

ORAL ABSTRACTS

912. Quality-of-Life Impact of an Investigational Subunit-Adjuvanted Herpes Zoster Vaccine in Adults ≥ 50 Years of Age

Desmond Curran, PhD¹; Eugene Athan, MBBS, FRACP, MPH²; Javier Diez-Domingo, MD, PhD³; Wayne Ghesquiere, MD, FRCPC⁴; Thomas C. Heineman, MD, PhD⁵; Himal Lal, MD⁶; Edward Leung, MD⁷; Myron J. Levin, MD⁸; Sean Matthews, MSc⁹; Janet E. McElhaney, MD¹⁰; Shelly A. McNeil, MD, FRCPC, FIDSA¹¹; Lidia Oostvogels, MD⁹; Karlis Pauksens, MD, PhD¹²; Joan Puig-Barb era, MD, MPH, PhD¹³; Antonio Volpi, MD¹⁴; Daisuke Watanabe, MD, PhD¹⁵; Wilfred Yeo, MB, ChB, MD¹⁶; Robert W. Johnson, MD¹⁷; ¹Health Economics, GSK Vaccines, Wavre, Belgium; ²Infectious Diseases, Barwon Health, Deakin University, Geelong, Australia; ³Vaccine Research Unit, Fundaci n para el Fomento de la Investigaci n Sanitaria y Biom dica, Valencia, Spain; ⁴Royal Jubilee Hospital and Victoria General Hospital, Victoria, British Columbia, Canada; ⁵GSK Vaccines, King of Prussia, Pennsylvania; ⁶Pfizer, Collegeville, Pennsylvania; ⁷Department of Medicine, United Christian Hospital, Kowloon, Hong Kong; ⁸Departments of Pediatrics and Medicine, University of Colorado Anschutz Medical Campus, Aurora, Colorado; ⁹GSK Vaccines, Wavre, Belgium; ¹⁰Health Sciences North Research Institute of Canada, Sudbury, Ontario, Canada; ¹¹Canadian Center for Vaccinology, IWK Health Centre and Nova Scotia Health Authority, Dalhousie University, Halifax, Nova Scotia, Canada; ¹²Uppsala University Hospital, Uppsala, Sweden; ¹³Fundaci n para el Fomento de la Investigaci n Sanitaria y Biom dica, Valencia, Spain; ¹⁴Universit  di Roma Tor Vergata, Rome, Italy; ¹⁵Aichi Medical University, Nagakute, Japan; ¹⁶School of Medicine, University of Wollongong, Wollongong, Australia; ¹⁷University of Bristol, Bristol, United Kingdom

Session: 122. Vaccines, Vaccine Preventable Disease, and their Impact
Friday, October 28, 2016: 8:30 AM

Background. Herpes zoster (HZ) and its complications can have a substantial impact on patients' quality of life (QL). The ZOE 50 (NCT01165177) and ZOE 70 (NCT01165229) randomized, placebo-controlled phase-3 studies investigated the efficacy of a subunit vaccine (HZ/su), containing recombinant varicella-zoster virus glycoprotein E and the AS01B Adjuvant System, in adults aged ≥ 50 and ≥ 70 years, respectively. Here we report the impact of HZ/su on QL parameters associated with HZ episodes.

Methods. Subjects received 2 doses of HZ/su or placebo intramuscularly 2 months apart. QL parameters were measured by standard instruments: The Short-Form health survey (SF-36) and Euro-Quality of Life-5 Dimension (EQ-5D) were assessed at baseline, at months 14, 26 and 38, and also during suspected HZ episodes in conjunction with the Zoster Brief Pain Inventory (ZBPI). In confirmed HZ cases, QL scores were compared between the 2 groups. The vaccine efficacy in reducing the ZBPI Burden of Illness and ZBPI Burden of Interference scores were estimated in all subjects in the modified total vaccinated cohort (mTVC). The latter 2 scores are calculated from the area under the curve (Days 0 to 182) of the ZBPI Worst pain and ZBPI Activities of Daily Living scores, respectively, assuming a score of 0 for subjects who do not have a confirmed HZ episode. These results focus on the ZOE 50 study population and the ZOE 50 and 70 pre-specified combined study populations, which include subjects, aged ≥ 70 years (ZOE 70+).

