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GSK provides an update on CALM-1 and CALM-2 phase III trials for camlipixant in refractory chronic cough (RCC)

GSK plc (LSE/NYSE: GSK) today provides an update on the CALM-1 and CALM-2 phase III clinical trials, which assessed the efficacy and safety of two doses of camlipixant (a P2X3 receptor antagonist) in adults with refractory chronic cough (RCC).[1,2] RCC is a complex and under-recognised disease with limited treatment options.[3-5]

CALM-1 met its primary endpoint with camlipixant 50mg twice daily showing statistically significant reductions in 24-hour cough frequency versus placebo at week 12. CALM-2 did not reach statistical significance in the same primary endpoint with 50mg twice daily at week 24.

Camlipixant 25mg twice daily did not reach statistical significance in either study. Key secondary endpoints, including a Chronic Cough Diary (CCD) measure, did not meet target thresholds in either study. Across both trials, the overall incidence and severity of treatment-related adverse events were similar in patients receiving either camlipixant or placebo.

Based on the aggregate data, the limited efficacy demonstrated is unlikely to transform patient care. GSK has decided not to progress further development of camlipixant in RCC. Results from the CALM phase III programme will be submitted for future presentation/publication to contribute to the scientific understanding of RCC.

The phase IIb BALANCE trial (NCT07519395) will continue to evaluate the efficacy and safety of camlipixant in adults with irritable bowel syndrome - diarrhoea (IBS-D) and irritable bowel syndrome - mixed (IBS-M).[6]

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 www.gsk.com.

GSK enquiries

Media:	Tim Foley	+44 (0) 20 8047 5502	(London)
	Sarah Clements	+44 (0) 20 8047 5502	(London)
	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Sydney Dodson-Nease	+1 215 370 4680	(Philadelphia PA)
Investor Relations:	Constantin Fest	+44 (0) 7831 826525	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Steph Mountifield	+44 (0) 7796 707505	(London)
	Sam Piper	+44 (0) 7824 525779	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 3126	(Philadelphia)

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This announcement contains inside information. The person responsible for arranging the release of this announcement on behalf of GSK is Victoria Whyte, Company Secretary.

Registered in England & Wales:
No. 3888792

Registered Office:
79 New Oxford Street
London
WC1A 1DG

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