GSK enters agreement to acquire Nuvalent, Inc.

Multi-product oncology deal for assets that have validated targets and aim to address efficacy and/or tolerability limitations of existing therapies

Includes two late-stage, potential best-in-class ROS1 (zidesamtinib) and ALK (neladalkib) inhibitors for non-small cell lung cancer (NSCLC), currently under US FDA review

for 2026 approvals

Accelerates entry into lung cancer, providing a platform for expansion with Ris-Rez, GSK's B7-H3 antibody-drug conjugate (ADC)

Acquisition expected to be accretive to sales and core operating profit in 2027 and core EPS in 2029 inclusive of synergies and reprioritisation

GSK plc (LSE/NYSE: GSK) today announced that it has entered an agreement to acquire Nuvalent, Inc. ("Nuvalent") (NASDAQ: NUVL) a Boston-based clinical-stage biopharmaceutical company focused on creating precisely targeted oncology therapies, for $10.6 billion. The acquisition is consistent with GSK's strategy of acquiring assets that have validated targets and meaningfully address efficacy and/or tolerability limitations of existing standard-of-care therapies. It includes three products in lung cancer in a single transaction.

Zidesamtinib (NVL-520) and neladalkib (NVL-655) are two late-stage, potential best-in-class, next-generation, highly selective ROS1 and ALK inhibitors for treatment of NSCLC. Both assets have received FDA Breakthrough Therapy and Orphan Drug Designations* and are in review with target decision dates of 18 September 2026 for zidesamtinib and 27 November 2026 for neladalkib. Subject to FDA approval, they are expected to launch in 2026 and have multi-blockbuster potential. The third asset, NVL-330, is a potential best-in-class HER2 inhibitor currently in phase I trials for HER2-altered NSCLC. The acquisition also includes Nuvalent's preclinical portfolio of multiple programmes, built from their proven precision medicine capabilities and

clinical insights from industry-leading physician-scientists.

Luke Miels, Chief Executive Officer, GSK said: "Today's acquisition is a multi-product deal, consistent with our approach to acquire assets that have clinically proven targets and meaningfully address an efficacy and/or tolerability gap. The two lead products are potential best-in-class assets that could launch this year if approved by the FDA and offer significant new treatment options to patients with two forms of non-small cell lung cancer.

The acquisition provides GSK with immediate new sales growth opportunities, improving profit contributions from 2027, and a platform in lung cancer for rapid expansion with Ris-Rez, our B7-H3 targeted ADC in phase III clinical development."

Pivotal data presented at the IASLC 2025 World Conference on Lung Cancer and the 2026 ASCO Annual Meeting show potential best-in-class profiles for zidesamtinib and neladalkib.[1,2] Both assets aim for longer effective treatment with better quality of life through high target-selectivity, durable treatment response, improved tolerability, enhanced blood-brain barrier penetration for tumour spread, and broader coverage of ALK and ROS1 mutations, potentially addressing efficacy and/or tolerability limitations of existing therapies. ROS1- and ALK-altered NSCLC primarily affect non-smoking adults aged 40-50, a uniquely defined and engaged patient population. There is substantive treatment experience with zidesamtinib and neladalkib already through their clinical development and patient assistance programmes.[3,4]

James Porter, PhD, Chief Executive Officer, Nuvalent, said: "Since our founding, we have leveraged our deep expertise in chemistry and structure-based drug design to develop a portfolio of novel, potentially best-in-class kinase inhibitors. Our close collaboration with leading physician-scientists and patient advocates has driven remarkable enrolment, accelerating development and building confidence in the clinical profile of these drugs. We're excited that GSK has recognised the significant value these programmes can offer patients and shares our vision for practice-changing innovation. GSK's proven track record, infrastructure, and expertise will support the successful commercialisation of zidesamtinib and neladalkib, as well as accelerate advancement of our broader discovery pipeline."

Financial considerations
Under the terms of the merger agreement, GSK will commence a tender offer to acquire all of Nuvalent's outstanding shares of Class A and Class B common stock at a purchase price of $124 per share in cash within 10 business days. The aggregate equity value of the transaction is estimated to be $10.6 billion (£8.0 billion). Net of cash acquired, GSK's aggregate investment is estimated to be $9.4 billion (£7.1 billion). The expected purchase price of $124 per share represents a 40% premium to the last closing price and a 26% premium to the 30 calendar day Volume-Weighted Average Price (VWAP).

