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# GSK and ViiV Healthcare to showcase advances across industry-leading infectious disease portfolio at IDWeek 2024

- 60 abstracts to be presented across broad and growing portfolio of vaccines and medicines aimed at getting ahead of infectious disease
- New data to be shared on GSK's RSV vaccine across different age groups of patients at increased risk
- Efficacy data for gepotidacin in patients with a high unmet need suffering from uUTIs to be shared against a backdrop of rising antimicrobial resistance
- New evidence to be shared on real-world impact of ViiV Healthcare's innovative, long-acting HIV prevention and treatment portfolio

GSK plc (LSE/NYSE: GSK) and ViiV Healthcare will share new data from their industry-leading, prevention-focused infectious disease pipeline and portfolio at the Infectious Disease Society of America's IDWeek 2024 annual meeting in Los Angeles from 16-19 October 2024. 60 abstracts will be presented, showcasing data for vaccines and medicines across a range of infectious diseases including respiratory syncytial virus (RSV), herpes zoster, uncomplicated urinary tract infections (uUTI) and HIV.

### **Vaccines**

22 abstracts from GSK's vaccines pipeline and portfolio have been accepted, including new data for *Arexvy* (Respiratory Syncytial Virus Vaccine, Adjuvanted) and *Shingrix* (Zoster Vaccine Recombinant, Adjuvanted). Presentations on GSK's RSV vaccine will include data across different age ranges in older adults and post-marketing safety data, plus 10 other abstracts featuring evidence across comorbidities of interest, seasons and geographies. Additional presentations include overviews of GSK's 5-in-1 meningococcal ABCWY vaccine candidate and the risks of invasive meningococcal disease in young children.

### **Medicines**

Among the abstracts from GSK's infectious disease therapeutics portfolio, 13 abstracts will highlight data for gepotidacin, an investigational, first-in-class oral antibiotic with a novel mechanism of action for uUTI and urogenital gonorrhoea (GC). This includes an oral presentation of clinical data from the EAGLE-2 and EAGLE-3 phase III trials, examining the efficacy of gepotidacin in patient subgroups with uUTIs with a high unmet need in the context of rising antimicrobial resistance (AMR). Additional data on surveillance and the burden of AMR in uUTIs and treatment failure in uUTIs will also be highlighted.

#### **HIV** prevention and treatments

Additionally, ViiV Healthcare will present 22 abstracts from its innovative HIV treatment and prevention portfolio. Two oral presentations will share real-world evidence from the OPERA and TRIO studies, evaluating the effectiveness of, adherence to and persistence in the use of *Apretude* (cabotegravir long-acting (LA)) for HIV pre-exposure prophylaxis (PrEP) across diverse populations.

Findings from the PILLAR study will highlight the impact of cabotegravir LA for PrEP on common challenges associated with daily oral PrEP, such as stigma and anxiety. Additional abstracts highlight ViiV's industry-leading long-acting and two-drug regimens for the treatment of HIV including treatment benefits, satisfaction and preference, offering new insights for healthcare providers seeking to optimise care to suit individual needs and circumstances.

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**Tony Wood, Chief Scientific Officer, GSK said:** "Infectious diseases represent a major threat to human health, which is why two-thirds of our pipeline focuses on pioneering new technologies to deliver preventative options – like vaccines and HIV PrEP – plus therapeutic solutions. At IDWeek 2024, we're proud to share data highlighting our scientific developments in the prevention and treatment of diseases like RSV, herpes zoster, uUTI and HIV, while also working to tackle the challenge of antimicrobial resistance."

For more than 70 years, GSK has been advancing a comprehensive portfolio of medicines and vaccines for infectious diseases. Considerable progress has been made, but there remains significant work to do to address the burden of infectious diseases on individuals, society and healthcare systems:

- More than one billion people are infected annually by seasonal respiratory viruses such as influenza and RSV.<sup>1,2</sup> People living with certain underlying health conditions are at increased risk of hospitalisation or death due to RSV.<sup>3</sup>
- About 40 million people live with HIV worldwide, many of whom still face stigma and do not have adequate access to care.<sup>4</sup>
- AMR threatens to undermine the progress that has been made to date and prevent further gains. Without action, AMR could contribute to 40 million deaths by 2050.<sup>5</sup>

In support of its ambition to get ahead of disease, GSK continues to advance the science, pursuing new solutions while continuing to build the evidence base for its vaccines and treatments. With the breadth of data presented at IDWeek, GSK and ViiV Healthcare highlight their goal to pioneer a new range of first- or best-in-class options to close the gap in prevention and treatment for patients who deserve more.

