, B-1420, Belgium.

Download English Version:

https://daneshyari.com/en/article/5855916

Download Persian Version:

https://daneshyari.com/article/5855916

<u>Daneshyari.com</u>