There is no change to GSK's 2026 full-year guidance range of 7-9% core operating profit and core EPS growth. The acquisition is expected to contribute to revenue growth from 2027, be incremental to the Group's existing ambition for sales of >£40 billion by 2031 and to strengthen core operating profit through the dolutegravir loss of exclusivity period (2028-2030). We expect accretion to core operating profit in 2027 and core EPS in 2029 inclusive of synergies and reprioritisation. Assuming the transaction closes in Q3 2026, we expect low single-digit percentage dilution to core EPS for the current year, FY 2027 and FY 2028.

The transaction will be funded primarily from new and existing debt facilities plus cash, with no impact expected to GSK's credit rating. GSK will maintain a strong investment grade credit profile and retains balance sheet capacity for further accretive business development.

GSK remains committed to its 70p expected dividend for 2026 and to its progressive dividend policy thereafter.

The transaction is subject to customary closing conditions, including the tender of a majority of Nuvalent's outstanding shares of Class A common stock in the tender offer and the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Act in the US. Promptly following the closing of the tender offer, GSK expects to acquire any remaining shares of Nuvalent through a second-step merger under Delaware law at the same price per share.

GSK will account for the transaction as a business combination. GSK will also assume Nuvalent's existing revenue-sharing arrangements of low-single-digit royalties payable to Royalty Pharma and Deerfield.

Advisors
Leerink Partners LLC and Citigroup Inc. are acting as financial advisors and Davis Polk & Wardwell LLP and Slaughter and May are serving as legal counsel to GSK in connection with the transaction. Centerview Partners LLC is serving as financial advisor and Ropes & Gray LLP is serving as legal counsel to Nuvalent. Jefferies LLC also provided financial advice to Nuvalent. Sidley Austin LLP is corporate counsel to Nuvalent.

About NSCLC
NSCLC is the most common form of lung cancer and is often characterised by specific genetic alterations, such as those in ALK, ROS1, or HER2. It can often metastasise (i.e. spread) to the central nervous system. It primarily affects working-age individuals. Current treatments are associated with mutation resistance and side effects, including metabolic and neurologic events, that can adversely impact patients' quality of life.

Additional information
This press announcement is for informational purposes only and is neither an offer to purchase nor a solicitation of an offer or a recommendation to sell securities, nor is it a substitute for the tender offer materials that GSK plc, GlaxoSmithKline LLC ("GSK LLC") and its wholly-owned subsidiary, Harmony Row Acquisition Co. will file with the Securities and Exchange Commission (the "SEC"). The tender offer for the outstanding shares of Nuvalent Class A common stock and Class B common stock described in this press announcement has not commenced. At the time the tender offer is commenced, GSK plc, GSK LLC and Harmony Row Acquisition Co. will file, or will cause to be filed, a Schedule TO Tender Offer Statement with the SEC, and, thereafter, Nuvalent will file a Schedule 14D-9 Solicitation/Recommendation Statement with the SEC, in each case with respect to the tender offer. **The Schedule TO Tender Offer Statement (including an offer to purchase, a related letter of transmittal and other offer documents) and the Schedule 14D-9 Solicitation/Recommendation Statement will contain important information that should be read carefully before any decision is made with respect to the tender offer**. Those materials (once they become available) will be made available to Nuvalent stockholders at no expense to them by the information agent for the tender offer, which will be announced. In addition, those materials and all other documents filed by or caused to be filed by Nuvalent or GSK plc with the SEC will be available at no charge on the SEC's website at www.sec.gov. In addition to the Schedule 14D-9 Solicitation/Recommendation Statement and Schedule TO Offer Statement (once each becomes available), Nuvalent and GSK plc file or furnish, as applicable, annual, quarterly and current reports and other information with the SEC. Nuvalent and GSK plc filings with the SEC are available to the public from commercial document-retrieval services and at the SEC's website at www.sec.gov.

About Nuvalent
Nuvalent (NASDAQ: NUVL) is a clinical-stage biopharmaceutical company focused on creating precisely targeted therapies for patients with cancer, designed to overcome the limitations of existing therapies for clinically proven kinase targets. Leveraging deep expertise in chemistry and structure-based drug design, Nuvalent develops innovative small molecules that have the potential to overcome resistance, minimize adverse events, address brain metastases, and drive more durable responses. Nuvalent is advancing a robust pipeline with investigational candidates for ROS1-positive, ALK-positive, and HER2-altered non-small cell lung cancer, and multiple discovery-stage research programs.