### Full list of GSK and ViiV Healthcare's presentations at IDWeek 2024:

Abstracts from GSK's Vaccines Portfolio		
Abstract title	Presenting author	Presentation
Persistence of Immunogenicity and Safety of the Respiratory Syncytial Virus Prefusion F Protein Vaccine (RSVPreF3 OA) Administered to Adults 50–59 Years of Age (YOA)	Corinne Vandermeulen	Poster presentation
Robust and Consistent Immune Response of the Adjuvanted Respiratory Syncytial Virus (RSV) Prefusion F Protein Vaccine (RSVPreF3 OA) Across Different Age Ranges and Frailty Status in Older Adults	Veronica Hulstrøm	Oral presentation
Early Post-Marketing Safety Surveillance for the Respiratory Syncytial Virus Prefusion F Protein Vaccine (RSVPreF3 OA)	Quentin Deraedt	Oral presentation
Characteristics Associated with the Presence of One or More Risk Factors for Severe Respiratory Syncytial Virus Disease Among Adults in the United States	Emily K. Horn	Poster presentation
Risk of COPD Exacerbations, Asthma Exacerbations, and Hospitalizations for Heart Failure after RSV Hospitalization Among US Adults Aged at Least 50 Years	David Singer	Poster presentation
Respiratory Syncytial Virus (RSV) Testing Patterns Among Medically Attended Cases of Acute Respiratory Illness from 2016 to 2023	David Singer	Poster presentation
RSV Vaccination Uptake Among US Adults Aged ≥60 Years Who Are at Increased Risk of Severe RSV Disease (August 2023–February 2024)	Elizabeth La	Poster presentation
Factors Associated with Healthcare Professionals' RSV Older Adult Vaccination Knowledge and Practices During the First Season of Vaccine Availability in the United States	Elizabeth La	Poster presentation

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Respiratory Syncytial Virus (RSV) Disease Burden in Older Adults with Acute Respiratory Infection (ARI) in Europe During the 2022/2023 RSV Season	Veronica Hulstrøm	Poster presentation	
Coinfections with Respiratory Syncytial Virus (RSV) in a Cohort of Adults with Pre Existing Comorbidities in Wisconsin from 2015–16 through 2019–20	Oluwakemi Alonge	Poster presentation	
Estimating the Public Health Impact of Pertussis Decennial Booster Vaccination for German Adults	Eliana Biundo	Poster presentation	
Quantifying the Health Equity Related Public Health Impact of Influenza Vaccination: A Pilot Study for United Kingdom	Eliana Biundo	Poster presentation	
Medical Need for Meningococcal Vaccination in Young Children from the Americas	Oluwatosin Olaiya	Poster presentation	
Clinical Profile of GSK's Pentavalent Meningococcal ABCWY Vaccine: An Overview	Woo-Yun Sohn	Poster presentation	
Characterization of Herpes Zoster Cases and Sustained High Vaccine Efficacy Against Herpes Zoster Complications in Individuals Vaccinated with Recombinant Zoster Vaccine During A Long-Term Follow-Up Study	Rafael Leon	Poster presentation	
Recombinant Zoster Vaccine Uptake Among Immunocompromised US Adults	Justin Gatwood	Poster presentation	
Herpes Zoster Burden Among US Adults with Immunocompromising or Comorbid Conditions: A Systematic Literature Review	Justin Gatwood	Poster presentation	
Worldwide Impact of Increased Recombinant Zoster Vaccine Coverage on the Burden of Herpes Zoster, Based on 11-Year Clinical Trial Follow-Up Data, in Adults Aged ≥50 Years	Desmond Curran	Poster presentation	
Incidence of Diagnosed Herpes Zoster and Risk of Complications by Race and Ethnicity: A Retrospective Cohort Study Among Adults in the United States	Nikita Stempniewicz	Poster presentation	
Vaccine Effectiveness and Safety of Recombinant Zoster Vaccine in Inflammatory Bowel Disease Patient Populations Aged 50 Years and Older	Bradley K. Ackerson	Poster presentation	
Recent Incidence Rate of Herpes Zoster Among Immunocompetent Adults Aged 18 and Older in the United States	Huifeng Yun	Poster presentation	
The Adjuvanted Recombinant Zoster Vaccine Is Effective in Preventing Herpes Zoster (HZ) Among Patients ≥50 Years of Age (YOA) with Selected Autoimmune Diseases in the United States: A Real- World Database Analysis (2018–2021)	Dagna Constenla	Poster presentation	
Abstracts from GSK's infectious disease medicines portfolio			
Discordant Clinical and Microbiological Responses are Associated with Late Clinical Relapse in Uncomplicated Urinary Tract Infections: Pooled Analysis of EAGLE-2/EAGLE-3 Trial Data	Amanda J. Sheets	Poster presentation	
Patient Characteristics Associated with Extended Spectrum Beta Lactamase-Producing Uropathogens: Pooled Results from Two Phase 3 Clinical Trials of Gepotidacin for the Treatment of Uncomplicated Urinary Tract Infection	Jeremy Dennison	Poster presentation	
Efficacy of Gepotidacin Versus Nitrofurantoin in a Nitrofurantoin Not Susceptible Population: A Pooled Analysis of the EAGLE-2 and EAGLE-3 Randomized	Jeremy Dennison	Oral presentation	