Results. The results from the analysis of the ZBPI questionnaire are presented in the table below.

Table

Statistic	ZOE 50		ZOE 70 +	
	HZ/su	Placebo	HZ/su	Placebo
mTVC Subjects	7304	7413	8250	8343
HZ Confirmed Cases	9	254	25	284
Maximum Worst Pain: Mean	5.5	6.7	5.7	7.0
Wilcoxon Test	P = 0.1133		P = 0.0316	
Maximum Average Pain: Mean	3.9	5.5	4.5	5.6
Wilcoxon Test	P = 0.0486		P = 0.0431	
Burden of Illness Efficacy	98.4%		92.1%	

Open Forum Infectious Diseases 2016;1(S1):S1-68

  The Author 2016. Published by Oxford University Press on behalf of the Infectious Diseases Society of America. This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs licence (<http://creativecommons.org/licenses/by-nc-nd/4.0/>), which permits non-commercial reproduction and distribution of the work, in any medium, provided the original work is not altered or transformed in any way, and that the work is properly cited. For commercial re-use, please contact journals.permissions@oup.com.

DOI: 10.1093/ofid/ofw194

continued.

Statistic	ZOE 50		ZOE 70 +	
	HZ/su	Placebo	HZ/su	Placebo
Burden of Interference Efficacy	99.1%		90.3%	

HZ/su: Herpes zoster subunit vaccine; mTVC: modified total vaccinated cohort

Results from the SF-36 and EQ-5D questionnaires involving repeated measurements over time will also be presented.

Conclusion. In addition to significantly reducing the risk of HZ, the vaccine also reduces the severity of HZ in those who develop breakthrough disease.

Disclosures. D. Curran, GSK group of companies: Employee, Salary and stock equity; J. Diez-Domingo, Sanofi Pasteur MSD: Board Member and Grant Investigator, Consulting fee and Research grant. GSK group of companies: Board Member, Consulting fee; T. C. Heineman, GSK group of companies: Employee, Salary and stock equity; H. Lal, Pfizer: Employee, Salary GSK group of companies: former employee, Salary; M. J. Levin, GSK group of companies: Investigator and Scientific Advisor, Consulting fee and Grant recipient. Merck, Sharp & Dohme: Intellectual Property and Scientific Advisor, Consulting fee and patent royalty; S. Matthews, GSK Vaccines: freelance, Consulting fee; J. E. McElhaney, GSK group of companies: Dr. McElhaney's institution, compensation for travel and meeting attendance. Pfizer: Dr. McElhaney's institution, compensation for travel and meeting attendance. Merck: Dr. McElhaney's institution, compensation for travel and meeting attendance. Sanofi Pasteur: Dr. McElhaney's institution, compensation for travel and meeting attendance; S. A. McNeil, GSK: Grant Investigator, Research grant and Research support. Pfizer: Grant Investigator, Consulting fee, Research grant, Research support and Speaker honorarium. Merck: Consultant and Investigator, Consulting fee, Research support and Speaker honorarium; L. Oostvogels, GSK group of companies: Employee, Salary and stock equity; K. Pauksens, Akademiska sjukhuset, Uppsala University Hospital: Investigator, The institution received compensation to perform clinical trial; J. Puig-Barb era, GSK group of companies: Grant Investigator, personal fees and Research grant. Novartis Vaccines: Grant Investigator, personal fees and Research grant; A. Volpi, SanofiPasteur MSD Italy: Scientific Advisor, Salary; D. Watanabe, GSK group of companies: Grant Investigator and personal fees, Grant recipient. Maarhu: Grant Investigator and personal fees, consulting and lectures. Mochida: personal fees, lectures. Japan Vaccines: personal fees, consulting; W. Yeo, GSK group of companies: payments, payments; R. W. Johnson, GSK group of companies: Board Member and personal fees, Consulting fee and personal fees. SanofiPasteur MSD: Board Member and personal fees, lectures to medical societies. Merck Inc: Board Member and personal fees, educational video production