IDEAYA Biosciences, Inc. Reports First Quarter 2025 Financial Results and Provides Business Update

- ~$1.05 billion of cash, cash equivalents and marketable securities as ofMarch 31, 2025, and an updated cash runway guidance into 2029; commercial readiness activities ongoing
- Over 300 patients enrolled in darovasertib and crizotinib registrational 1L HLA-A2-negative MUM trial; targeting median PFS results by YE 2025 to enable potential accelerated approval filing
- Successful FDA Type D meeting completed to finalize darovasertib Ph3 registrational trial design and received U.S. FDA Breakthrough Therapy Designation in neoadjuvant UM
- Targeting three darovasertib program clinical data updates at medical conferences in 2025, including 1L MUM mOS results in >40 patients and neoadjuvant UM data in >90 patients
- IDE849 (DLL3 TOP1 ADC) Phase 1 initiated in U.S., and partner Hengrui targeting clinical data update in over 40 SCLC patients at a medical conference in Q3 2025
- Oral presentation of potential best-in-class Phase 1 WRN inhibitor IDE275 at AACR 2025
- Three additional IND-filings targeted in 2025: PRMT5, B7H3/PTK7 ADC, and KAT6/7

SOUTH SAN FRANCISCO, Calif., May 6, 2025 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq: IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, provided a business update and announced financial results for the first quarter that ended March 31, 2025.

"We have provided an updated cash runway guidance into 2029, and this past quarter we made significant progress on the darovasertib program, including receiving U.S. FDA breakthrough therapy designation, and enrollment is ahead of schedule with over 300 patients in the 1L HLA-A2-negative MUM registrational trial for a targeted median PFS readout by year-end to enable a potential accelerated approval filing next year. We also advanced a broad clinical pipeline of potential first-in-class programs to continue to drive forward our growth strategy, including DLL3 TOP1 ADC IDE849 in lung cancer, Werner Helicase inhibitor IDE275 in MSI-high colorectal and endometrial cancer, and MAT2A inhibitor IDE397 in MTAP-deletion lung and urothelial cancer," said Yujiro S. Hata, President and Chief Executive Officer, IDEAYA Biosciences.

Recent Key Developments and Upcoming Milestones

Research and Clinical Development

Darovasertib: a potential first-in-class PKC inhibitor in Phase 2/3 clinical testing for the treatment of metastatic uveal melanoma (MUM) and as neoadjuvant treatment for primary uveal melanoma (UM).

- MUM
  - Part 2b with the selected optimal dose for the potential registration-enabling trial evaluating darovasertib and crizotinib in first line (1L) HLA-A2-negative MUM continues enrolling.
  - Median progression-free survival (PFS) readout for Phase 2/3 registration-enabling trial of the darovasertib and crizotinib combination in 1L HLA-A2-negative MUM targeted by year-end 2025. Rapid enrollment in the trial

continues with over 300 patients as of May 5, 2025.

- Phase 2 median overall survival (OS) readout from study IDE196-001 in over 40 1L MUM patients targeted at a medical conference in the second half of 2025. The readout will include both 1L HLA-A2-negative and HLA-A2-positive MUM patients. We continue to enroll additional HLA-A2-positive MUM patients in the IDE196-001 trial.