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Controlled Trials in Uncomplicated Urinary Tract Infection			
Impact of Empiric Treatment Failure on Clinical Outcomes and Healthcare Resource Utilization Among US Females with Uncomplicated Urinary Tract Infections	Debra L. Fromer	Poster presentation	
Impact of High Predicted Risk of Antimicrobial Resistance on Empiric Treatment Failure in US Females with Uncomplicated Urinary Tract Infections	Debra L. Fromer	Poster presentation	
Healthcare Resource Use and Costs of Acute Uncomplicated Cystitis in Japan	Meg Franklin	Poster presentation	
Systematic Literature Review of Acute Cystitis or Afebrile Urinary Tract Infection in Men	Fanny S. Mitrani-Gold	Poster presentation	
In Vitro Activity of Gepotidacin Against Klebsiella pneumoniae, Including Molecularly Characterized ESBL and Carbapenemase Positive Subsets Causing Urinary Tract Infections in the United States (2019–2022)	Rodrigo E. Mendes	Rapid fire poster presentation	
In Vitro Activity of Gepotidacin and Comparator Agents Against a Collection of K. pneumoniae Urine Isolates from the United States During 2019–2022	S.J. Ryan Arends	Poster presentation	
In Vitro Activity of Gepotidacin Against Klebsiella pneumoniae, Including Molecularly Characterized Fluoroquinolone Not Susceptible Subsets Causing Urinary Tract Infections in the United States (2019–2022)	Rodrigo E. Mendes	Poster presentation	
In Vitro Activity of Gepotidacin Tested Against Molecularly Characterized Escherichia coli Isolates Responsible for Urinary Tract Infections in the US (2019–2022)	Rodrigo E. Mendes	Poster presentation	
In Vitro Activity of Gepotidacin Against Molecularly Characterized Neisseria gonorrhoeae Isolates Exhibiting Reduced Susceptibility to Antibacterial Agents, 2018–2021	Mark Estabrook	Poster presentation	
A Comparative Analysis of Resistance Rates Among Escherichia coli and Klebsiella pneumoniae Isolates Collected from the Gepotidacin Uropathogen Global Surveillance Studies and Phase 3 Uncomplicated Urinary Tract Infection Clinical Studies	Renuka Kapoor	Poster presentation	
Activity of Ibrexafungerp and Comparator Antifungals Tested Against <i>Candida</i> and <i>Aspergillus</i> Isolates Collected from Invasive Infections in a Global Surveillance Program in 2023	Marisa L. Winkler	Poster presentation	
Intravenous-Line Related Complications in Patients Treated with Short Term Intravenous Antibiotics for Complicated Urinary Tract Infection and Other Infections: A Systematic Literature Review	Fanny Mitrani-Gold	Poster presentation	
Prevalence and Risk Factors of Antimicrobial Resistance and Multidrug Resistance in Patients with Complicated Urinary Tract Infections (cUTIs) and all UTIs: A Systematic Literature Review	Fanny Mitrani-Gold	Poster presentation	
Abstracts from ViiV Healthcare's portfolio			
PAIRED - PAtlent Reported Experiences and perceiveD benefit of treatment with dolutegravir/lamivudine (DTG/3TC): a diverse sample	Andrew P. Brogan	Poster presentation	