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.

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Cautionary statement regarding forward-looking statements
GSK plc cautions investors that any forward-looking statements or projections made by GSK plc, 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 in the “Risk Factors” section in GSK plc’s Annual Report on Form 20-F for the year ended December 31, 2025, and GSK’s Q1 Results for 2026. This communication includes forward-looking statements related to Nuvalent, neladalkib, zidesamtinib and the acquisition of Nuvalent by GSK plc that are subject to risks, uncertainties and other factors. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including all statements regarding the intent, belief or current expectation of Nuvalent and members of its senior management team and can typically be identified by words such as “believe,” “expect,” “estimate,” “predict,” “target,” “potential,” “likely,” “continue,” “ongoing,” “could,” “should,” “intend,” “may,” “might,” “plan,” “seek,” “anticipate,” “project” and similar expressions, as well as variations or negatives of these words. Forward-looking statements include, without limitation, statements regarding the merger, similar transactions, prospective performance, future plans, events, expectations, performance, objectives and opportunities and the outlook for Nuvalent’s business; the ability of Nuvalent to successfully commercialize its key products, including neladalkib and zidesamtinib; the anticipated timing of clinical data and regulatory filings or approvals relating to products; the possibility of favorable or unfavorable results from clinical trials; the anticipated benefits of the acquisition; filings and approvals relating to the transaction; the expected timing of the completion of the transaction; the parties’ ability to complete the transaction; and the accuracy of any assumptions underlying any of the foregoing. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties and are cautioned not to place undue reliance on these forward-looking statements. Actual results may differ materially from those currently anticipated due to a number of risks and uncertainties. Risks and uncertainties that could cause the actual results to differ from expectations contemplated by forward-looking statements include: uncertainties as to the timing of the tender offer and completion of the merger; the possibility that various closing conditions for the transaction may not be satisfied or waived, including that Nuvalent stockholders may not tender into the offer a majority of the shares of Class A common stock outstanding at the time of the expiration of the offer or that required regulatory approvals may not be obtained or are obtained subject to conditions that are not anticipated; the occurrence of any event, change or other circumstance that could give rise to the termination of the merger agreement; the failure to realize anticipated benefits of the proposed acquisition when expected or at all; potential adverse reactions or changes to business relationships resulting from the proposed acquisition, including the effect of the announcement, pendency or consummation of the acquisition on the ability of Nuvalent to retain and hire key personnel or maintain key vendor, supplier or partner relationships; risks that the proposed acquisition disrupts the current plans and operations of Nuvalent; transaction costs; risks associated with potential litigation or regulatory actions related to the transaction; and other risks and uncertainties described from time to time in documents filed with the SEC by Nuvalent, including current reports on Form 8-K, quarterly reports on Form 10-Q and annual reports on Form 10-K, as well as the Schedule 14D-9 to be filed by Nuvalent, or in GSK plc’s Annual Report on Form 20-F for the year ended December 31, 2025 filed with the SEC by GSK plc, as well as the Schedule TO to be filed by GSK plc. All forward-looking statements are based on information currently available to GSK plc and Nuvalent, and neither GSK plc nor Nuvalent assumes any obligation to update any forward-looking statements.

GSK uses number of adjusted measures, including Core results, to report the performance of its business, which are non-IFRS measures. These measures are defined and reconciliations to the nearest IFRS measure are available in GSK's Q1 2026 Results and GSK's Annual Report on Form 20-F for FY 2025.

GSK provides earnings guidance to the investor community on the basis of Core results. This is in line with peer companies and expectations of the investor community, supporting easier comparison of the Group’s performance with its peers. GSK is not able to give guidance for Total results as it cannot reliably forecast certain material elements of the Total results, particularly the future fair value movements on contingent consideration and put options that can and have given rise to significant adjustments driven by external factors such as currency and other movements in capital markets.

All expectations, guidance and outlooks regarding future performance should be read together with the section "Guidance and outlooks, assumptions and cautionary statements" on pages 44 and 45 of GSK's Q1 2026 Results and the statements on page 328 of GSK's Annual Report for FY 2025.