- Neoadjuvant UM

  - Successfully completed a Type D meeting with the FDA on Phase 3 registrational trial design for darovasertib as neoadjuvant therapy for primary UM. The Phase 3 study is expected to enroll approximately 520 patients randomized 2:1 to receive darovasertib or control. Two cohorts include enucleation-eligible UM patients (n=120) and plaque brachytherapy (PB)-eligible UM patients (n=400). Primary endpoints, which are supportive of full approval based on the FDA Type D Meeting, include eye preservation rate for enucleation patients and proportion of patients with best corrected visual acuity 15-letter loss from time of randomization and time of completion of PB for the PB cohort, with event-free survival (EFS) as a required secondary endpoint for both cohorts. Commencement of the Phase 3 registration-enabling trial for darovasertib in neoadjuvant UM is targeted for the first half of 2025.
  - U.S. FDA granted breakthrough therapy designation for single agent darovasertib for the neoadjuvant treatment of adult patients with primary uveal melanoma (UM) for whom enucleation has been recommended.
  - Two clinical updates from the Company-sponsored Phase 2 trial targeted at medical conferences in mid-2025 and the second half of 2025. The mid-2025 update will be focused on vision data and the plaque brachytherapy patients, and the update in second half of 2025 will include over 90 UM patients from both the enucleation and plaque brachytherapy eligible cohorts.

IDE397: a potential first-in-class Phase 2 MAT2A inhibitor for the treatment of MTAP-deletion solid tumors.

- Entered into an additional clinical study collaboration and supply agreement with Gilead to evaluate IDE397, IDEAYA's MAT2A inhibitor, in combination with Trodelvy® (sacituzimab govitecan-hziy), Gilead's Trop-2 directed ADC, in MTAP-deletion NSCLC.
- IDEAYA plans to enable the wholly-owned IDE397 and IDE892 ($PRMT5^{MTA}$) combination in patients with MTAP-deletion non-small cell lung cancer (NSCLC) in the second half of 2025.

IDE849 (SHR-4849): a potential first-in-class Phase 1 DLL3 TOP1i antibody drug conjugate (ADC) targeting small cell lung cancer (SCLC) and neuroendocrine tumors (NETs).

- U.S. IND clearance obtained for IDE849 Phase 1 study in small cell lung cancer (SCLC).
- IDE849 currently being evaluated by Hengrui Pharma in an ongoing Phase 1 trial in China in SCLC patients. In January 2025, partner Hengrui Pharma selected expansion doses for the study. Clinical efficacy and safety data from over 40 SCLC patients in the multi-site open label Phase 1 trial, including the dose escalation and multiple expansion doses, will be presented at a medical conference in Q3 2025.
- Initiation of evaluation of IDE849 and IDE161 combination targeted in the second half of 2025.

IDE275 (GSK959): a potential first-in-class and best-in-class Phase 1 Werner Helicase inhibitor for the treatment of high

microsatellite instability (MSI-High) tumors.

- Phase 1 dose escalation trial ongoing in MSI-H solid tumors with GSK.
- IDE275 highlighted in an oral presentation in the New Drugs on the Horizon series, and three poster presentations, at the American Association for Cancer Research (AACR) 2025 Annual Meeting. The preclinical data demonstrated the molecule's selectivity to treat MSI-H solid tumors and potential to be developed clinically as both a monotherapy agent and in combination with anti-PD1. A Trial in Progress poster for the ongoing SYLVER Phase 1/2 study (NCT06710847) was also presented at AACR 2025.

IDE161: a potential first-in-class Phase 1 PARG inhibitor for the treatment of solid tumors.

- Phase 1 monotherapy dose optimization is ongoing. The clinical focus for the IDE161 program moving forward will be on enrollment with combination with IDE849.
- Preclinical data on immune checkpoint inhibitor (ICI)-driven anti-tumor immunity was presented at AACR 2025
- Targeting to present preclinical combination mechanism and synergy efficacy data of IDE161 with TOP1-payload based ADCs at a medical conference in the third quarter of 2025

IDE705 (GSK101): a potential first-in-class Phase 1 Pol Theta Helicase Inhibitor in combination with PARP inhibitor for the treatment of HRD solid tumors.

- Targeting Phase 2 expansion in HRD solid tumors, which would trigger a potential $10 million milestone payment from GSK.

IDE892: a potential best-in-class MTA-cooperative PRMT5 inhibitor to enable wholly-owned combination with IDE397.