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of people with HIV-1 reporting high treatment		
satisfaction, good adherence, and high quality of life		
Real-world Experience with the Two-Drug Regimen	V. Paul DiMondi	Encore poster
Dolutegravir/Lamivudine for the Treatment of HIV-1		presentation
among Vulnerable People Living with HIV in Canada:		'
Preliminary Results from a Chart Review Study		
Extrapolating Expected Efficacy, Safety, and	William Short	Encore poster
Pharmacokinetics (PK) of Dolutegravir/Lamivudine	William Short	presentation
		presentation
(DTG/3TC) in Pregnant People Living with HIV-1 from		
Pregnancy Data with Combination DTG and/or 3TC		
Antiretroviral Therapies		
Real-world Virologic and Safety Outcomes in People	Andrés Doblado-	Encore poster
Living with HIV-1 Using Dolutegravir (DTG) +	Maldonado	presentation
Lamivudine (3TC) in Asia Stratified by Viral Load (VL),		
Including in Individuals with High VLs		
Evaluation of Weight Gain on Incident Hypertension	Clifford B. Jones	Encore poster
among People Living with HIV-1 Receiving	· · · · · · · · · · · · · · · · · · ·	presentation
Dolutegravir (DTG)-Based Regimens or Comparator		procentation
Antiretroviral Therapy (cART) in Randomized Clinical		
Trials through 96 Weeks s	Doob of D. William	Doctor procestation
Improved Testing for Chronic Disease Among Long-	Rachel P. Weber	Poster presentation
Acting Injectable Versus Daily Oral Antiretroviral		
Therapy Users in the OPERA Cohort		
Characteristics of Women Initiating CAB+RPV LA in	Jessica Altamirano	Poster presentation
the OPERA Cohort		
People with HIV in the US switching to cabotegravir +	Andrew Brogan	Poster presentation
rilpivirine long-acting (CAB+RPV LA) from oral	3	•
antiretroviral therapy (ART) have numerous real-world		
benefits, including high adherence and treatment		
satisfaction		
Feasibility, Fidelity, and Effectiveness of Administering	Cassidy Cutnor	Poster presentation
	Cassidy Gutner	Poster presentation
CABENUVA in Infusion Centers		<del>                                     </del>
Use of Long-Acting Cabotegravir/Rilpivirine in People	George Bchech	Poster presentation
Living with HIV with Renal Transplantation		
PrEP Decision Factors: a CHORUS Healthcare	Ricky Hsu	Poster presentation
Professional Survey		
Cabotegravir Long-Acting for Pre-Exposure	Ricky Hsu.	Oral presentation
Prophylaxis (PrEP): Real World Data on On-Time	,	·
Dosing, HIV Testing and HIV Acquisition from the		
OPERA Cohort		
Real-World Use of Cabotegravir Long-Acting for Pre-	Moti Ramgopal	Oral presentation
Exposure Prophylaxis: Data from Trio Health Cohort	wou Kangupai	Oral prosentation
	Tania Data at	Doctor presentation
Opportunities for PrEP Awareness and Engagement: A	Tonia Poteat	Poster presentation
Survey among Healthcare-Seeking Cisgender Women		
in the US		
Awareness and Preferences for Every 2 Month Long-	Aimee Metzner	Poster presentation
acting Injectable HIV Pre-Exposure Prophylaxis (PrEP)		
Versus Daily Oral PrEP among Cisgender Women in		
the United States and the Dominican Republic		
Social Determinants of Health and Side Effects	Deanna Kerrigan	Poster presentation
Significantly Predict Pre-Exposure Prophylaxis (PrEP)	· · · · · · · · · · · · · · · · · · · · · · · · · · · · · · · · · · · · · · · ·	
Preferences for Every 2 Month Long-Acting Injectable		
vs. Daily Oral PrEP among Cisgender Women in the		
United States and the Dominican Republic		
	Hodrico Holder	Doctor presentation
Patient Experiences at Month 6 after Initiation of Cabotegravir Long-Acting (CAB LA) for PrEP in the	Hadrian Holder	Poster presentation