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

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References

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Nuvalent Cautionary statement regarding forward-looking statements

This document includes forward-looking statements that are subject to risks, uncertainties, and other factors that could cause actual results to differ materially from those expressed or implied by the forward-looking statements. All statements, other than statements of historical fact, are generally forward-looking statements, including all statements regarding the intent, belief, or expectations of Nuvalent and its management. These forward-looking statements typically can be identified by words such as “believe,” “expect,” “estimate,” “predict,” “target,” “potential,” “likely,” “continue,” “ongoing,” “could,” “should,” “intend,” “may,” “might,” “plan,” “seek,” “anticipate,” “project” and similar expressions, as well as variations or negatives of these words. Forward-looking statements include, without limitation, statements regarding the proposed transaction, prospective performance, future plans, events, expectations, performance, objectives, opportunities, and the outlook for Nuvalent’s business; the anticipated timing of potential regulatory approval for Nuvalent’s product candidates; the timing of and receipt of filings and approvals relating to the transaction; the expected timing of the completion of the transaction; the ability to complete the transaction considering the various closing conditions; and the accuracy of any assumptions underlying any of the foregoing. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties; accordingly, investors are cautioned not to place undue reliance on forward-looking statements. Actual results may differ materially due to several factors. Factors that could cause future results to differ materially include: uncertainties as to the timing of the tender offer and merger; uncertainties as to how many of Nuvalent’s stockholders will tender their stock in the offer; the possibility that various closing conditions for the transaction may not be satisfied or waived, including that a governmental entity may prohibit, delay, or refuse to grant approval for the consummation of the transaction; the occurrence of any event, change, or other circumstance that could give rise to the termination of the merger agreement, including circumstances requiring Nuvalent to pay a termination fee pursuant to the merger agreement; the ability of the parties to consummate the proposed transaction on a timely basis or at all; the effects of the transaction (or the announcement or pendency thereof) on relationships with associates, vendors, manufacturers, suppliers, employees (including the risks relating to the ability to retain or hire key personnel), other business partners, or governmental entities or patient groups; transaction costs; the risk that the transaction will divert management’s attention from Nuvalent’s ongoing business operations or otherwise disrupts Nuvalent’s ongoing business operations; changes in Nuvalent’s businesses during the period before any closing; certain restrictions during the pendency of the proposed transaction that may impact Nuvalent’s ability to pursue certain business opportunities or strategic transactions; risks associated with litigation; risks unexpected concerns that may arise from additional data, analysis, or results obtained during preclinical studies and clinical trials; the risk that results of earlier clinical trials may not be predictive of the results of later-stage clinical trials; the risk that data from Nuvalent’s clinical trials may not be sufficient to support registration and that Nuvalent may be required to conduct one or more additional studies or trials prior to seeking registration of zidesamtinib or neladalkib; risks that Nuvalent may not achieve the goals and milestones set forth in its OnTarget 2026 operating plan; the occurrence of adverse safety events; risks that the FDA may not approve our potential products on the timelines we expect, or at all; risks of unexpected costs, delays, or other unexpected hurdles; risks that Nuvalent may not be able to nominate drug candidates from its discovery programs; the direct or indirect impact of public health emergencies or global geopolitical circumstances on the timing and anticipated timing and results of Nuvalent’s clinical trials, strategy, and future operations, including the ARROS-1, ALKOVE-1, ALKAZAR and HEROEX-1 trials; the timing and outcome of Nuvalent’s planned interactions with regulatory authorities; and risks related to obtaining, maintaining, and protecting Nuvalent’s intellectual property; and other factors as set forth in Nuvalent’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2026 filed with the SEC on May 7, 2026, and other reports filed with the SEC. The forward-looking statements set forth herein speak only as of the date hereof. Nuvalent undertakes no obligation to update any forward-looking statement, whether as a result of new information, future developments, or otherwise, except as may be required by applicable law.

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* The FDA Breakthrough Therapy designation is designed to expedite the development and review of medicines for serious conditions, where preliminary clinical evidence indicates the potential for substantial improvement over available therapy. Orphan Drug Designation is granted to support the development and evaluation of potential new medicines intended for the treatment, diagnosis or prevention of rare diseases or disorders.

https://investors.nuvalent.com/2026-06-09-GSK-enters-agreement-to-acquire-Nuvalent,-Inc