- IND filing targeted for mid-year 2025.
- Preclinical data providing insights into metabolite kinetics and PRMT5 dysregulation in MTAP-deficient cancers was presented at AACR 2025.

IDE034: a potential first-in-class B7H3/PTK7 TOP1i bispecific ADC with combination potential with IDE161.

- IND filing targeted for the second half of 2025.

IDE574: a potential first-in-class KAT6/7 dual inhibitor development candidate with combination opportunities with multiple programs in the Company's pipeline.

- IND filing targeted for the second half of 2025.
- Preclinical data on dual inhibition's impact on epigenetics and adaptive drug resistance was presented at AACR 2025.

Corporate Development and Operations

- Formed a research collaboration with ATTMOS to develop a physics-based computational platform for small molecule discovery, aimed at swiftly unlocking oncology targets traditionally considered undruggable. The collaboration will integrate IDEAYA's differentiated and proven capabilities in structural biology and pharmaceutical drug discovery across

multiple first-in-class oncology targets with ATTMOS's capabilities in computational chemistry method development, high performance computing, and software development.

- Joshua Bleharski, Ph.D., joined IDEAYA as Chief Financial Officer. Dr. Bleharski joins from J.P. Morgan, serving most recently as Managing Director and Global Co-Head of Biopharma in the Healthcare Investment Banking group. Josh spent nearly 17 years at J.P. Morgan advising clients in the biopharma sector on capital markets transactions, corporate strategy and other investment banking services representing more than $65 billion of value for biotechnology companies worldwide.
- Shanthakumar Tyavanagimatt, Ph.D., joined IDEAYA as Senior Vice President, Technical Operations, where he will lead IDEAYA's darovasertib global commercial supply chain readiness activities, as well as the technical operations activities across IDEAYA's preclinical and clinical-stage pipeline. Prior to IDEAYA, Shanthakumar brings over 20-years of technical operations experience to IDEAYA, including approximately 9-years at CTI Biopharma (acquired by SOBI, Inc.) where he led the technical operations function for multiple commercial product launches.
- Updated cash runway guidance into 2029 based on current operating plan.

Financial Results

As of March 31, 2025, IDEAYA had cash, cash equivalents and marketable securities of approximately $1.05 billion. This compared to cash, cash equivalents and marketable securities of approximately $1.08 billion as of December 31, 2024 The decrease in the balance as of March 31, 2025 was primarily driven by net cash used in operations which was offset by $25.0 million in net proceeds from the sale of common stock shares through at-the-market financings during the quarter.

IDEAYA projects that the $1.05 billion in cash, cash equivalent and marketable securities balance as of March 31, 2025 will be sufficient to fund its planned operations into 2029 based on its current operating plan. We have updated our operating plan costs with further pipeline prioritization, including focusing: 1) the IDE161 clinical program on the combination study with DLL3 TOP1 ADC IDE849, 2) the IDE397 and PRMT5 mechanism clinical combination activities to wholly-owned PRMT5 inhibitor IDE892 ($PRMT5^{MTA}$), and 3) the clinical dose escalation and expansion data for the IDE397 and Trodelvy® combination in MTAP-deletion UC, to be utilized for the MTAP-deletion NSCLC indication clinical expansion activities.

There was no collaboration revenue for the three months ended March 31, 2025, compared to $7.0 million in collaboration for the three months ended December 31, 2024. Collaboration revenue for the three months ended December 31, 2024 was related to a milestone payment from GSK that was earned for the IND clearance of IDE275 (GSK959) in October 2024.

Research and development (R&D) expenses for the three months ended March 31, 2025, totaled $70.9 million compared to $140.2 million for the three months ended December 31, 2024. The decrease was primarily due to a one-time $75.0 million upfront payment under the license agreement for IDE849 with Hengrui Pharma that occurred in December 2024, offset by higher clinical trial, consulting and personnel-related expenses to support our pipeline.