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First Male Gender Concordant Implementation Science Trial (PILLAR) in the US		
Improvement in Provider Experiences from Baseline to Month 12 with Integrating Cabotegravir Long-Acting (CAB LA) for PrEP into Care in an Implementation Science Trial (PILLAR)	Taimur Khan	Poster presentation
Change in Healthcare Professional's Identification, Counseling, and Adherence with Black Women for Long-Acting Cabotegravir (CAB LA) for PrEP Across Women's Health, Primary Care, and Infectious Diseases Sites: Findings from the EBONI Study	Dylan Baker	Poster presentation
Week 26 Interim Analysis of Implementation and Delivery of Long-Acting Injectable Cabotegravir for PrEP in a Community Pharmacy Setting	Elyse Tung	Oral presentation
CD4 T-cell, CD4/CD8 Ratio Improvement and a General Reduction in Inflammatory Biomarkers with Low-Level Viremia (LLV) up to Week 192 with Fostemsavir (FTR)-Based Regimens in Individuals with Multidrug-Resistant (MDR) HIV-1	Alftan Dyson	Encore poster presentation
Similar Efficacy, Safety and CD4 T-cell Increase up to Week 96 Observed with Fostemsavir (FTR)-Based Regimens in the BRIGHTE Study and Dolutegravir (DTG)-Based Regimens in the VIKING-3 Study in Individuals with Multidrug-Resistant (MDR) HIV-1	Alftan Dyson	Encore poster presentation

#### **GSK** in infectious diseases

GSK has pioneered innovation in infectious diseases for over 70 years, and the Company's pipeline of medicines and vaccines is one of the largest and most diverse in the industry, with a goal of developing preventive and therapeutic treatments for multiple disease areas or diseases with high unmet needs globally. With our infectious disease innovation, we're also helping address the growing number of infections which are resistant to existing medicines.

The development of gepotidacin has been funded in part with federal funds from the US Department of Health and Human Services, Administration for Strategic Preparedness and Response, Biomedical Advanced Research and Development Authority (BARDA), under Other Transaction Agreement number HHSO100201300011C and with federal funds awarded by the Defense Threat Reduction Agency under agreement number HDTRA1-07-9-0002.

In antimicrobials, in addition to gepotidacin, GSK entered into an exclusive licence agreement with Spero Therapeutics, Inc. in September 2022 to add tebipenem HBr, a late-stage antibiotic and potential treatment for complicated urinary tract infections (cUTIs), to the pipeline and are currently enrolling for PIVOT-PO, a phase III trial. In March 2023, GSK announced an exclusive licence agreement with Scynexis for *Brexafemme* (ibrexafungerp tablets), a first-in-class antifungal for the treatment of vulvovaginal candidiasis (VVC) and reduction in the incidence of recurrent VVC.

### **About ViiV Healthcare**

ViiV Healthcare is a global specialist HIV company established in November 2009 by GSK (LSE: GSK) and Pfizer (NYSE: PFE), dedicated to delivering advances in treatment and care for people living with HIV and for people who are at risk of acquiring HIV. Shionogi became a ViiV shareholder in October 2012. The company's aims are to take a deeper and broader interest in HIV and AIDS than any company has done before and take a new approach to deliver effective and innovative medicines for HIV treatment and prevention, as well as support communities affected by HIV. For more information on the company, its management, portfolio, pipeline, and commitment, please visit viivhealthcare.com.

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#### **About GSK**

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com.

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#### Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D "Risk factors" in GSK's Annual Report on Form 20-F for 2023, and GSK's Q2 Results for 2024.

#### Registered in England & Wales:

No. 3888792

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