General and administrative (G&A) expenses for the three months ended March 31, 2025 totaled $13.5 million compared to $11.0 million for the three months ended December 31, 2024. The increase was primarily due to higher personnel-related, consulting and legal patent expenses to support our growth.

The net loss for the three months ended March 31, 2025, was $72.2 million compared to the net loss of $130.3 million for the three months ended December 31, 2024. Total stock compensation expense for the three months ended March 31, 2025, was $10.2 million compared to $9.5 million for the three months ended December 31, 2024.

About IDEAYA Biosciences

IDEAYA is a precision medicine oncology company committed to the discovery and development of targeted therapeutics for patient populations selected using molecular diagnostics. IDEAYA's approach integrates capabilities in identifying and validating translational biomarkers with drug discovery to select patient populations most likely to benefit from its targeted therapies. IDEAYA is applying its research and drug discovery capabilities to synthetic lethality – which represents an emerging class of precision medicine targets.

IDEAYA's updated corporate presentation is available on its website, at its Investor Relations page: https://ir.ideayabio.com/.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to (i) the timing and content of clinical program updates, regulatory updates and clinical trial data readouts; (ii) the potential therapeutic benefits of IDEAYA therapeutics; (iii) the translation of preliminary clinical trial results into future clinical trial results and/or regulatory approval; (iv) timing of development and regulatory milestones; (v) the timing and potential of registration-enabling trial and readouts for darovasertib in 1L HLA-A2 negative MUM and potential for accelerated approval filing; (vi) the timing and potential for accelerated FDA approval of darovasertib in MUM; (vii) the timing of the initiation of registration-enabling Phase 3 trial for darovasertib in neoadjuvant UM; (viii) the timing of combination trial of IDE397 and IDE892 in patients with MTAP-deletion NSCLC; (ix) the timing and potential of a Phase 2 expansion monotherapy dose for IDE161; (x) the timing of initiating IDE161 and TOP1-payload ADC combination trial; (xi) timing of INDs for IDE892, IDE034, and IDE251; (xii) timing of data presentation for IDE275 and IDE849 at medical conferences; and (xiii) the extent to which IDEAYA's existing cash, cash equivalents, and marketable securities will fund its planned operations. Such forward-looking statements involve substantial risks and uncertainties that could cause IDEAYA's preclinical and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the drug development process, including IDEAYA's programs' early stage of development, the process of designing and conducting preclinical and clinical trials, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products, IDEAYA's ability to successfully establish, protect and defend its intellectual property, and other matters that could affect the sufficiency of existing cash to fund operations. IDEAYA undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of IDEAYA in general, see IDEAYA's Annual Report on Form 10-K dated February 18, 2025 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

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IDEAYA Biosciences, Inc.

Condensed Statements of Operations and Comprehensive Loss

(*in thousands, except share and per share amounts*)

	Three Months Ended	
	March 31, 2025	**December 31, 2024**
	(Unaudited)	
Collaboration revenue	—	$ 7,000
Operating expenses:		
Research and development	70,886	140,183
General and administrative	13,503	10,955
Total operating expenses	84,389	151,138
Loss from operations	(84,389)	(144,138)
Interest income and other income, net	12,211	13,826
Net loss	(72,178)	(130,312)
Unrealized gains (losses) on marketable securities	773	(3,024)
Comprehensive loss	$ (71,405)	$ (133,336)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.82)	$ (1.49)
Weighted-average number of shares outstanding, basic and diluted	88,356,335	87,340,758

IDEAYA Biosciences, Inc.

Condensed Balance Sheet Data

(*in thousands*)

	March 31, 2025	**December 31, 2024**
	(Unaudited)	
Cash and cash equivalents and short-term and long-term marketable securities	$ 1,051,173	$ 1,082,151

Total assets	1,100,641	1,124,091
Total liabilities	76,506	64,944
Total liabilities and stockholders' equity	$ 1,100,641	$ 1,124,091

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